

No. 26-1568

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**IN THE UNITED STATES COURT OF APPEALS  
FOR THE FIRST CIRCUIT**

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IN RE: MOTION TO QUASH ADMINISTRATIVE SUBPOENA TO RHODE  
ISLAND HOSPITAL

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CHILD ADVOCATE FOR RHODE ISLAND, et al.,

Petitioners-Appellees,

v.

UNITED STATES OF AMERICA,

Respondent-Appellant.

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On Appeal from the United States District Court  
for the District of Rhode Island

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**JOINT APPENDIX**

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APPEAL

**U.S. District Court  
District of Rhode Island (Providence)  
CIVIL DOCKET FOR CASE #: 1:26-mc-00007-MSM-AEM**

In Re: Motion to Quash Administrative Subpoena to Rhode  
Island Hospital  
Assigned to: District Judge Mary S. McElroy  
Referred to: Magistrate Judge Amy E. Moses  
Case in other court: First Circuit Court of Appeals, 26-01568  
Cause: no cause specified

Date Filed: 05/04/2026  
Date Terminated: 05/13/2026

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JA1



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State of Connecticut

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State of Delaware

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District of Columbia

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State of Illinois

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State of Maine

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State of Maryland

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State of Michigan

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State of Nevada

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State of New Jersey

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State of New Mexico

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State of New York

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State of Oregon

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State of Wisconsin

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| Date Filed | #        | Docket Text                                                                                                                                                                                                                                                                                                                                  |
|------------|----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 05/04/2026 | <u>1</u> | Emergency MOTION to Quash – New Case ( filing fee paid \$ 52.00, receipt number ARIDC-2273580 ), filed by Child Advocate for the State of Rhode Island. <b>Responses due by 5/18/2026.</b> (Attachments: # <u>1</u> Exhibit Exhibit 1, # <u>2</u> Exhibit Exhibit 2, # <u>3</u> Exhibit Exhibit 3)(Weizenbaum, Miriam) (Entered: 05/04/2026) |
| 05/04/2026 |          | Case assigned to District Judge Mary S. McElroy and Magistrate Judge Amy E. Moses. (Simoncelli, Michael) (Entered: 05/04/2026)                                                                                                                                                                                                               |
| 05/04/2026 | <u>2</u> | MOTION for Kevin Love Hubbard to Appear Pro Hac Vice ( filing fee paid \$ 100.00, receipt number ARIDC-2273657 ) filed by Child Advocate for the State of Rhode Island. (Weizenbaum, Miriam) (Entered: 05/04/2026)                                                                                                                           |
| 05/04/2026 |          | TEXT ORDER granting <u>2</u> Motion to Appear Pro Hac Vice of Kevin Love Hubbard. So Ordered by District Judge Mary S. McElroy on 5/4/2026. (Hill, Cherelle) (Entered: 05/04/2026)                                                                                                                                                           |
| 05/04/2026 | <u>3</u> | NOTICE of Appearance by Lynette J. Labinger on behalf of Child Advocate for the State of Rhode Island (Labinger, Lynette) (Entered: 05/04/2026)                                                                                                                                                                                              |
| 05/04/2026 |          | TEXT ORDER: The Government shall respond to <u>1</u> Emergency MOTION to Quash on or before 5/7/2026 by 2:00 pm. So Ordered by District Judge Mary S. McElroy on 5/4/2026. (Potter, Carrie) (Entered: 05/04/2026)                                                                                                                            |
| 05/04/2026 | <u>4</u> | NOTICE of Appearance by Amy Retsinas Romero on behalf of Child Advocate for the State of Rhode Island (Romero, Amy) (Entered: 05/04/2026)                                                                                                                                                                                                    |
| 05/04/2026 |          | NOTICE of Hearing on Motion <u>1</u> Emergency MOTION to Quash : Motion Hearing set for 5/12/2026 at 02:30 PM via Zoom before District Judge Mary S. McElroy. Zoom information to be emailed to counsel of record. The public is invited to view the hearing via the Court's YouTube channel. More information will be available on the      |

|            |           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|------------|-----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|            |           | Court's website <a href="http://www.rid.uscourts.gov">www.rid.uscourts.gov</a> . (Potter, Carrie) (Entered: 05/04/2026)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 05/04/2026 | <u>5</u>  | NOTICE by Child Advocate for the State of Rhode Island of <i>Related Proceedings</i> (Hubbard, Kevin) (Entered: 05/04/2026)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 05/05/2026 | <u>6</u>  | NOTICE of Appearance by Ross S. Goldstein on behalf of United States of America (Goldstein, Ross) (Entered: 05/05/2026)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 05/07/2026 | <u>7</u>  | NOTICE of Appearance by Patrick Runkle on behalf of United States of America (Runkle, Patrick) (Entered: 05/07/2026)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 05/07/2026 | <u>8</u>  | MOTION to Stay or <i>Transfer Venue</i> filed by United States of America. <b>Responses due by 5/21/2026.</b> (Runkle, Patrick) (Entered: 05/07/2026)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 05/07/2026 | <u>9</u>  | RESPONSE In Opposition to <u>1</u> Emergency MOTION to Quash – New Case ( filing fee paid \$ 52.00, receipt number ARIDC–2273580 ) filed by United States of America. <b>Replies due by 5/14/2026.</b> (Attachments: # <u>1</u> Exhibit RIH Notice of Privacy Practices)(Goldstein, Ross) (Entered: 05/07/2026)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 05/07/2026 |           | TEXT ORDER. The Government's Motion to Stay or Transfer Venue (ECF No. 8) is DENIED. When deciding whether to apply the first-to-file rule, courts must consider: "(1) which action was filed first; (2) the similarity of the parties; and (3) the similarity of the issues." <i>Waithaka v. Amazon.com, Inc.</i> , 404 F. Supp. 3d 335, 350 (D. Mass. 2019), <i>aff'd</i> , 966 F.3d 10 (1st Cir. 2020). While the Texas enforcement action was filed first, the remaining factors are not satisfied. The parties are not similar: the Child Advocate was not a party to the Texas proceeding, had no notice of those proceedings, and had no opportunity to be heard there. Rhode Island Hospital, the only party before the Texas court, is not a party here. The issues are not similar: the Texas court adjudicated the enforceability of the subpoena as between the government and Rhode Island Hospital; this Court is asked to adjudicate the independent constitutional privacy rights of minor patients who were never before any court. Those claims were neither raised nor considered in Texas and could not have been, as the affected parties were absent. The first-to-file rule does not apply. So Ordered by District Judge Mary S. McElroy on 5/7/2026. (Potter, Carrie) (Entered: 05/07/2026) |
| 05/07/2026 |           | NOTICE of Hearing on Motion <u>1</u> Emergency MOTION to Quash. Motion Hearing reset for 5/12/2026 at 02:00 PM in Courtroom 2 before District Judge Mary S. McElroy. <b>PLEASE NOTE THIS HEARING WILL NOW TAKE PLACE IN PERSON.</b> The public may view the hearing via the Court's YouTube channel. Please visit <a href="http://rid.uscourts.gov">rid.uscourts.gov</a> for additional information. (Potter, Carrie) (Entered: 05/07/2026)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 05/08/2026 | <u>10</u> | Consent MOTION for Leave to File Amicus Brief of <i>Rhode Island, Massachusetts, Arizona, California, Colorado, Connecticut, Delaware, the District of Columbia, Illinois, Maine, Maryland, Michigan, Minnesota, Nevada, New Jersey, New Mexico, New York, Oregon, Vermont, Washington, and Wisconsin</i> filed by State of Rhode Island. <b>Responses due by 5/22/2026.</b> (Attachments: # <u>1</u> Proposed States' Amicus Brief)(Rice, Sarah) (Entered: 05/08/2026)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 05/08/2026 | <u>11</u> | MOTION for Nina Monfredo to Appear Pro Hac Vice ( filing fee paid \$ 100.00, receipt number ARIDC–2276886 ) filed by National Center for Youth Law. (Smith, Nicole) (Entered: 05/08/2026)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 05/08/2026 | <u>12</u> | REPLY to Response re <u>9</u> Response to Motion, filed by Child Advocate for the State of Rhode Island. (Attachments: # <u>1</u> Exhibit 1)(Hubbard, Kevin) (Entered: 05/08/2026)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 05/09/2026 | <u>13</u> | Amicus Curiae APPEARANCE entered by Sonja L. Deyoe on behalf of LAMBDA Legal Defense and Education Fund, Inc.. (Deyoe, Sonja) (Entered: 05/09/2026)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 05/09/2026 | <u>14</u> | MOTION Leave to file Amicus – unopposed filed by LAMBDA Legal Defense and Education Fund, Inc.. <b>Responses due by 5/26/2026.</b> (Deyoe, Sonja) (Entered: 05/09/2026)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 05/09/2026 | <u>15</u> | AMICUS BRIEF by LAMBDA Legal Defense and Education Fund, Inc.. (Deyoe, Sonja) (Entered: 05/09/2026)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 05/09/2026 | <u>16</u> | NOTICE of Appearance by Stacey P. Nakasian on behalf of Rhode Island Hospital (Nakasian, Stacey) (Entered: 05/09/2026)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |

|            |           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|------------|-----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 05/09/2026 | <u>17</u> | MOTION to Intervene filed by Rhode Island Hospital. <b>Responses due by 5/26/2026.</b> (Attachments: # <u>1</u> Exhibit 1)(Nakasian, Stacey) (Entered: 05/09/2026)                                                                                                                                                                                                                                                                                                                                                     |
| 05/09/2026 | <u>18</u> | MOTION for Eric G. Olshan to Appear Pro Hac Vice ( filing fee paid \$ 100.00, receipt number ARIDC-2277072 ) filed by Rhode Island Hospital. (Nakasian, Stacey) (Entered: 05/09/2026)                                                                                                                                                                                                                                                                                                                                  |
| 05/09/2026 | <u>19</u> | MOTION for Kathryn M. Barber to Appear Pro Hac Vice ( filing fee paid \$ 100.00, receipt number ARIDC-2277073 ) filed by Rhode Island Hospital. (Nakasian, Stacey) (Entered: 05/10/2026)                                                                                                                                                                                                                                                                                                                               |
| 05/10/2026 | <u>20</u> | MOTION to Intervene ( <i>Corrected Filing to add exhibits</i> ) filed by Rhode Island Hospital. <b>Responses due by 5/26/2026.</b> (Attachments: # <u>1</u> Exhibit 1, # <u>2</u> Exhibit 2, # <u>3</u> Exhibit 3, # <u>4</u> Exhibit 4, # <u>5</u> Exhibit 5, # <u>6</u> Exhibit 6, # <u>7</u> Exhibit 7, # <u>8</u> Exhibit 8, # <u>9</u> Exhibit 9, # <u>10</u> Exhibit 10, # <u>11</u> Exhibit 11, # <u>12</u> Exhibit 12, # <u>13</u> Exhibit 13, # <u>14</u> Exhibit 14)(Nakasian, Stacey) (Entered: 05/10/2026) |
| 05/10/2026 | <u>21</u> | MOTION for A.D. Sean Lewis to Appear Pro Hac Vice ( filing fee paid \$ 100.00, receipt number ARIDC-2277083 ) filed by LAMBDA Legal Defense and Education Fund, Inc.. (Deyoe, Sonja) (Entered: 05/10/2026)                                                                                                                                                                                                                                                                                                             |
| 05/10/2026 | <u>22</u> | MOTION for Omar Gonzalez-Pagan to Appear Pro Hac Vice ( filing fee paid \$ 100.00, receipt number ARIDC-2277089 ) filed by LAMBDA Legal Defense and Education Fund, Inc.. (Deyoe, Sonja) (Entered: 05/10/2026)                                                                                                                                                                                                                                                                                                         |
| 05/11/2026 | <u>23</u> | MOTION for Karen Loewy to Appear Pro Hac Vice ( filing fee paid \$ 100.00, receipt number ARIDC-2277289 ) filed by LAMBDA Legal Defense and Education Fund, Inc.. (Attachments: # <u>1</u> Exhibit A)(Deyoe, Sonja) (Entered: 05/11/2026)                                                                                                                                                                                                                                                                              |
| 05/11/2026 | <u>24</u> | MOTION for Leave to File Amicus Brief filed by National Center for Youth Law. <b>Responses due by 5/26/2026.</b> (Attachments: # <u>1</u> Supporting Memorandum)(Bianchi, Gil) (Entered: 05/11/2026)                                                                                                                                                                                                                                                                                                                   |
| 05/11/2026 | <u>25</u> | NOTICE of Appearance by Gil Alan Bianchi, Jr on behalf of National Center for Youth Law (Bianchi, Gil) (Entered: 05/11/2026)                                                                                                                                                                                                                                                                                                                                                                                           |
| 05/11/2026 |           | TEXT ORDER granting <u>10</u> Motion for Leave to File Amicus Brief. So Ordered by District Judge Mary S. McElroy on 5/11/2026. (Potter, Carrie) (Entered: 05/11/2026)                                                                                                                                                                                                                                                                                                                                                 |
| 05/11/2026 | <u>26</u> | AMICUS BRIEF by State of RHODE ISLAND, MASSACHUSETTS, ARIZONA, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, THE DISTRICT OF COLUMBIA, ILLINOIS, MAINE, MARYLAND, MICHIGAN, MINNESOTA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, OREGON, VERMONT, WASHINGTON, AND WISCONSIN (Potter, Carrie) (Entered: 05/11/2026)                                                                                                                                                                                                      |
| 05/11/2026 |           | TEXT ORDER granting <u>14</u> MOTION Leave to file Amicus – unopposed . So Ordered by District Judge Mary S. McElroy on 5/11/2026. (Potter, Carrie) (Entered: 05/11/2026)                                                                                                                                                                                                                                                                                                                                              |
| 05/11/2026 |           | TEXT ORDER granting <u>17</u> Motion to Intervene; granting <u>20</u> Motion to Intervene. So Ordered by District Judge Mary S. McElroy on 5/11/2026. (Potter, Carrie) (Entered: 05/11/2026)                                                                                                                                                                                                                                                                                                                           |
| 05/11/2026 | <u>27</u> | NOTICE of Appearance by Brantley Mayers on behalf of United States of America (Mayers, Brantley) (Entered: 05/11/2026)                                                                                                                                                                                                                                                                                                                                                                                                 |
| 05/11/2026 | <u>28</u> | Emergency MOTION to Quash <i>Subpoena Duces Tecum</i> filed by Rhode Island Hospital. (Attachments: # <u>1</u> Exhibit, # <u>2</u> Exhibit, # <u>3</u> Exhibit, # <u>4</u> Exhibit, # <u>5</u> Exhibit, # <u>6</u> Exhibit, # <u>7</u> Exhibit, # <u>8</u> Exhibit, # <u>9</u> Exhibit, # <u>10</u> Exhibit, # <u>11</u> Exhibit, # <u>12</u> Exhibit, # <u>13</u> Exhibit)(Potter, Carrie) (Entered: 05/11/2026)                                                                                                      |
| 05/11/2026 |           | TEXT ORDER granting <u>24</u> Motion for Leave to File Amicus Brief. So Ordered by District Judge Mary S. McElroy on 5/11/2026. (Potter, Carrie) (Entered: 05/11/2026)                                                                                                                                                                                                                                                                                                                                                 |
| 05/11/2026 | <u>29</u> | AMICUS BRIEF by National Center for LGBTQ Rights and National Center for Youth Law. (Potter, Carrie) (Entered: 05/11/2026)                                                                                                                                                                                                                                                                                                                                                                                             |
| 05/11/2026 |           | TEXT ORDER granting <u>11</u> Motion to Appear Pro Hac Vice of Nina Monfredo. So Ordered by District Judge Mary S. McElroy on 5/11/2026. (Potter, Carrie) (Entered: 05/11/2026)                                                                                                                                                                                                                                                                                                                                        |



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| 05/11/2026 |           | TEXT ORDER granting <u>18</u> Motion to Appear Pro Hac Vice of Eric G. Olshan. So Ordered by District Judge Mary S. McElroy on 5/11/2026. (Potter, Carrie) (Entered: 05/11/2026)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 05/11/2026 |           | TEXT ORDER granting <u>19</u> Motion to Appear Pro Hac Vice of Kathryn M. Barber. So Ordered by District Judge Mary S. McElroy on 5/11/2026. (Potter, Carrie) (Entered: 05/11/2026)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 05/11/2026 |           | TEXT ORDER granting <u>21</u> Motion to Appear Pro Hac Vice of A.D. Sean Lewis. So Ordered by District Judge Mary S. McElroy on 5/11/2026. (Potter, Carrie) (Entered: 05/11/2026)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| 05/11/2026 |           | TEXT ORDER granting <u>22</u> Motion to Appear Pro Hac Vice of Omar Gonzalez-Pagan. So Ordered by District Judge Mary S. McElroy on 5/11/2026. (Potter, Carrie) (Entered: 05/11/2026)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 05/11/2026 |           | TEXT ORDER granting <u>23</u> Motion to Appear Pro Hac Vice of Karen Loewy. So Ordered by District Judge Mary S. McElroy on 5/11/2026. (Potter, Carrie) (Entered: 05/11/2026)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 05/11/2026 |           | TEXT ORDER. The Respondent is directed to provide to this Court the Hsiao Declaration and all other information provided to the Court in the Northern District of Texas to support its choice to enforce the subpoena in that Court. The information may be provided ex parte due to the sensitive nature of the information and must be provided by 5:00 p.m. today. The documents are to be produced by sending an email to carrie_potter@rid.uscourts.gov. So Ordered by District Judge Mary S. McElroy on 5/11/2026. (Potter, Carrie) (Entered: 05/11/2026)                                                                                                                                                                                                     |
| 05/11/2026 | <u>30</u> | NOTICE by United States of America of <i>Supplemental Authority</i> (Attachments: # <u>1</u> Exhibit Opinion and Order)(Goldstein, Ross) (Entered: 05/11/2026)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 05/11/2026 | <u>31</u> | NOTICE of Appearance by Jordan Campbell on behalf of United States of America (Campbell, Jordan) (Entered: 05/11/2026)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 05/12/2026 |           | Minute Entry for proceedings held before District Judge Mary S. McElroy: In Chambers Conference held on 5/12/2026 re: In Camera Documents. J. Campbell, B. Mayers and L. Zurier in attendance. (Historic Library at 1:40 pm.) (Potter, Carrie) (Entered: 05/12/2026)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 05/12/2026 |           | Minute Entry for proceedings held before District Judge Mary S. McElroy: Motion Hearing held on 5/12/2026 : K. Love Hubbard, A. Romero, L. Labinger, B. Mayers, J. Campbell, E. Olshan and S. Nakasian. Arguments heard from Child Advocate of RI (Love Hubbard), Rhode Island Hospital (Olshan) and USA (B. Mayers). Court questions; counsel responds. Oral Motion to Renew Transfer of Venue. Denied for reasons previously stated. DOJ to provide copy of sealed affidavit to opposing counsel with redactions, Affidavit of Mr. Gunn and notice about when the grand jury was convened in the Northern District of Texas by 9:00 am on 5/13/2026. Order to issue. (Court Reporter D. Veitch in Courtroom 1 at 2:00 pm.) (Potter, Carrie) (Entered: 05/12/2026) |
| 05/13/2026 | <u>32</u> | NOTICE by United States of America (Attachments: # <u>1</u> Gunn Declaration)(Mayers, Brantley) (Entered: 05/13/2026)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 05/13/2026 | <u>33</u> | TRANSCRIPT ORDER for proceedings held on 5/12/2026 before Judge Mary S. McElroy. <b>Realtime Transcript selected.</b> (Attachments: # <u>1</u> Email) (Gonzalez Gomez, Viviana) (Entered: 05/13/2026)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 05/13/2026 | <u>34</u> | TRANSCRIPT ORDER for proceedings held on 5/12/2026 before Judge McElroy. <b>Daily Transcript selected.</b> Transcript to be delivered following adjournment and prior to the normal opening hour of court on the following morning.. (Nakasian, Stacey) (Entered: 05/13/2026)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 05/13/2026 | <u>35</u> | TRANSCRIPT ORDER for proceedings held on 5/12/2026 before Judge McElroy. <b>Daily Transcript selected.</b> Transcript to be delivered following adjournment and prior to the normal opening hour of court on the following morning.. (Mayers, Brantley) (Entered: 05/13/2026)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |



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| 05/13/2026 | <u>36</u> | TRANSCRIPT ORDER ACKNOWLEDGMENT Entered re: <u>34</u> Transcript Order, <u>33</u> Transcript Order, <u>35</u> Transcript Order,. Daily Transcript Ordered. Court Reporter/Transcriber: Denise Veitch. (Dias, Jennifer) (Entered: 05/13/2026)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 05/13/2026 | <u>37</u> | TRANSCRIPT ORDER for proceedings held on 05/12/2026 before Judge Mary S. McElroy. <b>Daily Transcript selected.</b> Transcript to be delivered following adjournment and prior to the normal opening hour of court on the following morning.. (Weizenbaum, Miriam) (Entered: 05/13/2026)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 05/13/2026 | <u>38</u> | <p>MEMORANDUM AND ORDER : The Court's decision is based solely on its application of the law to the administrative subpoena at issue here. But the discrepancy between the honorable conduct expected of federal prosecutors and DOJ's tactics in this case is unsettling. The Court cannot help but share the sentiment that "[t]he presumption of regularity that has previously been extended to [DOJ] that it could be taken at its word with little doubt about its intentions and stated purposes no longer holds." <i>United States v. Oregon</i>, No. 6:25-CV-01666-MTK, 2026 WL 318402, at *11 (D. Or. Feb. 5, 2026). It is regrettable that this is now the case.</p> <p>The Emergency Motions to Quash (ECF Nos. <u>1</u> &amp; <u>28</u> ) are GRANTED. In granting these Motions, this Court quashes the administrative subpoena the instrument issued by the DOJ not the enforcement order entered by the Texas court. What this Court holds is that the subpoena itself lacks a congressionally authorized purpose, was issued for an improper purpose, and demands the production of records that cannot be obtained consistent with the constitutional privacy rights of Rhode Island children. Those are independent grounds for quashal of the subpoena that this Court has authority to adjudicate.</p> <p>In addition, the DOJ is hereby ENJOINED from receiving, using, retaining, or disseminating any patient-identifying information or protected health information produced by RIH in response to Administrative Subpoena No. 25-1431-032, including all materials responsive to Requests 11 through 15 and any other materials that identify, or reasonably permit the identification of, Rhode Island's children. So Ordered by District Judge Mary S. McElroy on 5/13/2026. (CP) (Entered: 05/13/2026)</p> |
| 05/13/2026 | <u>39</u> | JUDGMENT enters in accordance with the Memo and Order of 5/13/2026. So Ordered by District Judge Mary S. McElroy on 5/13/2026. CP) (Entered: 05/13/2026)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 05/14/2026 | <u>40</u> | TRANSCRIPT ORDER for proceedings held on 05/12/2026 – 05/12/2026 before Judge Mary S. McElroy. <b>Daily Transcript selected.</b> Transcript to be delivered following adjournment and prior to the normal opening hour of court on the following morning.. (Attachments: # <u>1</u> Email)(Hill, Cherelle) (Entered: 05/14/2026)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 05/14/2026 | <u>41</u> | Emergency MOTION to Clarify <u>38</u> Memorandum and Order,,,,, filed by Rhode Island Hospital. <b>Responses due by 5/28/2026.</b> (Nakasian, Stacey) (Entered: 05/14/2026)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 05/14/2026 | <u>42</u> | TRANSCRIPT ORDER ACKNOWLEDGMENT Entered re: <u>37</u> Transcript Order, <u>40</u> Transcript Order,. Daily Transcript Ordered. Court Reporter/Transcriber: Denise Veitch. (Dias, Jennifer) (Entered: 05/14/2026)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 05/14/2026 | <u>43</u> | <p>NOTICE OF APPEAL by United States of America as to <u>38</u> Memorandum and Order, <u>39</u> Judgment (No fee paid, USA, Waived by Statute, or IFP.)</p> <p><b>NOTICE TO COUNSEL: Counsel should register for a First Circuit CM/ECF Appellate Filer Account at <a href="http://pacer.psc.uscourts.gov/cmecf/">http://pacer.psc.uscourts.gov/cmecf/</a>. Counsel should also review the First Circuit requirements for electronic filing by visiting the CM/ECF Information section at <a href="http://www.ca1.uscourts.gov/cmecf">http://www.ca1.uscourts.gov/cmecf</a></b> Appeal Record due by 5/21/2026. (Mayers, Brantley) (Entered: 05/14/2026)</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 05/14/2026 |           | TEXT ORDER: Rhode Island Hospital's Emergency Motion to Clarify (ECF No. <u>41</u> ) is GRANTED IN PART. The Court issues an amended memorandum and order under a separate docket entry. So Ordered by District Judge Mary S. McElroy on 5/14/2026. (Potter, Carrie) (Entered: 05/14/2026)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 05/14/2026 | <u>44</u> | MEMORANDUM AND ORDER : Ultimately, the Court's decision is based solely on its application of the law to the administrative subpoena at issue here. But the discrepancy between the honorable conduct expected of federal prosecutors and DOJ's tactics in this case is unsettling. The Court cannot help but share the sentiment that                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |

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|            |           | <p>"[t]he presumption of regularity that has previously been extended to [DOJ] that it could be taken at its word with little doubt about its intentions and stated purposes no longer holds." <i>United States v. Oregon</i>, No. 6:25-CV-01666-MTK, 2026 WL 318402, at *11 (D. Or. Feb. 5, 2026). It is regrettable that this is now the case.</p> <p>The Emergency Motions to Quash (ECF Nos. <u>1</u> &amp; <u>28</u>) are GRANTED. In granting these Motions, this Court quashes the administrative subpoena the instrument issued by DOJ not the enforcement order entered by the Texas court. What this Court holds is that the subpoena itself lacks a congressionally authorized purpose, was issued for an improper purpose, and demands the production of records that cannot be obtained consistent with the constitutional privacy rights of Rhode Island children. Those are independent grounds for quashal of the subpoena that this Court has authority to adjudicate.</p> <p>In addition, DOJ is hereby ENJOINED from seeking, receiving, using, retaining, or disseminating any patient-identifying information or protected health information produced by RIH in response to Administrative Subpoena No. 25-1431-032, including but not limited to all materials responsive to Requests 11 through 15 and any other materials that identify, or reasonably permit the identification of, Rhode Islands children. So Ordered by District Judge Mary S. McElroy on 5/14/2026. (Potter, Carrie) (Entered: 05/14/2026)</p> |
| 05/14/2026 | <u>45</u> | CLERK'S CERTIFICATE AND APPELLATE COVER SHEET: Abbreviated record on appeal consisting of notice of appeal, order(s) being appealed, and a copy of the district court docket report transmitted to the U.S. Court of Appeals for the First Circuit in accordance with 1st Cir. R. 11.0(b) re: <u>43</u> Notice of Appeal. Documents Sent: 38, 39. (Attachments: # <u>1</u> Record on Appeal) (Gonzalez Gomez, Viviana) (Entered: 05/14/2026)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 05/14/2026 |           | USCA Case Number 26-1568 for <u>43</u> Notice of Appeal, filed by United States of America. (Gonzalez Gomez, Viviana) (Entered: 05/14/2026)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 05/14/2026 | <u>46</u> | <p>NOTICE OF APPEAL by United States of America as to <u>44</u> Memorandum and Order,,,,,, (No fee paid, USA, Waived by Statute, or IFP.)</p> <p><b>NOTICE TO COUNSEL: Counsel should register for a First Circuit CM/ECF Appellate Filer Account at <a href="http://pacer.psc.uscourts.gov/cmecf/">http://pacer.psc.uscourts.gov/cmecf/</a>. Counsel should also review the First Circuit requirements for electronic filing by visiting the CM/ECF Information section at <a href="http://www.ca1.uscourts.gov/cmecf">http://www.ca1.uscourts.gov/cmecf</a></b> Appeal Record due by 5/21/2026. (Mayers, Brantley) (Entered: 05/14/2026)</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 05/15/2026 | <u>47</u> | CLERK'S CERTIFICATE AND APPELLATE COVER SHEET: Abbreviated record on appeal consisting of notice of appeal, order(s) being appealed, and a certified copy of the district court docket report transmitted to the U.S. Court of Appeals for the First Circuit in accordance with 1st Cir. R. 11.0(b). <u>46</u> Notice of Appeal,, (Attachments: # <u>1</u> Record on Appeal)(Hill, Cherelle) (Entered: 05/15/2026)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 05/19/2026 | <u>48</u> | MOTION for Adam M. Cambier to Appear Pro Hac Vice ( filing fee paid \$ 100.00, receipt number ARIDC-2281529 ) filed by State of Rhode Island. (Harvey, Julia) (Entered: 05/19/2026)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 05/19/2026 | <u>49</u> | MOTION for Morgan Carmen to Appear Pro Hac Vice ( filing fee paid \$ 100.00, receipt number ARIDC-2281554 ) filed by State of Rhode Island. (Harvey, Julia) (Entered: 05/19/2026)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 05/19/2026 | <u>50</u> | MOTION for Jak Kundl to Appear Pro Hac Vice ( filing fee paid \$ 100.00, receipt number ARIDC-2281556 ) filed by State of Rhode Island. (Harvey, Julia) (Entered: 05/19/2026)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 05/19/2026 | <u>51</u> | MOTION for Allyson Slater to Appear Pro Hac Vice ( filing fee paid \$ 100.00, receipt number ARIDC-2281557 ) filed by State of Rhode Island. (Harvey, Julia) (Entered: 05/19/2026)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 05/19/2026 |           | TEXT ORDER granting <u>48</u> Motion to Appear Pro Hac Vice of Adam M Cambier ; granting <u>49</u> Motion to Appear Pro Hac Vice of Morgan Carmen, ; granting <u>50</u> Motion to Appear Pro Hac Vice of Jak Kundl ; granting <u>51</u> Motion to Appear Pro Hac Vice of Allyson Slater. So Ordered by District Judge Mary S. McElroy on 5/19/2026. (Potter,                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |

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|            |           | Carrie) (Entered: 05/19/2026)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 05/19/2026 | <u>52</u> | Supplemental Record on Appeal transmitted to U.S. Court of Appeals for the First Circuit. <u>46</u> Notice of Appeal. (Attachments: # <u>1</u> ROA)(Potter, Carrie) (Entered: 05/19/2026)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 05/20/2026 | <u>53</u> | ORDER of the U.S. Court of Appeals for the First Circuit entered as to <u>46</u> Notice of Appeal, filed by United States of America. ORDER entered by Gustavo A. Gelp, Appellate Judge; Lara E. Montecalvo, Appellate Judge and Joshua D. Dunlap, Appellate Judge: The Child Advocate's motion for an injunction pending appeal is DENIED. DUNLAP, Circuit Judge, concurring. [26-1568] (Gonzalez Gomez, Viviana) (Entered: 05/20/2026)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 05/21/2026 | <u>54</u> | TRANSCRIPT of Motion to Quash, held on May 12, 2026, before District Judge Mary S. McElroy. Court Reporter Denise P. Veitch, Telephone number (401)752-7031. Transcript may be viewed at the court public terminal or purchased through the Court Reporter before the deadline for Release of Transcript Restriction. After that date it may be obtained through the Court Reporter or PACER. <b>NOTICE TO COUNSEL: Redaction Requests must be filed for personal identifiers only. All other redactions must be requested by motion. For local policy and sample redaction request visit our website at <a href="http://www.rid.uscourts.gov">www.rid.uscourts.gov</a> and select Transcripts under the Case Information menu option.</b> Redaction Request due 6/11/2026. Redacted Transcript Deadline set for 6/22/2026. Release of Transcript Restriction set for 8/19/2026. (Veitch, Denise) (Main Document 54 replaced on 5/28/2026) (Potter, Carrie). (Entered: 05/21/2026) |
| 06/05/2026 |           | TEXT ORDER. Because of the representations made to this Court by the respondents' attorneys, as well as the findings of the Court in its order of May 14, 2026, this matter is referred for further proceedings under R.I. Dist. Ct. Local Rule 210(b). So Ordered by District Judge Mary S. McElroy on 6/5/2026. (Potter, Carrie) (Entered: 06/05/2026)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF RHODE ISLAND

In Re: Administrative Subpoena  
25-1431-032 to Rhode Island Hospital

Misc. Action No. \_\_\_\_\_

**EMERGENCY MOTION TO QUASH**  
**SUBPOENA DUCES TECUM**

**REQUEST FOR EXPEDITED  
RELIEF PURSUANT TO LR CV 9**

# INTRODUCTION

The Child Advocate for the State of Rhode Island brings this motion to quash to protect the constitutional privacy rights and well-being of vulnerable children in the care, custody, or treatment of the Rhode Island Department of Children, Youth & Families (DCYF), and in fulfillment of her legal obligation to secure and ensure the legal and civil rights of children in DCYF care or custody. The United States Department of Justice (DOJ) served a subpoena, Administrative Subpoena 25-1431-032, on Rhode Island Hospital (RI Hospital), commanding production of information and documents relating to RI Hospital's provision of medical care for gender dysphoria (the Subpoena). The sweeping Subpoena seeks an extraordinarily broad set of sensitive medical records—including the identities, diagnoses, clinical assessments, and intimate personal details—of minor patients who received gender-affirming medical care, including children in DCYF care or custody. This unprecedented intrusion into

the private medical information of children, many of whom are among the most vulnerable in our state's care, cannot be justified by any legitimate law enforcement purpose.

On April 30, 2026, though the Subpoena was issued to RI Hospital in Providence, Rhode Island, and from DOJ's Consumer Protection Branch/Enforcement and Affirmative Litigation Branch in Washington, D.C., the government filed a Petition for Enforcement of the Subpoena in the United States District Court for the Northern District of Texas. *In Re: Administrative Subpoena 25-1431-032*, No. 4-26MC-006-0 (N.D. Tex. Apr. 30, 2026). The district court in Texas granted the government's motion to compel the same day, hours later, without any filed opposition, ordering RI Hospital to "provide all records responsive to each request in the subpoena within 14 days of the entry of this order." *Id.* at ECF No. 2. This Court's intervention is therefore immediately necessary, before May 13, 2026, to protect the constitutional privacy rights of Rhode Island's children.

DOJ does not have a legitimate law enforcement purpose for the Subpoena, as its own statements make clear. To the contrary, DOJ issued the Subpoena as part of a coordinated campaign by the Trump Administration to eliminate access to medical care for gender dysphoria, lifesaving care that is recognized as medically necessary by every major medical association, even where it is expressly protected by state law, as it is in Rhode Island. The Administration has made no secret of its true goal: to end medical care for gender dysphoria through intimidation, harassment, and the threat of criminal prosecution. Indeed, the Administration intends to eliminate the

recognition of transgender people it deems to fall outside a new “immutable biological reality of sex” it seeks to impose.<sup>1</sup> Incredibly, after another court quashed an identical subpoena, on the very ground that DOJ issued the subpoena not to investigate legal violations but instead to intimidate and coerce providers into abandoning lawful medical care, DOJ issued a public response eliminating any doubt about its improper purpose: “As Attorney General Bondi has made clear, this Department of Justice will use every legal and law enforcement tool available to protect innocent children from being mutilated under the guise of ‘care.’”<sup>2</sup>

This Subpoena is not a legitimate exercise of federal law enforcement authority. It is an improper attempt to regulate the practice of medicine in an area traditionally reserved to the states, to override Rhode Island’s choice to protect this necessary medical treatment, and to discriminate against people in protected classes that Rhode Island (and federal) laws explicitly protect. The fact that DOJ is so brazen about its true purpose does not make it any less improper. The Subpoena therefore constitutes an abuse of the narrowly circumscribed authority provided to the government under 18 U.S.C. § 3486 to investigate federal health care offenses, and represents a grave, improper, and unjustified intrusion on patient privacy.

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<sup>1</sup> See *Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government*, The White House (Jan. 20, 2025), <https://www.whitehouse.gov/presidential-actions/2025/01/defending-women-from-gender-ideology-extremism-and-restoring-biological-truth-to-the-federal-government/> (last visited May 1, 2026).

<sup>2</sup> Josh Gerstein, *DOJ tried to subpoena an online trans health care provider. A judge quashed it*, Politico (Oct. 29, 2025), <https://www.politico.com/news/2025/10/29/doj-subpoena-gender-affirming-care-ruling-00627891> (last visited May 1, 2026).

The Court is not writing on a blank slate. There have now been seven decisions from other federal courts quashing or limiting identical subpoenas issued to other providers of medical care for gender dysphoria. *See In re Admin. Subpoena No. 25-1431-019*, 800 F. Supp. 3d 229 (D. Mass. 2025); *QueerDoc, PLLC v. U.S. Dep’t of Just.*, 807 F. Supp. 3d 1295 (W.D. Wash. 2025); *In re Subpoena No. 25-1431-014*, 810 F. Supp. 3d 555, 607 (E.D. Pa. 2025); *In re Subpoena Duces Tecum No. 25-1431-016*, No. 2:25-MC-00041-JHC, 2025 WL 3562151, at \*16 (W.D. Wash. Sept. 3, 2025); *In re 2025 UPMC Subpoena*, No. 2:25-MC-01069-CB, 2025 WL 3724705, at \*3 (W.D. Pa. Dec. 24, 2025), *judgment entered*, No. 2:25-MC-01069-CB, 2026 WL 570419 (W.D. Pa. Mar. 2, 2026); *In re Dep’t of Just. Admin. Subpoena No. 25-1431-030*, No. 25-MC-00063-SKC-CYC, 2026 WL 33398, at \*2 (D. Colo. Jan. 5, 2026); *In re Children’s Nat’l Hosp.*, No. 1:25-CV-03780-JRR, 2026 WL 160792, at \*9 (D. Md. Jan. 21, 2026). This Court should join that consensus and conclude that the Subpoena was issued in bad faith and with an improper purpose. If the Subpoena is not quashed, it threatens irreparable harm to the privacy rights of Rhode Island’s children, their mental and physical health, and the physician-patient relationship upon which their care depends.

## BACKGROUND

**I. Medical Care for Gender Dysphoria Is Medically Necessary and Legally Protected Healthcare in Rhode Island.**

Medical care for gender dysphoria represents evidence-based best practice for treatment of gender dysphoria, including in minors. All major medical organizations recognize gender dysphoria—which occurs when there is a conflict between the sex a person is assigned at birth and the gender with which they identify—as a medical



condition that can cause significant distress, and that appropriate medical care can effectively treat gender dysphoria.<sup>3</sup> A “Systematic Medical Evidence Review of Hormonal Transgender Treatment Report,” conducted in response to the Utah legislature’s efforts to ban medical care for gender dysphoria for transgender minors, concluded that

the consensus of the evidence supports that [medical care for gender dysphoria] treatments are effective in terms of mental health, psychosocial outcomes, and the induction of body changes consistent with the affirmed gender in pediatric GD patients. The evidence also supports that the treatments are safe in terms of changes to bone density, cardiovascular risk factors, metabolic changes, and cancer.<sup>4</sup>

There is no “one-size-fits-all” approach to medical care for gender dysphoria: it is adapted to the needs of each patient, and treatments can include puberty suppression or hormone therapy.<sup>5</sup> Medical care for gender dysphoria is thus a vital lifeline

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<sup>3</sup> See, e.g., *Clarification on Evidence-Based Gender-Affirming Care H-185.927*, American Medical Association (2024), <https://tinyurl.com/38mcbdjK> (last visited May 1, 2026) (“medical and surgical treatments for gender dysphoria and gender incongruence, as determined by shared decision making between the patient and physician, are medically necessary as outlined by generally-accepted standards of medical and surgical practice.”); *What is Gender Dysphoria*, American Psychiatric Association, <https://www.psychiatry.org/patients-families/gender-dysphoria/what-is-gender-dysphoria> (last visited May 1, 2026) (outlining treatment options).

<sup>4</sup> *Gender-Affirming Medical Treatments for Pediatric Patients with Gender Dysphoria*, University of Utah College of Pharmacy, Drug Regimen Review Center (Aug. 6, 2024), at 90, <https://le.utah.gov/AgencyRP/reportingDetail.jsp?rid=636> (last visited May 1, 2026).

<sup>5</sup> Eli Coleman et al., *Standards of Care for the Health of Transgender and Gender Diverse People*, Version 8, International Journal of Transgender Health, World Professional Association for Transgender Health (WPATH) (2022), at S7, <https://tinyurl.com/459r3jth> (last visited May 1, 2026). In very rare cases, treatment includes gender-affirming surgery, *id.*, although RI Hospital does not perform surgeries as treatment for gender dysphoria for minors.



for many gender-diverse individuals, who may otherwise experience severe distress, anxiety, depression, and suicidal ideation without treatment.<sup>6</sup>

Reflecting this well-established medical consensus, Rhode Island law provides explicit guarantees of a patient’s ability to receive medical care for gender dysphoria, including R.I. Gen. Laws § 23-101, known as the Healthcare Provider Shield Law. That law specifically defines “Legally protected healthcare activity” in Rhode Island to include “gender-affirming healthcare services.” R.I. Gen. Laws § 23-101-2. The Rhode Island General Assembly passed the Healthcare Provider Shield law after finding, among other things, that “Access to transgender healthcare services . . . is a legal right in this state [and] [i]nterference with legally protected healthcare activity, or the aiding and assisting of legally protected healthcare activity, as defined by this act, whether or not under the color of law, is against the public policy of this state.”<sup>7</sup>

The Healthcare Provider Shield Law was enacted specifically to protect Rhode Island patients and providers from exactly the type of interference the federal government is now attempting—investigations and enforcement actions from other jurisdictions seeking to punish the provision of lawful healthcare. The law creates a cause of action for “[a]ny person in this state upon whom a subpoena seeking information concerning legally protected healthcare activity . . . [to] move to modify or quash such subpoena on any grounds provided by court rule, statute, or on the

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<sup>6</sup> Patrick Boyle, What Is Gender-Affirming Care? Your Questions Answered, Association of American Medical Colleges (AAMC) (April 12, 2022), <https://tinyurl.com/5n6nj8ej> (last visited May 1, 2026).

<sup>7</sup> General Assembly 2024 -- S 2262 SUBSTITUTE A, <https://webserver.rilegislature.gov/BillText24/SenateText24/S2262A.pdf> (last visited May 1, 2026).

grounds that the subpoena is inconsistent with the public policy as set out in this act” and prohibits Rhode Island courts from enforcing out-of-state subpoenas, judgments, or other legal process related to legally protected healthcare activity. R.I. Gen. Laws § 23-101-5. And in 2015, the Rhode Island Executive Office of Health and Human Services issued guidance expressly stating that Rhode Island Medicaid covers medical care for gender dysphoria, including specifically for patients age 17 and younger.<sup>8</sup> There is no doubt, therefore, that medical care for gender dysphoria is available and protected by law in Rhode Island, and consistent with the medically appropriate standards of care.

Moreover, Rhode Island state law provides comprehensive legal protections for transgender people. State law prohibits discrimination against a person on the basis of gender identity or expression in employment, housing, credit, and public accommodations. R.I. Gen. Laws § 28-5-3; § 28-5-7; § 34-37-4; § 34-37-4.3; § 11-24-2. A place of “public accommodation” is any place that is open to the public, including clinics and hospitals. R.I. Gen. Laws § 11-24-3. As a result, medical facilities in Rhode Island are not permitted to refuse, withhold, or deny a person services because of a person’s perceived or actual gender identity or expression, including discriminatory denial of privacy protections.

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<sup>8</sup> See *Rhode Island Gender Dysphoria/Gender Nonconformity Coverage Guidelines*, Rhode Island Executive Office of Health and Human Services (Oct. 28, 2015), [https://eohhs.ri.gov/sites/g/files/xkgbur226/files/Portals/0/Uploads/Documents/MA-Providers/MA-Reference-Guides/Physician/gender\\_dysphoria.pdf](https://eohhs.ri.gov/sites/g/files/xkgbur226/files/Portals/0/Uploads/Documents/MA-Providers/MA-Reference-Guides/Physician/gender_dysphoria.pdf) (last visited May 1, 2026).

## **II. RI Hospital's Provision of Medical Care for Gender Dysphoria to Patients in DCYF Care or Custody.**

RI Hospital provides medical care for gender dysphoria, including care to some minor patients who are in DCYF care or custody. Declaration of the Child Advocate, Katelyn Medeiros (Medeiros Decl.) ¶ 5, attached hereto as Exhibit 1. This medical care is individualized to each patient and their family, and may include mental health counseling, social support, and in appropriate cases, medication such as puberty blockers or hormone therapy.<sup>9</sup>

## **III. The Administration's Campaign To Eliminate Medical Care for Gender Dysphoria.**

The Subpoena issued to RI Hospital, and more than 20 identical subpoenas DOJ served on health care providers that provide medical care for gender dysphoria to patients around the country,<sup>10</sup> are not isolated law enforcement actions; rather, they are components of a coordinated federal campaign by the Trump Administration to target transgender individuals and eliminate access to gender-affirming medical care nationwide, even where such care is lawful and protected under state law. Without seeking any legislation from Congress to carry out this attempt to federalize the regulation of medical care, the Administration began a concerted effort to change how

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<sup>9</sup> *Gender and Sexual Health Services*, Brown University Health, <https://www.brown-health.org/centers-services/gender-and-sexual-health-services> (last visited May 1, 2026).

<sup>10</sup> See, e.g., *Department of Justice Subpoenas Doctors and Clinics Involved in Performing Transgender Medical Procedures on Children*, DOJ Office of Public Affairs, <https://www.justice.gov/opa/pr/departments-justice-subpoenas-doctors-and-clinics-involved-performing-transgender-medical> (last visited May 1, 2026).

doctors treat patients with gender dysphoria, as part of a campaign to deny the very existence of transgender Americans and those with gender identities it disfavors.

On January 28, 2025, President Trump issued Executive Order 14187, titled “Protecting Children from Chemical and Surgical Mutilation.”<sup>11</sup> The Order villainized medical professionals who provide lifesaving treatment for allegedly “maiming and sterilizing a growing number of impressionable children under the radical and false claim that adults can change a child’s sex through a series of irreversible medical interventions.”<sup>12</sup> The Order went on to declare that “[t]his dangerous trend will be a stain on our Nation’s history, and it must end.”<sup>13</sup> The Order equated “gender affirming care” with “chemical and surgical mutilation” and directed the Attorney General to prioritize investigations related to such care.<sup>14</sup>

The Administration has also characterized lifesaving medical care for gender dysphoria as “child abuse” and equated it with “sexual mutilation.”<sup>15</sup> In April 2025, the White House issued a proclamation for National Child Abuse Prevention Month claiming that “the sinister threat of gender ideology” is “one of the most prevalent

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<sup>11</sup> *Protecting Children from Chemical and Surgical Mutilation*, The White House (Jan. 28, 2025), <https://www.whitehouse.gov/presidential-actions/2025/01/protecting-children-from-chemical-and-surgical-mutilation/> (last visited May 1, 2026).

<sup>12</sup> *Id.*

<sup>13</sup> *Id.*

<sup>14</sup> *Id.*

<sup>15</sup> *National Child Abuse Prevention Month, 2025*, The White House (April 3, 2025), <https://www.whitehouse.gov/presidential-actions/2025/04/national-child-abuse-prevention-month-2025/> (last visited May 1, 2026).

forms of child abuse facing our country today,” specifically calling out “hormone therapy [and] puberty blockers.”<sup>16</sup> The Administration “pledge[d] to stop the atrocity of child abuse in all its forms” and “affirm[ed] that every perpetrator who inflicts violence on our children will be punished to the fullest extent of the law”—explicitly characterizing this lifesaving medical care as abuse and violence.<sup>17</sup>

Following the Trump Administration’s marching orders, on April 22, 2025, then-Attorney General Pam Bondi issued a memorandum to DOJ leadership titled “Preventing the Mutilation of American Children.”<sup>18</sup> The memorandum stated that “the Department will act decisively to protect our children and hold accountable those who mutilate them under the guise of care.”<sup>19</sup> The memo directed DOJ to investigate healthcare providers offering medical care for gender dysphoria, using the pretext of alleged Federal Food, Drug, and Cosmetic Act (FDCA) and False Claims Act (FCA) violations. Then-Attorney General Bondi concluded the memo by making the real purpose of these investigations crystal clear, denigrating the dedicated medical professionals who provide this lifesaving care by comparing them to drug cartels and terrorists:

Protecting America’s children must be our top priority, whether from drug cartels, terrorists, or even our own medical community. Every day, we hear more harrowing stories about children who will suffer for the

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<sup>16</sup> *Id.*

<sup>17</sup> *Id.*

<sup>18</sup> *Memorandum from Attorney General, Preventing the Mutilation of American Children*, Office of the Attorney General, at 3-4 (April 22, 2025) (hereinafter “Preventing the Mutilation of American Children Memo”), <https://tinyurl.com/2b9kaja7> (last visited May 1, 2026).

<sup>19</sup> *Id.*

rest of their lives because of the unconscionable ideology behind “gender-affirming care.” Under my leadership, *the Department of Justice will bring these practices to an end.*<sup>20</sup>

In other words, the unambiguous purpose of these investigations is to attack and suppress an “unconscionable ideology” the Administration disfavors, part of its coordinated effort to deny the very existence of all who do not fit its preferred ideology of an imagined “immutable biological reality” of binary sex.

On June 11, 2025, the Assistant Attorney General for the Civil Division issued a memorandum stating that the Division would use “all available resources to prioritize investigations of doctors, hospitals, pharmaceutical companies, and other appropriate entities” providing medical care for gender dysphoria under the guise of FDCA and FCA investigations.<sup>21</sup> The memorandum explicitly referenced the Attorney General’s directive to “hold accountable those who mutilate [children] under the guise of care.”<sup>22</sup>

On July 9, 2025, DOJ publicly announced that it had “sent more than 20 subpoenas to doctors and clinics involved in performing transgender medical procedures on children.”<sup>23</sup> The Attorney General personally stated: “Medical professionals and

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<sup>20</sup> *Id.*, emphasis added.

<sup>21</sup> *Memorandum from Assistant Attorney General Brett A. Shumate, Civil Division Enforcement Priorities*, Office of the Assistant Attorney General, at 2-3 (June 11, 2025) (hereinafter “Civil Division Memo”), <https://tinyurl.com/mr3bym4f> (last visited May 1, 2026).

<sup>22</sup> *Id.*

<sup>23</sup> *Department of Justice Subpoenas Doctors and Clinics Involved in Performing Transgender Medical Procedures on Children*, DOJ Office of Public Affairs, <https://www.justice.gov/opa/pr/departments-justice-subpoenas-doctors-and-clinics-involved-performing-transgender-medical> (last visited May 1, 2026).

organizations that mutilated children in the service of a warped ideology will be held accountable by this Department of Justice.”<sup>24</sup> DOJ’s purpose in issuing the subpoenas is plain from its repeated public statements: to intimidate and coerce providers into abandoning lawful medical care.

The Trump Administration’s campaign has already accomplished its explicit goal of chilling access to medical care for gender dysphoria. Clinics that serve transgender individuals are even shutting down entirely.<sup>25</sup> The White House celebrated that 18 hospitals had curtailed their medical care for gender dysphoria programs as a result of the Administration’s efforts.<sup>26</sup> At a Federal Trade Commission conference in July 2025, a DOJ supervisor of these investigations responded to a comment that “there’s a very good chance [medical care for gender dysphoria] will stop even in blue states” by stating: “Working on it.”<sup>27</sup>

The message is unmistakable: the Trump Administration is attempting to use the DOJ’s law enforcement power to eliminate medical care for gender dysphoria,

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<sup>24</sup> *Id.*

<sup>25</sup> See Sonja Sharp, *Children’s Hospital Los Angeles Halts Transgender Care Under Pressure from Trump*, Los Angeles Times (June 12, 2025), <https://tinyurl.com/276vhe7y> (last visited May 1, 2026).

<sup>26</sup> See *President Trump Promised to End Child Sexual Mutilation — and He Delivered*, The White House (July 25, 2025), <https://www.whitehouse.gov/articles/2025/07/president-trump-promised-to-end-child-sexual-mutilation-and-he-delivered/> (last visited May 1, 2026).

<sup>27</sup> See *Transcript of The Dangers of “Gender-Affirming Care” for Minors*, Federal Trade Commission (July 9, 2025), [https://www.ftc.gov/system/files/ftc\\_gov/pdf/FTC-The-Dangers-of-Gender-Affirming-Care-for-Minors-Transcript.pdf](https://www.ftc.gov/system/files/ftc_gov/pdf/FTC-The-Dangers-of-Gender-Affirming-Care-for-Minors-Transcript.pdf) (last visited May 1, 2026).



regardless of state law, medical consensus, or the constitutional rights of patients, as part of its broader campaign against transgender people.

#### **IV. The Administration’s Broader Attacks on Transgender People.**

This Subpoena is only one part of the Trump Administration’s coordinated effort to deny the existence of gender identity, strip rights from transgender people, and eliminate access to medical care for gender dysphoria entirely. This targeted campaign began on Inauguration Day, when the Administration issued Executive Order 14168 titled “Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government,” stating “[i]t is the policy of the United States to recognize two sexes, male and female. These sexes are not changeable and are grounded in fundamental and incontrovertible reality.”<sup>28</sup>

The President subsequently issued related Executive Orders including banning transgender people from participating in the military<sup>29</sup> and withholding federal funds from schools “promoting gender ideology.”<sup>30</sup> The Administration also repealed a number of prior executive orders that extended a variety of protections to

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<sup>28</sup> *Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government*, The White House (Jan. 20, 2025), <https://www.whitehouse.gov/presidential-actions/2025/01/defending-women-from-gender-ideology-extremism-and-restoring-biological-truth-to-the-federal-government/> (last visited May 1, 2026).

<sup>29</sup> *Prioritizing Military Excellence and Readiness*, The White House (Jan. 27, 2025), <https://www.whitehouse.gov/presidential-actions/2025/01/prioritizing-military-excellence-and-readiness/> (last visited May 1, 2026).

<sup>30</sup> *Ending Radical Indoctrination in K-12 Schooling*, The White House (Jan. 29, 2025), <https://www.whitehouse.gov/presidential-actions/2025/01/ending-radical-indoctrination-in-k-12-schooling/> (last visited May 1, 2026).

transgender people.<sup>31</sup> The language of these Executive Orders denigrates and attacks the integrity of transgender people, including by stating they are not capable of living an “honorable, truthful, and disciplined lifestyle.”<sup>32</sup> And the Administration has attempted to enforce its preferred ideology by disqualifying grant applicants from federal funding unless they agree that they “[do] not and will not deny the sex binary in humans or promote the notion that sex is a chosen or mutable characteristic.”<sup>33</sup> These actions, taken together, make clear that the Administration is intent on targeting transgender people in many facets of their lives, including their healthcare, to the point of denying their very existence.

**V. The Subpoena Seeks Access to Highly Sensitive Medical Records of Minor Patients.**

In the context of the Trump Administration’s multi-pronged effort to attack transgender people and end medical care for gender dysphoria, on July 9, 2025, DOJ served RI Hospital with an administrative subpoena purportedly issued pursuant to 18 U.S.C. § 3486. *See In Re: Administrative Subpoena 25-1431-032*, No. 4-26MC-006-0, ECF No. 1 (N.D. Tex. Apr. 30, 2026). On April 30, 2026, the government filed a

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<sup>31</sup> *Initial Rescissions of Harmful Executive Orders and Actions*, The White House (Jan. 20, 2025), <https://www.whitehouse.gov/presidential-actions/2025/01/initial-rescissions-of-harmful-executive-orders-and-actions/> (last visited May 1, 2026).

<sup>32</sup> *Prioritizing Military Excellence and Readiness*, The White House (Jan. 27, 2025), <https://www.whitehouse.gov/presidential-actions/2025/01/prioritizing-military-excellence-and-readiness/> (last visited May 1, 2026).

<sup>33</sup> *Continuum of Care Builds Notice of Funding Opportunity Number FR-6902-N-25A*, United States Department of Housing and Urban Development (Sept. 5, 2025), <https://simpler.grants.gov/opportunity/23e87946-467a-486f-b6c5-db8c6b3c2317> (last visited May 1, 2026).

Petition for Enforcement of the Administrative Subpoena in the United States District Court for the Northern District of Texas. *Id.* A copy of the Subpoena, which the government filed with its motion to compel in the Northern District of Texas, is attached hereto as Exhibit 2. The Subpoena is identical or substantially similar to those issued to other children’s hospitals nationwide.<sup>34</sup> The subpoena seeks an extraordinarily broad range of sensitive information for a “Relevant Time Period” spanning from January 1, 2020 through the present—more than five years of records.

Most troubling are the following requests:

**Request 11:** “Documents sufficient to identify each patient (by name, date of birth, social security number, address, and parent/guardian information) who was prescribed puberty blockers or hormone therapy.”

**Request 12:** “For each such patient identified in [Request 11], documents relating to the clinical indications, diagnoses, or assessments that formed the basis for prescribing puberty blockers or hormone therapy.”

**Request 13:** “All documents relating to informed consent, patient intake, and parent or guardian authorization for minor patients identified in [Request 11], including any disclosures about off-label use (i.e., uses not approved by the United States Food and Drug Administration) and potential risks.”<sup>35</sup>

These requests demand the identities and complete medical histories of every minor patient who received medical care for gender dysphoria at RI Hospital over more than five years. The medical records responsive to these requests contain the most intimate details imaginable: children’s mental health struggles, experiences

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<sup>34</sup> See *In Re: Subpoena No. 25-1431-014*, 2:25-mc-00039 (E.D. Pa. July 8, 2025), ECF No. 1; *In Re: Administrative Subpoena No. 25-1431-019*, 1:25-mc-91324 (D. Mass. July 8, 2025), ECF No. 5-1; *QueerDoc, PLLC v. U.S. Dep’t of Just.*, No. 2:25-MC-00042-JNW (W.D. Wash. Oct. 27, 2025).

<sup>35</sup> See Exhibit 2.

with bullying or discrimination, family dynamics, sexual development, gender identity, trauma histories, suicidal ideation, and deeply personal conversations with physicians and therapists. For children in DCYF care, these records may also contain information about abuse or neglect, foster care placements, court involvement, and other highly sensitive circumstances. The records would identify not only the children themselves but also their parents, guardians, foster families, siblings, friends, teachers, social workers, and others mentioned in clinical notes.

In other words, for a population of children that already lacks trust in the legal and medical systems, DOJ now seeks unfettered access to everything from their Social Security numbers and addresses to the intimate details about their state of mind, their sexual orientation and gender identity, and the course of treatment they chose with their physician and custodians. And DOJ has stated that it will not just scrutinize that information but that it may share that information with others.<sup>36</sup>

## **VI. The Subpoena's Impact on Children in Rhode Island.**

Children whose medical records are sought by this subpoena—including those in DCYF care or custody—are among the most vulnerable individuals in Rhode Island. Many have experienced significant trauma. Many struggle with mental health challenges. Many have been victims of abuse, neglect, discrimination, or bullying. For

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<sup>36</sup> *Memorandum For Select Component Heads: Preventing the Mutilation of American Children*, Office of the Attorney General (Apr. 22, 2025), <https://www.justice.gov/ag/media/1402396/dl> (“I will partner with state attorneys general to identify leads, share intelligence, and build cases.”) (Last visited May 1, 2026).

many of these children, medical care for gender dysphoria has been, quite literally, lifesaving.

The prospect that their most intimate medical information will be turned over to federal prosecutors who have publicly characterized their necessary medical treatment as “mutilation” and “child abuse” is devastating. Children in DCYF care already face significant challenges in trusting adults and authority figures. Learning that the federal government seeks their private medical records, with the stated goal of “bringing an end” to the care they need, will compound their trauma and sense of vulnerability.

Moreover, many children who received medical care for gender dysphoria have not publicly disclosed their transgender status. Being “outed” to a hostile government by this “investigation” could subject them to harassment, discrimination, bullying, or even violence. Transgender individuals, particularly youth, face dramatically elevated rates of victimization.<sup>37</sup> The risk of harm is particularly acute given the Administration’s inflammatory rhetoric equating this medical care with abuse and mutilation.

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<sup>37</sup> See Michelle M. Johns, et al., *Transgender Identity and Experiences of Violence Victimization, Substance Use, Suicide Risk, and Sexual Risk Behaviors Among High School Students, Morbidity and Mortality Weekly Report*, US Department of Health and Human Services/Centers for Disease Control and Prevention (Jan. 25, 2019), <https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6803a3-H.pdf> (last visited May 1, 2026).

These harms also extend beyond those whose records are directly sought. If children and families fear that seeking medical care will result in federal investigation, they will be less likely to seek necessary treatment or to be candid with their healthcare providers. This chilling effect undermines the physician-patient relationship and threatens public health.

## **VII. The Child Advocate.**

The Office of the Child Advocate (“OCA”) was established by the Rhode Island General Assembly to serve as an independent voice for children in the care or custody of DCYF. R.I. Gen. Laws § 42-73-1 *et seq.* The Child Advocate is appointed by the Governor and confirmed by the Senate to serve as the state’s watchdog for children’s rights and welfare. *Id.*

By statute, the Child Advocate has broad authority to “take all possible action including, but not limited to ... formal legal action, to secure and ensure the legal, civil, and special rights of children” who are in DCYF protective care, custody, or receiving treatment services. R.I. Gen. Laws § 42-73-7. This mandate expressly includes protecting children’s legal rights through litigation when necessary. The General Assembly entrusted the Child Advocate with this authority precisely to ensure that vulnerable children have a powerful advocate who can take legal action to protect their interests. The Child Advocate therefore has a statutory duty to protect these children’s rights, including their constitutional right to privacy in their medical records and their right to access lawful medical treatment without federal government interference or intimidation.

### LEGAL STANDARD

A motion to quash a subpoena issued under 18 U.S.C. § 3486 is subject to the standard generally applicable to a motion to quash an administrative subpoena. *See Doe v. United States*, 253 F.3d 256, 268 (6th Cir. 2001). An administrative subpoena is enforceable only if “(1) the subpoena is issued for a congressionally authorized purpose, the information sought is (2) relevant to the authorized purpose and (3) adequately described, and (4) proper procedures have been employed in issuing the subpoena.” *U.S. Dep’t of Just. v. Ricco Jonas*, 24 F.4th 718, 726 (1st Cir. 2022); *United States v. Powell*, 379 U.S. 48, 57-58 (1964). “The requirement that subpoenas be used only for a legitimate and authorized governmental purpose prohibits the government from ‘engaging in arbitrary fishing expeditions’ and from ‘selecting targets of investigation out of malice or an intent to harass.’” *In re Subpoena Duces Tecum*, 228 F.3d 341, 349 (4th Cir. 2000) (cleaned up) (quoting *United States v. R. Enters., Inc.*, 498 U.S. 292, 299 (1991)). “Persons from whom [an agency] seeks relevant information are not required to submit to [the agency’s] demand, if in any respect it is unreasonable or overreaches the authority Congress has given.” *Okla. Press Pub. Co. v. Walling*, 327 U.S. 186, 217 (1946); *see also Doe*, 253 F.3d at 265 (holding that an administrative subpoena must “satisf[y] the terms of its authorizing statute”). Section 3486 administrative subpoenas, like the Subpoena at issue here, may only be used in investigations concerning the limited universe of federal criminal offenses identified in the statute. *See* 18 U.S.C. § 3486(a)(1)(A).

Additionally, even where a subpoena satisfies these baseline requirements, courts must consider whether a subpoena was issued for a proper purpose. *Ricco Jonas*, 24 F.4th at 726. A subpoena issued for an improper purpose, such as harassment, or issued in bad faith, cannot be enforced. *See United States v. Powell*, 379 U.S. 48 (1964); *In Re: Administrative Subpoena No. 25-1431-019*, 800 F. Supp. 3d 229, 236-37 (D. Mass. September 9, 2025) (quashing an identical subpoena to Boston Children’s Hospital because it “was issued for an improper purpose, motivated only by bad faith.”). The First Circuit has concluded that courts “have adequate justification to deny enforcement of [a] subpoena” when there is evidence that a subpoena’s issuance was motivated by bad faith. *United States v. Comley*, 890 F.2d 539, 542 (1st Cir. 1989) (citing *United States v. Westinghouse Elec. Corp.*, 788 F.2d 164, 166–67 (3d Cir. 1986) (“[I]f a subpoena is issued for an improper purpose, such as harassment, its enforcement constitutes an abuse of the court’s process.”)).

## **ARGUMENT**

### **I. The Child Advocate Has Standing To Challenge the Subpoena.**

The Child Advocate has standing to move to quash the subpoena on behalf of children in DCYF custody or care whose medical records are sought. A party has standing to move to quash a subpoena issued to a non-party if “the information sought by the subpoena implicates a personal right or privilege of the party.” *Ponder v. Ocwen Loan Servicing, LLC*, No. CV 19-MC-91215-ADB, 2019 WL 2249675, at \*2 (D. Mass. May 24, 2019) (collecting cases). “The personal right or privilege claimed need not be weighty: parties need only have some personal right or privilege in the information sought to have standing to challenge a subpoena to a third party.” *S.E.C. v.*



*Navellier & Assocs., Inc.*, No. 17-cv-11633, 2019 WL 688164, at \*2 (D. Mass. Feb. 19, 2019) (quoting *Degradis v. Children’s Hosp. Bos.*, 203 F. Supp. 3d 193, 198 (D. Mass. 2016)). And, generally, “the subject of an administrative subpoena has an opportunity to challenge the subpoena before yielding the information.” *United States v. Sturm, Ruger & Co.*, 84 F.3d 1, 3 (1st Cir. 1996).

The Child Advocate “monitors each child in the care of DCYF to protect their legal rights and ensure their safety, including their physical, mental, medical, educational, and behavioral needs while in out-of-home placements. [ ] [The Child Advocate] has the right to intervene in any case where a child’s safety, education, and physical and mental welfare are not being met, and if a resolution cannot be reached, [the Child Advocate] can initiate litigation on the child’s behalf.” *Off. of the Child Advocate on Behalf of Jane Doe v. Providence Pub. Sch. Dep’t*, No. 25-CV-649-JJM-AEM, 2026 WL 1068031, at \*4 (D.R.I. Apr. 20, 2026). Here, the Child Advocate seeks to protect the constitutional privacy rights of identifiable children in the state of Rhode Island’s care whose medical records are sought by the subpoena. These children face concrete injury—invasion of their privacy, disclosure of their most intimate medical information, potential “outing” of their gender identity, and exposure to harassment or discrimination—that is directly traceable to the subpoena and redressable by quashing it.

Moreover, the Child Advocate has statutory authority under Rhode Island law to bring this motion. R.I. Gen. Laws § 42-73-7 expressly empowers the Child Advocate

to “take all possible action including, but not limited to ... formal legal action, to secure and ensure the legal, civil, and special rights of children” in DCYF care or custody. Denying the Child Advocate standing to challenge a subpoena that threatens these children’s constitutional privacy rights would frustrate the Rhode Island General Assembly’s intent in creating the Office of the Child Advocate.

Moreover, this Court is unquestionably the proper venue in which the Child Advocate should bring this motion to quash. The Child Advocate, and the children in DCYF custody or care on whose behalf she brings this motion, are all located in Rhode Island. RI Hospital, to whom the subpoena was issued, is located in Rhode Island and carries on business only in Rhode Island. The records DOJ seeks to obtain are all located in Rhode Island. And DOJ served the subpoena on RI Hospital in Rhode Island, with instructions to produce records in Washington, D.C. *See, e.g.*, 18 U.S.C. § 3486(a)(3) (“The production of records relating to a Federal health care offense shall not be required under this section at any place more than 500 miles distant from the place where the subpoena for the production of such records is served.”). The Child Advocate was not a party to, and had no notice of, the Texas proceeding, and has had no opportunity to be heard on the Subpoena in any court.

## **II. The Subpoena Was Issued for an Improper Purpose and in Bad Faith.**

The subpoena must be quashed because it was issued for an improper purpose: to eliminate medical care for gender dysphoria at a federal level, rather than to investigate any legitimate federal crime. A subpoena issued “for an improper purpose, such as to harass” or “to put pressure” on recipients is not enforceable. *Powell*, 379 U.S. at 58. Similarly, subpoenas issued in bad faith or motivated by animus cannot

be enforced. *Comley*, 890 F.2d at 542; *see also Sec. & Exch. Comm'n v. Wheeling-Pittsburgh Steel Corp.*, 648 F.2d 118, 129 (3d Cir. 1981).

**A. The Subpoena's Purpose Is To End Gender-Affirming Medical Care, Not Investigate Crime.**

As discussed in more detail above, the Administration has openly and repeatedly stated that its purpose in conducting the investigations that produced the Subpoena is to “end” medical care for gender dysphoria. These statements are directly relevant to the Court’s inquiry in evaluating whether the Subpoena was issued for a congressionally authorized purpose or instead an improper one. The subpoena was issued at the actual direction of the Attorney General. *See* Exhibit 2. DOJ’s own counsel admitted in related litigation that DOJ believes “it is a rational governmental objective or purpose to eliminate the medicalized gender-affirming care of minors and that’s exactly what this investigation is about.” *See* Tr. of Mot. Hr’g 25:14-17, *In Re: Administrative Subpoena No. 25-1431-019*, 1:25-mc-91324 (D. Mass. Sep. 1, 2025), ECF No. 30.

As a district court in the Western District of Washington concluded, quashing an identical subpoena, “[n]o clearer evidence of improper purpose could exist than the Government’s own repeated declarations that it seeks to end the very practice it claims to be merely investigating.” *QueerDoc*, 807 F. Supp. 3d at 1303. Incredibly, in a public response issued to questions about that court’s order quashing an identical subpoena, DOJ doubled down and eliminated any remaining doubt about its true purpose: “As Attorney General Bondi has made clear, this Department of Justice will

use every legal and law enforcement tool available to protect innocent children from being mutilated under the guise of ‘care.’”<sup>38</sup>

That is not a legitimate law enforcement purpose. The regulation of medical practice is “primarily, and historically, a matter of local concern.” *Hillsborough Cnty. v. Automated Med. Lab’ys, Inc.*, 471 U.S. 707, 719 (1985). While Congress may “set uniform national standards in these areas,” it has done so only rarely. *See Gonzales v. Oregon*, 546 U.S. 243, 271 (2006). When the federal government seeks to disrupt areas of traditional state authority, courts require a clear statement that Congress intended such a shift. *See West Virginia v. EPA*, 597 U.S. 697, 722-24 (2022) (citing *Oregon* as example of “major questions doctrine”). There is no congressional statement here, much less a clear one, that would allow the Administration to regulate the practice of medicine federally.

Indeed, just last year the Supreme Court reaffirmed that “[w]e afford States ‘wide discretion to pass legislation in areas where there is medical and scientific uncertainty,’” including specifically in the area of medical care for gender dysphoria. *United States v. Skrametti*, 605 U.S. 495, 524 (2025) (quoting *Gonzales v. Carhart*, 550 U.S. 124, 163 (2007)). Rhode Island has not merely declined to ban medical care for gender dysphoria—it has affirmatively protected it from exactly the type of interference DOJ is now attempting. The Rhode Island Healthcare Provider Shield Law specifically protects patients and providers from investigations and enforcement actions

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<sup>38</sup> Josh Gerstein, *DOJ tried to subpoena an online trans health care provider. A judge quashed it*, Politico (Oct. 29, 2025), <https://www.politico.com/news/2025/10/29/doj-subpoena-gender-affirming-care-ruling-00627891> (last visited May 1, 2026).

by other jurisdictions seeking to punish the provision of lawful healthcare. R.I. Gen. Laws § 23-101. The Subpoena represents precisely the type of interference the Rhode Island General Assembly sought to prevent. The Healthcare Provider Shield Law demonstrates Rhode Island’s clear and emphatic public policy: medical care for gender dysphoria is not merely lawful, it is a protected right, and interference with that right, “whether or not under the color of law,” violates state law.

When a state has exercised its traditional authority over the practice of medicine by not only permitting but affirmatively protecting certain medical care, the federal government’s attempt to override that policy choice through a pretextual criminal investigation is particularly improper. DOJ seeks to accomplish through a pretextual criminal investigation what it lacks authority to achieve through legislation: a nationwide ban on medical care for gender dysphoria that overrides state law and policy. An attempt to intimidate physicians into stopping medical care that is protected under state law is an impermissible goal for the federal government. *See Gonzales*, 546 U.S. at 273-75 (Attorney General could not revoke physicians’ licenses under federal Controlled Substances Act for prescribing drugs in compliance with Oregon’s Death With Dignity Act); *Hillsborough Cnty.*, 471 U.S. at 719. There is a straight path between the government’s explicit directives to end medical care for gender dysphoria and the DOJ’s bad faith subpoena. *See In re Children’s Nat’l Hosp.*, No. 1:25-CV-03780-JRR, 2026 WL 160792, at \*6 (D. Md. Jan. 21, 2026) (quashing an identical subpoena on the grounds that it “lacks a proper investigative purpose.”)

Pursuing an unlawful end—and trying to dress that aim up with pretextual justifications—is the very definition of bad faith.

**B. DOJ’s Purported Legal Bases for the Subpoena Are Pretextual.**

In support of its efforts to enforce the Subpoena in Texas, and identical subpoenas in other cases, DOJ has claimed the subpoenas are proper because it is investigating potential violations of the FDCA or the FCA. *See, e.g.*, Declaration of Lisa K. Hsiao, filed in *In Re: Administrative Subpoena 25-1431-032*, No. 4-26MC-006-0 (N.D. Tex. Apr. 30, 2026), attached hereto as Exhibit 3; *In Re: Administrative Subpoena 25-1431-032*, No. 4-26MC-006-0, ECF No. 1 (N.D. Tex. Apr. 30, 2026); *In re Admin. Subpoena No. 25-1431-019*, ECF No. 36 (D. Mass. Oct. 7, 2025). But these theories are both legally deficient and factually unsupported, especially in the context of DOJ’s own repeated and public statements about its true purpose in issuing the subpoenas.

**1. The FDCA Does Not Prohibit Off-Label Prescribing.**

Physicians may prescribe an approved drug for an unapproved use without violating the FDCA. The FDCA “does not regulate the practice of medicine,” and off-label prescribing “is an accepted and necessary corollary of the FDA’s mission to regulate in this area without directly interfering with the practice of medicine.” *Buckman v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 350 (2001). Indeed, the FDCA expressly states that it does not empower the primary agency charged with enforcing the FDCA—namely, the FDA—to interfere with the authority of a medical provider to “prescribe or administer any legally marketed device to any patient for any condition or disease within a legitimate health care practitioner-patient relationship.” 21 U.S.C. § 396.

The FDA’s own guidance likewise consistently upholds doctors’ right to engage in off-label prescription and administration for legitimate medical purposes. For example, one guidance document states: “[O]nce a drug or medical device has been approved or cleared by FDA, generally, health care professionals can lawfully use or prescribe that product for uses or treatment indications that are not included in the product’s approved labeling. . . . [T]he FDA recognizes that these off-label uses may even constitute a medically recognized standard of care.”<sup>39</sup> Similarly, DOJ’s own Office of Legal Counsel also affirms that off-label prescribing and administration is not a violation of the FDCA: “[W]hile the FDCA bars a manufacturer or distributor from selling any drug or device for an unapproved use, physicians may, with limited exceptions, prescribe and administer FDA-approved drugs and devices for unapproved uses.”<sup>40</sup>

Courts have consistently recognized the rule that off-label prescribing and use of drugs is permissible. *See Buckman Co.*, 531 U.S. at 350; *United States v. Fackeau*,

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<sup>39</sup> Guidance for Industry: Responding to Unsolicited Requests for Off-Label Information about Prescription Drugs and Medical Devices, U.S. Food & Drug Admin. (Dec. 2011) (draft guidance for comment purposes only), <https://www.fda.gov/media/82660/download> (last visited May 1, 2026); *see also Understanding Unapproved Use of Approved Drugs “Off Label”*, U.S. Food & Drug Admin. (Feb. 5, 2018), <https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label> (last visited May 1, 2026) (“[O]nce the FDA approves a drug, healthcare providers generally may prescribe the drug for an unapproved use when they judge that it is medically appropriate for their patient.”)

<sup>40</sup> Steven A. Engel, *Whether the Food and Drug Administration Has Jurisdiction over Articles Intended for Use in Lawful Executions*, 43 Op. O.L.C. 81, 85 (2019), <https://www.justice.gov/olc/opinion/file/1162686/dl?inline> (last visited May 1, 2026).

89 F.4th 1, 13 (1st Cir. 2023), cert. denied, 145 S. Ct. 137 (2024) (“[T]he FDCA expressly protects the ‘authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease.’” (quoting 21 U.S.C. § 396)). Indeed, it is well established that “medical professionals may lawfully prescribe and administer a device for an off-label use as long as that device has received [FDA] clearance for any intended use.” *Facteau*, 89 F.4th at 15; *see also Washington Legal Found. v. Henney*, 202 F.3d 331, 333 (D.C. Cir. 2000) (“[N]either Congress nor the FDA has attempted to regulate the off-label use of drugs by doctors and consumers. A physician may prescribe a legal drug to serve any purpose that he or she deems appropriate, regardless of whether the drug has been approved for that use by the FDA.”); *U.S. ex rel. Nowak v. Medtronic, Inc.*, 806 F. Supp. 2d 310, 317 (D. Mass. 2011) (“[T]he FDA ... cannot prevent a doctor from prescribing a device for an off-label use for any purpose she deems medically necessary.”)

DOJ itself recently made these same representations to the Third Circuit, arguing that “off-label prescription of a drug can sometimes be both medically accepted and reasonable and necessary for a given patient” and that the FDCA’s “misbranding provisions govern how drugs may be marketed; they do not govern whether federal healthcare programs will reimburse for the drugs, as prescribed for particular patients.” *Penelow v. Janssen Prods. LP*, No. 25-1818, ECF No. 56 at 36 (3d Cir. Aug. 27, 2025). If the FDCA does not prohibit the conduct DOJ now seeks to investigate criminally, then the investigation cannot be justified under the FDCA.



2. DOJ Cannot Convert RI Hospital's Clinical Treatment Decisions into Commercial Distribution of Misbranded Drugs.

In an effort to avoid the settled rule that the FDCA does not prohibit off-label prescribing, in its motion to compel compliance with the Subpoena, filed in Texas, the government claims that RI Hospital is a distributor or seller of misbranded drugs under 21 U.S.C. §§ 331, 352. That theory fails.

The FDCA's misbranding provisions regulate the labeling, marketing, and commercial distribution of medical products; they do not transform a physician's patient-specific therapeutic judgment, informed-consent discussion, or medical chart into manufacturer-style "labeling" for a drug. DOJ's recharacterization of hospital-based medical care as drug "distribution" is a transparent attempt to circumvent the FDCA's express protection of medical practice. When a hospital pharmacy fills a prescription written by a treating physician for an individual patient, that act is part of the delivery of medical care, not independent commercial drug distribution. The cases DOJ cites for the breadth of the FDCA's misbranding provisions—*Kordel v. United States*, 335 U.S. 345 (1948); *United States v. Urbuteit*, 335 U.S. 355 (1948); *47 Bottles, More or Less*, 320 F.2d 564 (3d Cir. 1963)—all involve manufacturers and commercial distributors who marketed drugs to the public for unapproved purposes. None involved a healthcare provider dispensing an FDA-approved drug pursuant to an individualized clinical judgment by a treating physician. There is a fundamental difference between a manufacturer promoting a drug for an unapproved indication through advertising and sales representatives, and a physician prescribing an approved drug

off-label based on that physician's medical judgment about a particular patient's needs. DOJ's theory erases that distinction entirely.

If accepted, DOJ's theory would criminalize virtually all off-label prescribing through the back door. If a hospital's act of dispensing an FDA-approved drug pursuant to a physician's off-label prescription automatically renders the drug "misbranded" because its labeling lacks directions for the off-label use, then *every* hospital that fills an off-label prescription, a routine and pervasive practice across American medicine, would be committing a federal crime. That result is untenable, and it is plainly not what Congress intended when it enacted the FDCA's misbranding provisions.

The regulation DOJ invokes, 21 C.F.R. § 201.128, titled "Meaning of 'intended uses,'" is not an independent criminal prohibition. It defines "intended use" for purposes of specific FDA labeling provisions. By its terms, the regulation refers to the objective intent of "the persons legally responsible for the labeling of an article (or their representatives)." *Id.* The "seller" language DOJ quotes must be read in that context. A manufacturer, packer, distributor, or commercial seller that promotes a product for a new unapproved use may create a new intended use and trigger labeling obligations. But a treating physician who prescribes or administers an FDA-approved prescription drug to an individual patient is not thereby acting as the drug's manufacturer, packer, or commercial labeler. Nor does a hospital medical record, intake form, informed-consent form, or patient-specific clinical discussion become "labeling" merely because it mentions the physician's therapeutic purpose.

RI Hospital and its clinicians are not alleged to have manufactured a drug, changed a package insert, repackaged the drug for commercial resale, distributed the drug to other prescribing physicians, or disseminated product labeling on behalf of a manufacturer. The alleged conduct is the provision of medical care: prescribing or administering FDA-approved drugs in a practitioner-patient relationship, documenting the clinical basis for that care, and obtaining informed consent.

Nor can DOJ avoid this problem by invoking manufacturer off-label-promotion cases. The examples DOJ cites in its motion to compel, filed in Texas, involve manufacturers or commercial entities alleged to have promoted products for unapproved uses, paid incentives, distributed sales materials, or otherwise caused product distribution through marketing schemes. Those cases may support subpoenas for manufacturer communications, contracts, payments, sales aids, speaker arrangements, or other non-patient-specific commercial materials. They do not justify treating RI Hospital's clinical records as drug "labeling," and they do not support compelled disclosure of children's identities, diagnoses, Social Security numbers, parent or guardian information, consent forms, and medical histories.

The same is true of DOJ's suggestion that "scientific exchange information" or communications with pharmaceutical representatives may support an FDCA theory. Even assuming DOJ has a legitimate basis to investigate a manufacturer or distributor, that theory would call for narrowly tailored requests for communications with the manufacturer, financial arrangements, and promotional materials. It would not

justify wholesale production of patient charts. A manufacturer-promotion investigation does not require DOJ to identify every Rhode Island child who received care, read their mental-health assessments, obtain their parent or guardian information, or review individualized informed-consent discussions. The mismatch between DOJ's manufacturer-promotion theory and its demand for patient-level records confirms that the subpoena is not tailored to any lawful FDCA inquiry.

Finally, DOJ's reliance on strict liability and the responsible-corporate-officer doctrine does not cure the missing predicate. Those doctrines do not create an FDCA violation where none exists. They address responsibility for a cognizable violation of the Act; they do not make lawful off-label treatment, clinical counseling, informed consent, or routine hospital dispensing into misbranding.

3. DOJ's Off-Label Justification for the Subpoena Would Violate the First Amendment.

DOJ's novel theories of justification for the Subpoena in this case, which appear to turn in part on the guidance doctors give patients to use medications off-label, would also violate the First Amendment rights of doctors to communicate with their patients. It has long been recognized that "punish[ing] physicians on the basis of the content of doctor-patient communications" is impermissible under the First Amendment. *See, e.g., Conant v. Walters*, 309 F.3d 629, 637 (9th Cir. 2002). If DOJ is permitted to prosecute doctors for off-label prescribing and administration, it will undermine the ability of doctors "to speak frankly and openly to patients," which is "[a]n integral component of the practice of medicine." *Id.* at 636.

Indeed, courts have consistently concluded that efforts to prohibit “off-label promotion by a pharmaceutical manufacturer while simultaneously allowing off-label use ‘paternalistically’ interferes with the ability of physicians and patients to receive potentially relevant treatment information; such barriers to information about off-label use could inhibit, to the public’s detriment, informed and intelligent treatment decisions.” *United States v. Caronia*, 703 F.3d 149, 166 (2d Cir. 2012) (citing *Va. Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 770 (1976)); *see also Sorrell v. IMS Health Inc.*, 564 U.S. 552 (2011). The First Amendment implications of allowing DOJ to investigate off-label prescriptions as potential criminal activity with the Subpoena, standing alone, would be sufficient to doom DOJ’s novel, expansive theories of FDCA liability.

4. There is no Good-Faith Basis for a False Claims Act Investigation, and the Subpoena Is Not Authorized for that Purpose.

DOJ may also suggest it is investigating potential false claims to federal healthcare programs under the FCA. But this theory lacks any legal or factual foundation. First, DOJ has conceded in other matters involving identical subpoenas that its authority to issue the Subpoena is limited to investigations of alleged FDCA violations, not the FCA. *See In Re: Administrative Subpoena No. 25-1431-019*, 1:25-mc-91324, ECF No. 37 at ¶ 5 (D. Mass. Oct. 7, 2025) (“Pursuant to Attorney General Order Number 3591-2015, dated November 10, 2015, the Attorney General authorized the Assistant Attorney General for the Civil Division to issue and serve administrative subpoenas pursuant to 18 U.S.C. §§ 3486(a)(1)(A) and (a)(1)(B) *to investigate violations of the FDCA* that relate to a health care benefit program.” (emphasis

added)); *see also id.*, ECF No. 36 at 4 (“Causing the distribution of unapproved drugs can be an *FDCA violation*, which can be a federal health care offense. 21 U.S.C. § 331(d); 18 U.S.C. § 24.” (emphasis added)). The alleged FDCA violations have nothing to do with billing issues; they relate to alleged off-label use of medications or distribution of misbranded or unapproved drugs. *In Re: Administrative Subpoena No. 25-1431-019*, ECF No. 37 at ¶¶ 11-18.

Nevertheless, DOJ has also claimed the Subpoena seeks evidence that relates to billing for medical care for gender dysphoria and related records. *See id.* ¶¶ 31, 35. That evidence is not relevant to alleged FDCA violations. Evidence of any billing fraud would be relevant only if there were an underlying FDCA violation, which there is not, and even then, only if the intent to defraud were connected to the FDCA violation. *See United States v. Mitcheltree*, 940 F.2d 1329, 1349 (10th Cir. 1991) (“[T]he specific intent requirement in § 333(a)(2) requires not only proof of misbranding under § 331, but also proof of an intent to mislead or defraud *which is connected to the misbranding violation under § 331.*”) (emphasis added). Instead, that kind of evidence would be relevant to an FCA investigation, which DOJ has admitted cannot be the basis for a subpoena under 18 U.S.C. § 3486. The mismatch between DOJ’s FDCA theories and the purported evidence it seeks only further confirms that this asserted basis for the investigation is pretextual.

Even if an FCA investigation of billing practices were a legitimate basis, and it is not, the DOJ’s stated purpose for that investigation is legally and factually deficient. The Civil Division memorandum that prompted these subpoenas specifically

referenced investigating providers who “attempt to evade state bans on gender dysphoria treatments by knowingly submitting claims to Medicaid with false diagnosis codes.”<sup>41</sup> But Rhode Island has no such ban; to the contrary, medical care for gender dysphoria is lawful and protected healthcare, and the state affirmatively protected this care from exactly the type of federal interference DOJ is now attempting. There is thus no reason for any Rhode Island provider to “evade” anything, and no basis for investigating false billing. Medicare and many state Medicaid programs explicitly cover this care.<sup>42</sup> The Subpoena seeks to override Rhode Island’s express legislative determination that medical care for gender dysphoria is a protected legal right and that interference with such care is against state law and public policy.

**C. The Requests Are Not Tailored to Any Legitimate Investigation.**

Even if DOJ had a legitimate investigative theory—and it does not—the Subpoena’s requests are not narrowly tailored to any such theory. The Fourth Amendment requires that administrative subpoenas “be sufficiently limited in scope [and] relevant in purpose[.]” *See v. City of Seattle*, 387 U.S. 541, 544 (1967). The Fourth Amendment therefore requires that an administrative subpoena “be disallowed if it is far too sweeping in its terms to be regarded as reasonable. . . . And the requirement that subpoenas be used only for a legitimate and authorized governmental purpose

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<sup>41</sup> Memorandum from Assistant Attorney General Brett A. Shumate, Civil Division Enforcement Priorities, at 3 (June 11, 2025)

<sup>42</sup> *See Rhode Island Gender Dysphoria/Gender Nonconformity Coverage Guidelines*, Rhode Island Executive Office of Health and Human Services (Oct. 28, 2015), [https://eohhs.ri.gov/sites/g/files/xkgbur226/files/Portals/0/Uploads/Documents/MA-Providers/MA-Reference-Guides/Physician/gender\\_dysphoria.pdf](https://eohhs.ri.gov/sites/g/files/xkgbur226/files/Portals/0/Uploads/Documents/MA-Providers/MA-Reference-Guides/Physician/gender_dysphoria.pdf) (last visited May 1, 2026).

prohibits the government from engaging in arbitrary fishing expeditions and from selecting targets of investigation out of malice or an intent to harass.” *In re Dep’t of Just. Admin. Subpoena No. 25-1431-030*, No. 25-MC-00063-SKC-CYC, 2026 WL 33398, at \*8 (D. Colo. Jan. 5, 2026) (cleaned up).

If DOJ were truly investigating off-label promotion by pharmaceutical manufacturers, it would not need the identities, Social Security numbers, and complete medical histories of minor patients. If DOJ were truly investigating billing fraud, anonymized billing records would suffice. Instead, the subpoena seeks the most intimate details of children’s lives, going far beyond anything necessary to investigate the purported violations.

**D. The Evidence of Bad Faith and Improper Purpose Is Overwhelming.**

DOJ’s effort to block lawful medical treatment by opening an unfounded and politically motivated attack on medical care for gender dysphoria, under the pretext of a law enforcement investigation, is not a congressionally authorized purpose. Nor is issuing a subpoena in search of “wrongdoing, as yet unknown,” that could later be a proper or authorized purpose. *In re Sealed Case (Administrative Subpoena)*, 42 F.3d 1412, 1418 (D.C. Cir. 1994). That is precisely what the Administration seeks to do with these subpoenas: they were issued in an attempt to bring an end to a type of medical treatment that this Administration disfavors, but that is lawful and protected in Rhode Island. DOJ’s bad faith is evident from multiple sources. In summary, as discussed in more detail above:



- The Administration has demonized lifesaving medical care for gender dysphoria as “mutilation,” “maiming,” “sterilization,” and “child abuse.”
- The Administration has asserted that transgender citizens cannot lead an “honorable, truthful, and disciplined lifestyle,” and that their medical treatment is part of a “warped ideology” and “evil and backwards lies” that cause “sexual mutilation.” This inflammatory language reveals animus toward transgender individuals and those who provide them care.
- The Administration has attempted to deny the existence of transgender people, forcing grant applicants to agree that they “[do] not and will not deny the sex binary in humans or promote the notion that sex is a chosen or mutable characteristic.”
- The Attorney General explicitly stated the DOJ’s goal is to “bring these [medical care for gender dysphoria] practices to an end”—a policy objective, not a law enforcement purpose.
- DOJ issued subpoenas to at least 20 children’s hospitals nationwide on or around the same date, without any particularized allegations of wrongdoing at any of them. This dragnet approach is inconsistent with targeted criminal investigation.
- The Attorney General took the unprecedented step of publicly announcing the subpoenas to “send a clear and chilling message” to providers. DOJ policy generally prohibits commenting on ongoing investigations, but here the

announcement served to accomplish the true goal of the subpoenas: to intimidate and harass.

- DOJ’s counsel admitted in litigation that the investigation is about eliminating medical care for gender dysphoria as a “rational governmental objective.”
- The White House has celebrated that hospitals have stopped providing medical care for gender dysphoria as a result of these efforts.
- A DOJ supervisor involved in these investigations stated he is “working on” ensuring care will stop “even in blue states.”
- In response to another district court quashing an identical subpoena, DOJ doubled down and made its true purpose clear: it issued the subpoena “to protect innocent children from being mutilated under the guise of ‘care.’”

This is not a legitimate criminal investigation. It is a campaign of harassment and intimidation designed to achieve a policy goal—the end of medical care for gender dysphoria—that Congress has not authorized and the Executive Branch otherwise lacks authority to pursue. One federal court has already found that an identical subpoena “was issued for an improper purpose, motivated only by bad faith” because “the Administration has been explicit about its disapproval of the transgender community and its aim to end [medical care for gender dysphoria]” and “the true purpose of issuing the subpoena is to interfere with the [state’s] right to protect [medical care for gender dysphoria] within its borders, to harass and intimidate [the hospital] to stop providing such care, and to dissuade patients from seeking such care.” *In re Admin.*

*Subpoena No. 25-1431-019*, 800 F. Supp. 3d at 239. Another court quashed an identical subpoena because the evidence “demonstrates that DOJ has abandoned good faith investigation in favor of policy enforcement through prosecutorial coercion.” *QueerDoc*, 807 F. Supp. 3d at 1302. As that court made clear, its finding was “not speculation about hidden motives—it is the Administration’s explicit agenda.” *Id.* This Court should reach the same conclusion.

### **III. The Privacy Interests of Children Far Outweigh Any Legitimate Governmental Need.**

Even if the Subpoena were issued for a proper purpose—and it was not—it must be quashed because the children whose records DOJ seeks have constitutional privacy interests that far outweigh any governmental need for the information. Because the Subpoena specifically targets highly sensitive medical records pertaining to care for transgender youth, compliance with the subpoena would subject transgender patients and those with gender dysphoria to invasive and sweeping government scrutiny, in violation of their constitutional rights to privacy.

#### **A. Children Have a Constitutional Right to Privacy in Their Medical Records.**

The Constitution provides for “the most comprehensive of rights and the right most valued by civilized men”— “the right to be let alone.” *Olmstead v. United States*, 277 U.S. 438, 478 (1928) (Brandeis, J., dissenting). This includes “the individual interest in avoiding disclosure of personal matters,” *Whalen v. Roe*, 429 U.S. 589, 599 (1977). “[T]here can be no question that . . . medical records, which may contain intimate facts of a personal nature, are well within the ambit of materials entitled to privacy protection.” *United States v. Westinghouse Elec. Corp.*, 638 F.2d 570, 577 (3d

Cir. 1980); *see also In re Search Warrant (Sealed)*, 810 F.2d 67, 71 (3d Cir. 1987) (“medical records are clearly within this constitutionally protected sphere”). In the First Circuit, “courts have identified two clusters of personal privacy rights recognized by the Fourteenth Amendment. One bundle of rights relates to ensuring autonomy in making certain kinds of significant personal decisions; the other relates to ensuring confidentiality of personal matters.” *Vega-Rodriguez v. Puerto Rico Telephone Co.*, 110 F.3d 174, 182–83 (1st Cir. 1997); *Borucki v. Ryan*, 827 F.2d 836, 840 (1st Cir. 1987).

“The autonomy branch of the Fourteenth Amendment right to privacy is limited to decisions arising in the personal sphere—matters relating to marriage, procreation, contraception, family relationships, child rearing, and the like.” *Vega-Rodriguez*, 110 F.3d at 183. The confidentiality branch, also referred to as “informational privacy,” *see National Aeronautics and Space Administration v. Nelson*, 562 U.S. 134, 146 (2011), “includes ‘the individual interest in avoiding the disclosure of personal matters ...’” *Daury v. Smith*, 842 F.2d 9, 13 (1st Cir. 1988) (citing *Whalen*, 429 U.S. at 599).

District courts in the First Circuit have had no trouble concluding that “forced disclosure of plaintiffs’ transgender status violates their constitutional right to decisional privacy. Much like matters relating to marriage, procreation, contraception, family relationships, and child rearing, ‘there are few areas which more closely intimate facts of a personal nature’ than one’s transgender status.” *Arroyo Gonzalez v. Rossello Nevares*, 305 F. Supp. 3d 327, 333 (D.P.R. 2018) (quoting *Doe v. Town of*

*Plymouth*, 825 F. Supp. 1102, 1107 (D. Mass. 1993)). The same court concluded that requiring a person to disclose their transgender status separately violates their “constitutional right to informational privacy. Such forced disclosure of a transgender person’s most private information is not justified by any legitimate government interest.” *Id.*

Moreover, patients, like the children the Child Advocate represents here, have a reasonable expectation of privacy in their medical records such that “unlike prescription drug records, medical records are not subject to pervasive regulatory disclosures under both federal and state law.” *Ricco Jonas*, 24 F.4th at 736. The medical records DOJ seeks to obtain with the Subpoena are not mere prescription drug records; rather, they contain “sensitive medical history and other information, . . . patients’ complaints and symptoms, and the patients’ family members.” *Id.* (cleaned up).

The records sought here are thus precisely the sort the Constitution protects. They contain the most intimate details of children’s mental health, gender identity, sexual development, family relationships, trauma histories, and struggles with their sense of self. The Subpoena would, by definition, force the children whose records DOJ would obtain to disclose their transgender status, and so violates their constitutional right to privacy. In practice, the breadth of the information DOJ seeks also means that any anonymization of these records would be insufficient and ineffective because the volume and detail in those records would inevitably point to a particular child and their family. See *Nw. Mem’l Hosp. v. Ashcroft*, 362 F.3d 923, 929 (7th Cir. 2004) (holding that redaction of medical records would not be sufficient to protect

patients' privacy interests). Moreover, the information sought is so deeply personal that "[e]ven if there were no possibility that a patient's identity might be learned from a redacted medical record, there would be an invasion of privacy." *Id.*

The DOJ has also announced its intention to "partner with state attorneys general to identify leads [and] share intelligence. . . ." <sup>43</sup> Since there is no explicit prohibition on the sharing of information accessed through a subpoena permitted by 18 U.S.C. § 3486, identifying leads and sharing intelligence may mean providing patient information and data to state law enforcement officials. *See* 18 U.S.C. § 3486(e)(1); 5 U.S.C. § 552a(b)(7) (Privacy Act provision permitting disclosure to state law enforcement officials). Such information sharing is terrifying to any parent or guardian who sought medically approved and legal care for their child, particularly now that the Administration is characterizing this care as child abuse and some states are attempting to criminally prosecute parents for obtaining care for their children. <sup>44</sup> And even if the government does not publicly disclose the records or share them with hostile state governments, the harm from disclosure to DOJ agents and prosecutors is substantial. These children will know that federal agents, hostile to their medical treatment, have access to their most intimate information.

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<sup>43</sup> *Memorandum For Select Component Heads: Preventing the Mutilation of American Children*, Office of the Attorney General (Apr. 22, 2025), <https://www.justice.gov/ag/media/1402396/dl> (last visited May 1, 2026).

<sup>44</sup> Ken Paxton, Attorney General of Texas, *Opinion No. KP-0401, Whether certain medical procedures performed on children constitute child abuse* (Feb. 18, 2022) ("Texas law also imposes a duty on [the Texas Department of Family and Protective Services] to investigate the parents of a child who is subjected to these abusive gender-transitioning procedures"), <https://gov.texas.gov/uploads/files/press/O-MastersJaime202202221358.pdf> (last visited May 1, 2026).

Compelling disclosure of records that identify individuals based on their transgender status also offends the Equal Protection Clause. *Romer v. Evans*, 517 U.S. 620 (1996), establishes that government actions singling out a class for adverse treatment cannot survive even rational basis review when motivated by animus or moral disapproval. 517 U.S. at 632-35. A subpoena that targets patients because of their transgender identity serves no legitimate investigatory purpose; instead, it functions as an expression of disfavor toward a protected class. The Subpoena should be quashed for this independent reason.

**B. Disclosure Would Harm the Physician-Patient Relationship.**

Disclosure of the records DOJ seeks in the Subpoena would also severely damage the physician-patient relationship—not just for the children whose records are sought, but for all patients and families considering seeking care. Confidentiality is central to the physician-patient relationship because patients rightly assume that, in general, sensitive personal information they share with their providers will not be disclosed further. The relationship depends on trust. If patients fear that private and sensitive information is subject to collection and review by federal law enforcement, it is reasonable to expect that they will be less likely to pursue necessary medical treatment, or to be candid with their medical providers.

The compelled exposure of these children’s medical records would thus chill their exercise of constitutionally protected rights to seek medical treatment and to associate with providers who deliver that care. The chilling effect therefore extends beyond patients of RI Hospital. When families considering medical care for gender

dysphoria for their children learn that seeking such care may result in a federal investigation, they may delay or forgo necessary medical treatment. Some may even avoid seeking any mental health care for fear it could lead to unwanted scrutiny. This undermines public health and puts vulnerable children at risk.

**C. DOJ Has No Legitimate Need for the Information It Seeks.**

DOJ cannot articulate any legitimate need to obtain children's identities and comprehensive medical records for every patient who received either puberty blockers or hormone therapy during the last five years. As discussed above, if DOJ were investigating off-label promotion by manufacturers, it would not need patient records at all. If it were investigating billing practices, anonymized records would suffice. There is no compelling explanation for why DOJ needs to know the names, addresses, and Social Security numbers of minor patients, or to read the intimate details of their mental health assessments. In fact, as part of related litigation, DOJ has already failed to identify a particular need for patient and parent information, instead making general assertions that "the acts being investigated here are, at base, statutory violations commonly investigated by the Government in many contexts over many decades" and that "[t]he document requests here are common in such investigations." *In Re: Subpoena No. 25-1431-014*, 2:25-mc-00039, ECF No. 13 at 7 (E.D. Pa. July 8, 2025). That generalized justification for the Subpoena cannot outweigh the core constitutional privacy rights it would invade.

DOJ has statutory authority to investigate criminal health care offenses and may subpoena records in pursuit of legitimate investigations of those offenses. The Subpoena in this case, to the contrary, represents a barely disguised political agenda



in search of a healthcare offense. In sum, “DOJ issued the subpoena first and searched for a justification second.” *QueerDoc*, 807 F. Supp. 3d at 1303. DOJ is seeking to “use its subpoena power to go on a fishing expedition” through “an astonishingly broad array of documents and information that are virtually unlimited in scope.” *In re Admin. Subpoena No. 25-1431-019*, 800 F. Supp. 3d at 238. The Court should not permit it to do so, and should quash the Subpoena.

### **CONCLUSION**

For all these reasons, the Child Advocate respectfully requests that the Court protect the rights of Rhode Island’s children and quash the Subpoena in its entirety. In the alternative, the Child Advocate requests that the Court order Rhode Island Hospital not to comply with the Subpoena, or at a minimum not to provide any information regarding names, dates of birth, Social Security numbers, addresses, parent/guardian information, diagnoses, clinical assessments, consent forms, billing records linked to identified patients, or other personal health information.

Pursuant to LR Cv 7(c), counsel requests oral argument for this motion.

Dated: May 4, 2026

Respectfully submitted,

/s/ Miriam Weizenbaum

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^Pro Hac Vice forthcoming

# CERTIFICATE OF SERVICE

I hereby certify that on May 4, 2026, I electronically filed the within Motion to Quash and it is available for viewing and downloading from the Court's CM/ECF System, and that the participants in the case that are registered CM/ECF users will be served electronically by the CM/ECF system.

In addition, I served the within Motion via electronic mail to:

Kevin Bolan  
Chief, Civil Division  
United States Attorney's Office  
District of Rhode Island  
[Kevin.Bolan@usdoj.gov](mailto:Kevin.Bolan@usdoj.gov)

Ross S. Goldstein  
United States Department of Justice  
Enforcement and Affirmative Litigation Branch  
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/s/ Kevin Love Hubbard  
Kevin Love Hubbard

# UNITED STATES OF AMERICA

## DEPARTMENT OF JUSTICE

### SUBPOENA DUCES TECUM

No. 25-1431-032

**To:** Rhode Island Hospital  
593 Eddy Street  
Providence, Rhode Island 02903

***YOU ARE HEREBY COMMANDED TO APPEAR BEFORE Patrick Runkle, Ross Goldstein, and/or Francisco Unger, officials of the United States Department of Justice, and you are hereby required to bring with you and produce the following:***

Please see Attachment A

***which are necessary in the performance of the responsibility of the United States Department of Justice to investigate Federal health care offenses as defined in 18 U.S.C. § 24(a).***

***Please contact Assistant Director Patrick Runkle, Assistant Director Ross Goldstein, or Trial Attorney Francisco Unger at 202-616-0295 if you have any questions regarding this Subpoena Duces Tecum.***

#### PLACE AND TIME FOR APPEARANCE:

United States Department of Justice, Consumer Protection Branch, 450 Fifth Street NW, Washington, DC  
on Thursday, the 7<sup>th</sup> day of August, 2025, at ten o'clock a.m.

---

Failure to comply with the requirements of this subpoena will render you liable to proceedings in the district court of the United States to enforce obedience to the requirements of this subpoena, and to punish default or disobedience.

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Issued under authority of Section 248 of the Health Insurance Portability & Accountability Act of 1996,  
Public Law No. 104-91 (18 U.S.C. § 3486)



#### IN TESTIMONY WHEREOF

Brett A. Shumate, Assistant Attorney General, the undersigned official of the United States Department of Justice, has set his hand this 3<sup>rd</sup> day of July, 2025.

---

(signature)

**RETURN OF SERVICE**

*I, being a person over 18 years of age, hereby certify that a copy of this subpoena was duly served on the person named herein by means of:*

**1. Personal delivery to an individual, to wit:**

\_\_\_\_\_  
*(name)*

\_\_\_\_\_  
*(title)*

\_\_\_\_\_  
*(address)*

**2. Personal delivery to an address, to wit:**

\_\_\_\_\_  
*(description of premises)*

\_\_\_\_\_  
*(address)*

**3. Registered or certified mailing to:**

\_\_\_\_\_  
*(name)*

\_\_\_\_\_  
*(address)*

At \_\_\_\_\_ a.m. | p.m. on

\_\_\_\_\_  
*(date)*

\_\_\_\_\_  
*(signature)*

\_\_\_\_\_  
*(title)*

**UNITED STATES OF AMERICA  
DEPARTMENT OF JUSTICE**

**SUBPOENA DUCES TECUM**

*Upon contumacy or refusal to obey, this subpoena shall be enforced by order of the appropriate United States District Court.*

## **ATTACHMENT A TO SUBPOENA TO:**

RHODE ISLAND HOSPITAL  
593 EDDY STREET  
PROVIDENCE, RHODE ISLAND 02903

### **I. DEFINITIONS**

1. “You,” “Your Company,” and “the Company,” means:
  - a. Rhode Island Hospital, a Rhode Island nonprofit corporation, whose principal place of business is located at 593 Eddy Street, Providence, Rhode Island, without regard to any name under which it has done business;
  - b. All of its predecessors, subsidiaries, affiliates, branches, divisions, groups, business units, business segments, operations, units, parent organizations, successors, assigns, plants, and any joint ventures of which they were or are a part, including but not limited to Hasbro Children’s Hospital Gender and Sexual Health Program; and
  - c. Each of its present or former officers, directors, employees, attorneys, representatives, and agents acting or purporting to act or appearing to act on behalf of the Company, whether or not acting within the proper scope of his or her actual authority.
2. “Employee” means any person including, but not limited to, any independent contractor or agent, all past and present directors, officers, agents, representatives, attorneys, accountants, advisors, and consultants who acted or purported to act on behalf of the Company or who have performed any service for the Company or under its name, whether on a full-time, part-time, piece-work, commission, volunteer, or other basis, and whether paid or unpaid.
3. “Document” should be afforded the broadest possible meaning and includes every writing or record of whatever type or description, including but not limited to any electronically stored data or paper document, in the possession, custody, or control of the Company. This includes, but is not limited to:
  - a. All material that is handwritten, typed, printed, recorded, transcribed, taped, filmed, in graphic form, or in aural form;
  - b. Drawings, designs, manuals, memoranda, emails, reports, financial reports, notes, diaries, notations of any sort of conversations, working papers, letters, envelopes, telegrams, messages, studies, analyses, books,

articles, notebooks, booklets, circulars, bulletins, notices, instructions, pamphlets, pictures, films, videos, voice recordings, maps, work papers, arithmetical computations, calendars (including electronic calendars), date books, task lists, minutes, all communications of any type (e.g., e-mail, voice mail, text messaging, WhatsApp and similar applications), social media content (including posts, messages, comments, and metadata), audio and video files,

- c. Electronically stored data on magnetic or optical storage media as an “active” file or files (readily readable by one or more computer applications or forensics software), including metadata;
  - d. Any electronic files saved as a backup, including metadata;
  - e. Any deleted but recoverable electronic files, including metadata;
  - f. Any electronic file fragments (files that have been deleted and partially overwritten with new data), including metadata;
  - g. Every copy of every document where such copy is not identical to the original because of any addition, deletion, alteration, or notation; and
  - h. All attachments, enclosures, or other matter affixed to, transmitted with, or incorporated by reference within documents responsive to this Subpoena including, but not limited to, any pages showing who reviewed, approved, or rejected a particular document.
- 4. “Relevant Time Period” means January 1, 2020, through the present date. All responsive documents that were prepared, dated, sent, received, altered, in effect, or which came into existence during this period are to be produced pursuant to this Subpoena.
  - 5. “Or” as well as “and” shall be construed interchangeably in a manner that gives this Subpoena the broadest possible meaning.
  - 6. “Any” shall be construed to include the word “all” and the term “all” shall be construed to include the word “any.”
  - 7. “Relate to” means to make a statement about, refer to, discuss, describe, reflect, identify, deal with, consist of, or in any way pertain, in whole or in part to the subject.
  - 8. “Communication” means any transmission or exchange of information, statements, ideas, inquiries, or data between two or more persons orally, in writing, digitally, visually, or electronically regardless of the medium or platform used, including social media interactions, voicemails, and virtual

meetings (e.g., Zoom, WebEx, Microsoft Teams). The term includes all drafts, versions, replies, responses, forwards, and attachments associated with or forming part of the communication, as well as any records or logs reflecting the time, date, participants, and content of such communications.

9. “Gender-related care” means any medical, surgical, psychological, or social treatment provided to individuals to alter their physical appearance or social presentation to resemble characteristics typically associated with the opposite biological sex.
10. “Puberty blockers” means any gonadotropin-releasing hormone (“GnRH”) agonists or related drugs (e.g., leuprolide, triptorelin) used to delay the onset of puberty.
11. “Hormones” includes testosterone, estrogen, and any other hormonal drugs used in hormonal treatments sometimes known as “gender affirming hormone therapy” (“GAHT”) or transgender hormone therapy used to induce cross-sex characteristics.
12. “Minor” means any patient under the age of 18 at the time of consultation, treatment, or prescription.

## II. GENERAL INSTRUCTIONS

1. You are required to produce the **originals** of each document and other item that is responsive, in whole or in part, to any request set forth in this Subpoena, together with all copies of any such document that exist.
  - a. If a copy is identical to the original, you are not required to produce it, but if you choose not to, your records custodian (the “Custodian,” as described below) must maintain a written log identifying the location(s) where each identical copy of the original document was located, including all locations, if more than one. This includes, in the case of information stored in electronic form, a description, including drives, directories, and computers of where the document is located.
  - b. If a copy differs from the original by virtue of any addition, deletion, alteration, notation, or inscription on any part of the front or back of the document, the original and copy must each be produced.
2. **No document called for by this subpoena shall be destroyed, modified, redacted, removed, or otherwise made inaccessible.** Documents called for by this Subpoena for which a claim of privilege is made, in compliance with the instruction below, shall be retained and protected.



3. Your Company is to designate someone as the person responsible to produce documents on the Subpoena return date (the “Custodian”).
  - a. Such Custodian shall have personal, direct, and thorough knowledge of, and responsibility for, the search conducted by the Company for documents responsive to this Subpoena.
  - b. The Custodian shall be prepared on the return date to submit to examination concerning the method and completeness of the Company’s response, the exact location(s) within the Company’s premises at which documents produced in response to the Subpoena were found, and other matters pertaining to the search.
  - c. The Custodian shall further be prepared to provide a written log identifying the location(s) in which each produced document was located, indicating all locations, if more than one. This includes, in the case of information stored in electronic form, a description, including drives, directories, and computers, of where the document is located.
4. The Company shall identify the paragraph and subparagraph of Section III of this Attachment to the Subpoena (“Documents to Be Produced”) to which each document produced pursuant to this Subpoena is responsive.
5. If the Company has knowledge of any document that would be responsive to this Subpoena, but has been lost, destroyed, or discarded, it shall identify the document to the extent possible, and provide an explanation of the loss, destruction or discarding, including identification of each person authorizing or having knowledge of the loss, destruction, or discarding.
6. The singular form of a word shall be construed to include within its meaning the plural form of the word, and *vice versa*, and the use of any tense of any verb shall be considered to include all other tenses in a manner that gives this Subpoena the broadest reading.
7. All electronically stored information must be collected using a forensically sound process. When the image file is produced, the Company must preserve the integrity of the electronic document’s contents, including the original formatting of the document, its metadata and, where applicable, its revision history.
8. If the Company withholds any document on the ground of any claimed privilege, it shall provide a statement with respect to each document setting forth
  - a. The name and title of the author (and if different, the preparer and signatory);

- b. The name(s) and title(s) of the individual(s) to whom the document was addressed;
- c. The name(s) and title(s) of the individuals to whom the document or a copy of the document was sent or to whom the document or a copy, or any part thereof, was shown;
- d. The date of the document;
- e. The number of pages;
- f. A brief description of the subject matter;
- g. A statement of the specific basis on which privilege is claimed; and
- h. The paragraph or subparagraph in Section III of this Attachment ("Documents to Be Produced") to which it is responsive.

### **III. DOCUMENTS TO BE PRODUCED**

- 1. Complete personnel files for each employee, contractor, or affiliate of the Company in the following categories: (a) executives, management employees, or board members with authority to direct any aspect of the Company's affairs; (b) employees, contractors, or affiliates who have authority to prescribe medications or perform medical evaluations; and (c) employees, contractors, or affiliates who are engaged in billing activities.
- 2. All documents, including billing records, insurance claims, internal protocols, or guidance, concerning the use of ICD (*i.e.*, International Classification of Diseases) diagnosis codes in connection with the treatment of minor patients receiving gender-related care.
- 3. All documents that show or relate to any use of diagnosis codes for minors other than those specifically identifying transsexualism, gender dysphoria, gender incongruence, or gender identity disorder (*e.g.*, codes for endocrine disorder, unspecified hormonal disorders, medication management, etc.).
- 4. All documents reflecting communications among Company employees (including physicians, billing staff, and administrators), or between the Company and any third party, relating to whether or how to code or bill for treatment of gender dysphoria by using alternative diagnoses or alternative ICD codes.

5. All communications with public or private health care benefit programs or plans regarding the use of ICD codes for gender-related care, including any inquiries, denials, or appeals related to claims for such care.
6. Any training materials, coding manuals, presentations, or communications relating to billing or coding practices for gender-related care, puberty blockers, or hormone therapy.
7. All documents relating to communications between You and any pharmaceutical manufacturer of puberty blockers or hormones, or any compounding pharmacy providing puberty blockers or hormones, relating to the use of such drugs in gender-related care for minors.
8. All documents relating to communications with pharmaceutical sales representatives, marketing departments, or medical science liaisons regarding the use of puberty blockers or hormones for gender-related care or the treatment of gender dysphoria, including with regard to the safety and efficacy of such drugs for those uses.
9. All documents, including presentations and promotional materials, received from pharmaceutical manufacturers or compounding pharmacies concerning uses of their products in minors for gender-related care or for the treatment of gender dysphoria, including so-called “scientific exchange” materials.
10. All documents relating to contracts, sponsorships, speaking engagements, consulting agreements, grants, or financial or promotional arrangements between You and any manufacturer or compounder of puberty blockers or hormones.
11. Documents sufficient to identify each patient (by name, date of birth, social security number, address, and parent/guardian information) who was prescribed puberty blockers or hormone therapy.
12. For each such patient identified in Subpoena specification 11, *supra*, documents relating to the clinical indications, diagnoses, or assessments that formed the basis for prescribing puberty blockers or hormone therapy.
13. All documents relating to informed consent, patient intake, and parent or guardian authorization for minor patients identified in Subpoena specification 11, *supra*, including any disclosures about off-label use (*i.e.*, uses not approved by the United States Food and Drug Administration) and potential risks.
14. All documents reflecting communications with pharmaceutical manufacturers, compounding pharmacies, or government agencies relating to the safety of puberty blockers or hormones used in the treatment of minor patients.

15. All documents relating to any adverse event, side effect, or medically unfavorable consequence or outcome in a minor patient with regard to gender-related care.

#### **IV. FORM OF PRODUCTION**

Documents responsive to this Subpoena should be produced in the format specified in the “Production Specifications,” attached as ATTACHMENT B to this Subpoena.

**SUBPOENA ATTACHMENT B**

**Specifications for Production of ESI and Digitized (“Scanned”) Images  
 (“Production Specifications”)**

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**Collection of Electronically Stored Information (ESI)**

Careful consideration should be given to the methodology, implementation and documentation of ESI collection to ensure that all responsive data and metadata are preserved in the collection process. Consideration should also be given as to whether production media should be encrypted when producing to the government when required by law (i.e. Health Insurance Portability and Accountability Act (HIPAA), Family Educational Rights and Privacy Act (FERPA), etc. *See* Section 24 below.

**1. Specification Modifications**

Any modifications or deviations from the Production Specifications may be done only with the express permission of the government and these modifications or deviations should be communicated to the government and approved by the government in written form. Any responsive data or documents that exist in locations or native forms not discussed in these Production Specifications remain responsive and, therefore, arrangements should be made with the government to facilitate their production.

**2. Production Format of ESI and Imaged Hard Copy Documents**

Responsive ESI shall be produced in its unprocessed form (i.e., in its native format), without altering native electronic file formats and maintains the integrity of all source, custodian, application, embedded and metadata related thereto. The native electronic file formats provided shall be of a type and nature which is functionally useable by all parties. No alteration shall be made to file names or extensions for responsive native electronic files. If a producing party is converting native files to image files for its own purposes, the Government requests a copy of that image file along with production of the native file.

For ESI, a producing party may provide an image file without a native file only if the affected document requires a privilege redaction or other permitted redaction.. Except as outlined below in sections 5 – 21, the redacted document shall be rendered to TIFF image format, and accompanied by an Opticon/Concordance® Image Cross Reference file. Paper documents shall also be imaged pursuant to the requirements below.

All applicable metadata/database (see section 3 below) shall be extracted and provided in Concordance® load file format.

- a. **Image File Format:** All imaged documents shall be produced in black and white TIFF format unless the image requires color. An image requires color when color in the document adds emphasis to information in the document or is itself information that would not be readily apparent on the face of a black and white image.
- b. When producing black and white paper documents scanned to images, or rendered ESI, they shall be produced as 300 dpi, 1 bit, single-page TIFF files, CCITT

July 2022

Group IV (2D Compression). When producing in *color*, paper documents scanned to images, or rendered ESI, they shall be produced as 300 dpi single-page JPG. Images should be uniquely and sequentially Bates numbered and unless otherwise specified, Bates numbers should be an endorsement on each image.

- i. All TIFF file names shall include the unique Bates number burned into the image. (See section 22, below, regarding Bates number instructions.)
- ii. All TIFF image files shall be stored with the “.tif” extension.
- iii. Images without corresponding extracted text shall be OCR’d using standard COTS products.
  1. An exception report shall be provided when limitations of paper digitization software/hardware or attribute conversion do not allow for OCR text conversion of certain images. The report shall include the DOCID or Bates number(s) corresponding to each such image.
- iv. All pages of a document or all pages of a collection of documents that comprise a folder or other logical grouping, including a box, shall be delivered on a single piece of media.
- v. No image folder shall contain more than 2,000 images.

- c. **Opticon/Concordance® Image Cross Reference file:** Images should be accompanied by an Opticon load file that associates each Bates number with its corresponding single-page TIFF image file. The Cross Reference file should also contain the relative image file path for each Bates numbered page. The Opticon/Concordance® Image Cross Reference file is a page level load file, with each line representing one image.

Below is a sample:

```
REL000000001,,\IMAGES\001\REL000000001.TIF,Y,,
REL000000002,,\IMAGES\001\REL000000002.TIF,,,
REL000000003,,\IMAGES\001\REL000000003.TIF,,,
REL000000004,,\IMAGES\001\REL000000004.TIF,Y,,
REL000000005,,\IMAGES\001\REL000000005.TIF,,,
```

The fields are, from left to right:

- Field One – (REL000000001) – the Bates Number. This value must be unique for each row in the OPT file. The first page of each document must match the DOCID or BEGDOC# value of the respective document.
- Field Two – (blank) – the volume identifier. This field is not required.
- Field Three – (. \IMAGES\001\REL000000001.TIF) – The relative file path to the image to be loaded.
- Field Four – (Y) – the document marker. A “Y” indicates the start of a unique document.
- Field Five – (blank) – The folder indicator. This field is not required, and typically is not used.

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- Field Six – (blank) – The box indicator. This field is not required, and typically is not used.
- Field Seven – (blank) – The page count. This field is not required.

d. **Concordance® Load File:** Images should also be accompanied by a flat, document-level load file to provide the metadata and native files containing delimited text that will populate fields in a searchable, flat database environment. The file encoding must be one of four types: Western European (Windows), Unicode (UTF16), Big-Endian Unicode or UTF8. The file should contain the required fields listed below in section 3.

1. Text delimited load files are defined using the standard Concordance delimiters. For example:

|                        |               |
|------------------------|---------------|
| <i>Field Separator</i> | ¶ or Code 020 |
| <i>Text Qualifier</i>  | þ or Code 254 |
| <i>Newline</i>         | ® or Code 174 |
| <i>Multi-value</i>     | ; or Code 059 |
| <i>Nested values</i>   | \ or Code 092 |

2. This load file should contain the relative file path to the individual multi-page, document level text files.
3. This load file should also contain the relative file path to all provided native files, such as Microsoft Excel or PowerPoint files.
4. There should be one line for every record in a collection.
5. The load file must contain a header listing the metadata/database fields contained within. For example, if the data file consists of a First Page of a Record (BegDoc#), Last Page of a Record (ending Bates / ENDDOC#), DOCID, DOCDate, File Name, and a Title, then the structure may appear as follows:

```
þBEGDOCþ¶þENDDOCþ¶þDOCIDþ¶þDOCDATEþ¶þFILENAM
Eþ¶þTITLEþ
```

d. **The extracted/OCR text** should be provided for each document as a separate single text file. The file name should match the BEGDOC# or DOCID for that specific record and be accompanied by the .txt extension.

e. **Directory and folder structure:** The directory structure for productions should be:

\CaseName\LoadFiles

\CaseName\Images < For supporting images (can include subfolders as needed, should not include more than 2,000 files per folder)

\CaseName\Natives <Native Files location (can include subfolders as needed, should not include more than 2,000 files per folder)

\CaseName\Text <Extracted Text files location (can include subfolders as needed, should not include more than 2,000 files per folder)

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\CaseName\**Translated Images** < For supporting images of translated documents (as needed for rendered translated documents; can include subfolders as needed, should not include more than 2,000 files per folder)  
 \CaseName\**Translated Text** <Translated Text files location (as needed for translated text; can include subfolders as needed, should not include more than 2,000 files per folder).

### 3. Required Metadata/Database Fields

A “✓” denotes that the indicated field should be present in the load file produced. “Other ESI” includes data discussed in sections 5 – 21 below, but does not include email, email repositories (section 11), “stand alone” items (section 12), imaged hard copy material (section 9) and production from ESI collected from Smart Phones, Mobile Devices and Other Technology (section 13). Email, email repositories, and “stand alone” materials (section 12) should comply with “Email” column below. Imaged hard copy materials should comply with the “Hard Copy” column. Production from ESI collected from Smart Phones, Mobile Devices and Other Technology should comply with the requirements of section 13. The parties will meet and confer about any field which cannot be populated automatically (i.e. would require manual population of information).

| Field name              | Field Description                                                                                              | Field Type                 | Field Value | Hard Copy | E-mail | Other ESI |
|-------------------------|----------------------------------------------------------------------------------------------------------------|----------------------------|-------------|-----------|--------|-----------|
| COLLECTION SOURCE       | Name of the Company/Organization data was collected from                                                       | Text                       | 160         | ✓         | ✓      | ✓         |
| SOURCE ID (BOX #)       | Submission/volume/box number                                                                                   | Text                       | 10          | ✓         | ✓      | ✓         |
| CUSTODIAN               | Custodian/Source - format: Last, First or ABC Dept.                                                            | Text                       | 160         | ✓         | ✓      | ✓         |
| DUPECUSTODIAN           | Custodian/Source – all custodians who had the document before de-duplication; format: Last, First or ABC Dept. | Text – semicolon delimited | Unlimited   |           | ✓      | ✓         |
| DUPECUSTODIAN FILE PATH | Listing of all the file locations of the document before de-duplication                                        | Text – semicolon delimited | Unlimited   |           | ✓      | ✓         |
| AUTHOR                  | Creator of the document                                                                                        | Text                       | 500         |           |        | ✓         |
| BEGDOC#                 | Start Bates (including prefix) - No spaces                                                                     | Text                       | 60          | ✓         | ✓      | ✓         |
| ENDDOC#                 | End Bates (including prefix) - No spaces                                                                       | Text                       | 60          | ✓         | ✓      | ✓         |
| DOCID                   | Unique document Bates # or populate with the same value as Start Bates (DOCID = BEGDOC#)                       | Text                       | 60          | ✓         | ✓      | ✓         |



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| Field name  | Field Description                                                                                                                                   | Field Type                 | Field Value | Hard Copy | E-mail | Other ESI |
|-------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|-------------|-----------|--------|-----------|
| PGCOUNT     | Page Count                                                                                                                                          | Number                     | 10          | ✓         | ✓      | ✓         |
| GROUPID     | Contains the Group Identifier for the family, in order to group files with their attachments                                                        | Text                       | 60          |           | ✓      | ✓         |
| PARENTID    | Contains the Document Identifier of an attachment's parent                                                                                          | Text                       | 60          |           | ✓      | ✓         |
| ATTACHIDS   | Child document list; Child DOCID or Child Start Bates                                                                                               | Text – semicolon delimited | Unlimited   | ✓         | ✓      | ✓         |
| ATTACHLIST  | List of Attachment filenames                                                                                                                        | Text – semicolon delimited | Unlimited   |           | ✓      | ✓         |
| BEGATTACH   | Start Bates number of parent                                                                                                                        | Text                       | 60          | ✓         | ✓      | ✓         |
| ENDATTACH   | End Bates number of last attachment                                                                                                                 | Text                       | 60          | ✓         | ✓      | ✓         |
| RECORD TYPE | Use the following choices: Image, Loose E-mail, E-mail, E-Doc, Attachment, Hard Copy or Other. If using Other, please specify what type after Other | Text                       | 60          | ✓         | ✓      | ✓         |
| FROM        | Sender (i.e.: e-mail address, Last name, First name)                                                                                                | Text                       | 160         |           | ✓      | ✓         |
| TO          | Recipient (i.e.: e-mail address, Last name, First name)                                                                                             | Text – semicolon delimited | Unlimited   |           | ✓      | ✓         |
| CC          | Carbon Copy Recipients (i.e.: e-mail address, Last name, First name)                                                                                | Text – semicolon delimited | Unlimited   |           | ✓      | ✓         |
| BCC         | Blind Carbon Copy Recipients (i.e.: e-mail address, Last name, First name)                                                                          | Text – semicolon delimited | Unlimited   |           | ✓      | ✓         |
| SUBJECT     | Subject line of email                                                                                                                               | Text                       | Unlimited   |           | ✓      |           |
| TITLE       | Document Title                                                                                                                                      | Text                       | Unlimited   |           |        | ✓         |
| CONVINDE    | E-mail system ID used to track replies, forwards, etc.                                                                                              | Text                       | Unlimited   |           | ✓      |           |

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| Field name     | Field Description                                                                                                                                  | Field Type    | Field Value                | Hard Copy | E-mail | Other ESI |
|----------------|----------------------------------------------------------------------------------------------------------------------------------------------------|---------------|----------------------------|-----------|--------|-----------|
| DOCDATE        | Last Modified Date for files and Sent date for e-mail, this field inherits the date for attachments from their parent. Do not provide 00/00/0000.  | Date          | MM/DD/YY<br>YY             |           | ✓      | ✓         |
| TEXT FILEPATH  | Relative file path of the text file associated with either the extracted text or the OCR                                                           | Text          | Unlimited                  | ✓         | ✓      | ✓         |
| DATE TIME SENT | Date and time Sent (USE TIME ZONE OF COLLECTION LOCALITY)<br>Numbers must be populated. If date is unknown, leave blank. Do not provide 00/00/0000 | Date and Time | MM/DD/YY<br>YY<br>HH:MM:SS |           | ✓      |           |
| DATE TIME CRTD | Date Created (USE TIME ZONE OF COLLECTION LOCALITY)<br>Numbers must be populated. If date is unknown, leave blank. Do not provide 00/00/0000       | Date and Time | MM/DD/YY<br>YY<br>HH:MM:SS |           | ✓      | ✓         |
| DATE TIME SVD  | Date Saved (USE TIME ZONE OF COLLECTION LOCALITY)<br>Numbers must be populated. If date is unknown, leave blank. Do not provide 00/00/0000         | Date and Time | MM/DD/YY<br>YY<br>HH:MM:SS |           | ✓      | ✓         |
| DATE TIME MOD  | Date Last Modified (USE TIME ZONE OF COLLECTION LOCALITY)<br>Numbers must be populated. If date is unknown, leave blank. Do not provide 00/00/0000 | Date and Time | MM/DD/YY<br>YY<br>HH:MM:SS |           | ✓      | ✓         |
| DATE TIME RCVD | Date Received (USE TIME ZONE OF COLLECTION LOCALITY)<br>Numbers must be populated. If date is unknown, leave blank. Do not provide 00/00/0000      | Date and Time | MM/DD/YY<br>YY<br>HH:MM:SS |           | ✓      |           |

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| Field name       | Field Description                                                                                                                                                                                                           | Field Type    | Field Value                | Hard Copy | E-mail | Other ESI |
|------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|----------------------------|-----------|--------|-----------|
| DATE TIME ACCD   | Date Accessed (USE TIME ZONE OF COLLECTION LOCALITY)<br>Numbers must be populated. If date is unknown, leave blank. Do not provide 00/00/0000                                                                               | Date and Time | MM/DD/YY<br>YY<br>HH:MM:SS |           | ✓      | ✓         |
| TIME ZONE OFFSET | Time zone of collection locality, relative to Coordinated Universal Time (UTC). E.g., for US Central Standard Time (CST), the value for this field should be -6.0                                                           | Decimal       | 10                         |           | ✓      |           |
| FILE SIZE        | Native File Size in KBs                                                                                                                                                                                                     | Decimal       | 10                         |           |        | ✓         |
| FILE NAME        | File name - name of file as it appeared in its original location                                                                                                                                                            | Text          | Unlimited                  |           |        | ✓         |
| APPLICATION      | Application used to create native file (e.g. Excel, Outlook, Word)                                                                                                                                                          | Text          | 160                        |           | ✓      | ✓         |
| FILE EXTENSION   | Extension for the file (e.g. .doc, .pdf, .wpd)                                                                                                                                                                              | Text          | 10                         |           | ✓      | ✓         |
| FILEPATH         | Data's original source full folder path                                                                                                                                                                                     | Text          | Unlimited                  |           | ✓      | ✓         |
| NATIVE LINK      | Relative file path location to the native file                                                                                                                                                                              | Text          | Unlimited                  |           | ✓      | ✓         |
| FOLDER ID        | Complete E-mail folder path (e.g. Inbox\Active) or Hard Copy container information (e.g. folder or binder name)                                                                                                             | Text          | Unlimited                  | ✓         | ✓      |           |
| HASH VALUE       | Identifying value of an electronic record that is used for deduplication during processing. MD5 or SHA1 hash algorithms may be used, but must be kept consistent throughout all productions and communicated to Government. | Text          | Unlimited                  |           | ✓      | ✓         |
| MESSAGEHEADER    | E-mail header.                                                                                                                                                                                                              | Text          | Unlimited                  |           | ✓      |           |
| ATTACHMCOUNT     | Number of attachments (any level child document) associated with a ParentID                                                                                                                                                 | Text          | 10                         |           | ✓      |           |

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| Field name          | Field Description                                                                                                                                                                    | Field Type | Field Value | Hard Copy | E-mail | Other ESI |
|---------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|-------------|-----------|--------|-----------|
| FILE TYPE           | Description that represents the file type to the Windows Operating System. E.g., Adobe Portable Document Format, Microsoft Word 97 – 2003, or Microsoft Office Word Open XML Format. | Text       | 160         |           | ✓      | ✓         |
| HAS HIDDEN CONTENT  | Identifies whether the document has comments, track changes or other hidden content or data associated with it                                                                       | Text       | Yes/No      |           | ✓      | ✓         |
| MESSAGE TYPE        | Exchange Message class or equivalent                                                                                                                                                 | Text       | 60          |           | ✓      |           |
| EXTENDED PROPERTIES |                                                                                                                                                                                      | Text       | Unlimited   |           | ✓      | ✓         |
| HAS REDACTIONS      | Identifies whether a record has been produced with redactions; should be populated with Y for records with redactions and N for records without redactions.                          | Text       | Yes/No      | ✓         | ✓      | ✓         |
| HAS TRANSLATIONS    | Identifies whether a document has been produced with translated text or audio contains a transcript                                                                                  | Text       | Yes/No      | ✓         | ✓      | ✓         |

#### 4. Search, De-Duplication, Near-Duplicate Identification, Technology Assisted Review, E-mail Conversation Threading and Other Culling Procedures

- a. De-duplication of exact hash copies shall only be permitted if the producing party can meet all the provisions of this section. If a producing party cannot comply with any requirement of this section, it shall not conduct de-duplication of exact hash copies.
- b. De-duplication of exact hash copies shall be performed globally – across all custodians. The custodian of each record shall be populated in the DupeCustodian field.
- c. All files found on the National Institute of Standards and Technology (NIST) list, commonly referred to as deNISTing, should be excluded from delivery to the Government. All available metadata from files withheld from delivery due to the deNISTing process will be available upon request.
- d. All files should be globally de-duplicated with the following conditions:

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- i. The “DupeCustodian” metadata field (listing of all custodians who had the document before de-duplication) must be provided with the document production.
  - ii. The “DupeCustodian File Path” metadata field (listing all the file locations of the document before de-duplication) must be provided with the document production.
  - iii. All files and metadata for the duplicate documents removed during de-duplication must be preserved and available for production upon request.
  - iv. No customization of hashing may occur without prior express approval by the Government.
  - v. De-duplication must be done by document family, not by individual document.
  - vi. A detailed description of the steps taken to de-duplicate (including the process of obtaining hash values) must be provided to the Government. For every production after the first, a separate Unified Custodian overlay shall be provided. If no overlay is necessary due to the fact that no documents de-duped out in connection with previously produced documents, this shall be expressly stated in the cover letter accompanying the subsequent production(s).
- e. The Producing Party shall not use any other procedure to cull, filter, group, separate or de-duplicate, or near-deduplicate, etc. (i.e., reduce the volume of) responsive material before discussing with and obtaining the written approval of the government. All objective coding (e.g., near duplicate ID or e-mail thread ID) shall be discussed and produced to the government as additional metadata fields. The Producing Party will not employ analytic software or technology to search, identify, or review potentially responsive material, including but not limited to, technology assisted review or predictive coding, without first discussing with the government.

## **5. Hidden Text**

All hidden text (e.g. track changes, hidden columns, mark-ups, notes) shall be expanded and rendered in the image file. Except for Adobe PDF files, for any files that cannot be expanded, the native files shall be produced with the image file. If an Adobe PDF’s hidden text cannot be expanded and rendered in an image file, it need only be produced in native form if individually requested by a specific document identifier or bates number.

## **6. Embedded Files and File Links**

All non-graphic embedded objects (Word documents, Excel spreadsheets, .wav files, etc.) that are found within a file shall be extracted and produced. For purposes of production, the embedded files shall be treated as attachments to the original file, with the parent/child relationship preserved.

The parties shall meet and confer regarding how to treat file links, including links within e-mails to centralized document repositories (e.g. MS OneDrive and Google Drive).

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## **7. Image-Only Files**

All image-only files (non-searchable .pdfs, multi-page TIFFs, Snipping Tool and other screenshots, etc., as well as all other images that contain text) shall be produced with OCR text and metadata/database fields identified in section 3 for “Other ESI.”

## **8. Encrypted Files**

Any data (whether individual files or digital containers) that is protected by a password, encryption key, digital rights management, or other encryption scheme, shall be decrypted prior to processing for production.

- a. The unencrypted text shall be extracted and provided per section 2.d. The unencrypted files shall be used to render images and provided per sections 2.a and 2.b. The unencrypted native file shall be produced pursuant to sections 10-21.
- b. If such protected data is encountered but unable to be processed, each file or container shall be reported as an exception in the accompanying Exception Report (pursuant to section 27) and shall include all available metadata associated with the data, including custodian information.

## **9. Production of Imaged Hard Copy Records**

All imaged hard copy material shall reflect accurate document unitization including all attachments and container information (to be reflected in the PARENTID, ATTACHID, BEGATTACH, ENDATTACH and FOLDERID).

- a. Unitization in this context refers to identifying and marking the boundaries of documents within the collection, where a document is defined as the smallest physical fastened unit within a bundle. (e.g., staples, paperclips, rubber bands, folders, or tabs in a binder).
- b. The first document in the collection represents the parent document and all other documents will represent the children.
- c. All imaged hard copy documents shall be produced as 300 dpi single-page TIFF files, CCITT Group IV (2D Compression). All documents shall be produced in black and white TIFF format unless the image requires color. An image requires color when color in the document adds emphasis to information in the document or is itself information that would not be readily apparent on the face of a black and white image. Images identified as requiring color shall be produced as color 300 dpi single-page JPEG files.
- d. All objective coding (e.g., document date or document author) should be discussed and could be produced to the government as additional metadata/database fields should they be deemed as necessary.

## **10. Production of Spreadsheets and Presentation Files**

All spreadsheet and presentation files (e.g. Excel, PowerPoint) shall be produced in the unprocessed “as kept in the ordinary course of business” state (i.e., in native format), with an associated placeholder image and endorsed with a unique Bates number. *See* section 22 below.

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The file produced should maintain the integrity of all source, custodian, application, embedded and related file system metadata.

#### **11. Production of E-mail Repositories**

E-mail repositories, also known as e-mail databases (e.g., Outlook PST, Lotus NSF), can contain a variety of items, including: messages, calendars, contacts, tasks, etc. E-mail database systems should not be produced without consultation with and written consent of the government about the format for the production of such databases.

#### **12. Production of Items Originally Generated in E-mail Repositories but Found and Collected Outside of E-mail Repositories, i.e., “Stand-alone” Items**

Any parent e-mail or other parent items (e.g., calendar, contacts, tasks, notes, etc.) found and collected outside of e-mail repositories (e.g., items having extensions .msg, .htm, .mht, etc.), shall be produced with the “Loose E-mail” metadata fields outlined in section 3, including but not limited to any attachments, maintaining the family (parent/child) relationship.

#### **13. Production of ESI Collected from Mobile Devices, Messaging Platforms, Workplace Collaboration Tools and Other Technologies**

The responding party shall identify, collect, and produce any and all data which is responsive to the requests, collected from mobile devices, messaging platforms, workspace collaboration tools and other technologies. These technologies include, but are not limited to smart phones, cell phones, tablets, PDAs, Blackberry, smart phone data, tablet data, voicemail messaging data, instant messaging, chat messaging, text messaging, Slack, conference call data, video/audio conferencing, workspace collaboration tools (e.g., GoTo Meeting, WebEx, MS Teams, Zoom), and related/similar technologies. However, such data, logs, metadata or other files related thereto, as well as other less common but similar data types, shall be produced after consultation with and written consent of the government about the format for the production of such data.

The expectation of the government is that all familial relationships for all data will be maintained. Similar to email conversations and families, the expectation is that all messages/texts in a conversation will be provided the same conversation index and groupid data (maintaining the familial relationship) allowing the government to read the entire conversation in context. Messages should be produced to align with the formats listed in section 2 and as individual Unicode text files, and attachments should be produced as native files with images and OCR text.

While the parties shall meet and confer on precise metadata formats, as an example, metadata collected from mobile devices shall be provided in formats such as the following:

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| Field Name           | Field Description                                                      | Mobile | Mobile Cellebrite Categories |        |         |       |                 |                |                |       |                  |
|----------------------|------------------------------------------------------------------------|--------|------------------------------|--------|---------|-------|-----------------|----------------|----------------|-------|------------------|
|                      |                                                                        |        | Chats                        | MMS    | SMS     | Email | Instant Message | Voicemail      | Recordings     | Notes | Calendar         |
| TXT-ROWNUMBER        | Row number.                                                            | ✓      | #                            | #      | #       | #     | #               | #              | #              | #     | #                |
| TXT-CHATNUMBER       | Chat number, identifies chat groups.                                   | ✓      | Chat #                       |        |         |       |                 |                |                |       |                  |
| TXT-STARTTIME        | Start date-time for conversation, calendar item.                       | ✓      | Start Time: Date             |        |         |       |                 |                |                |       | Start Date: Date |
| TXT-ENDTIME          | End date-time for calendar item.                                       | ✓      |                              |        |         |       |                 |                |                |       | End Date: Date   |
| TXT-LASTACTIVITYTIME | End date-time for conversation.                                        | ✓      | Last Activity: Date          |        |         |       |                 |                |                |       |                  |
| TXT-PARTICIPANTS     | Who was involved in the conversation, meeting.                         | ✓      | Participants                 |        | Party   |       |                 |                |                |       | Attendees        |
| TXT-MSGNUMBER        | Individual identifier for message.                                     | ✓      | Instant Message #            |        |         |       |                 |                |                |       |                  |
| TXT-BODY             | Body of the chat, message, item.                                       | ✓      | Body                         | Body   | Message |       |                 |                |                | Body  |                  |
| TXT-STATUS           | Whether the text was Sent or Read on the device.                       | ✓      | Status                       | Status | Status  |       |                 |                |                |       | Status           |
| TXT-LOCATION         | GPS Information.                                                       | ✓      | Location                     |        |         |       | Location        |                |                |       | Location         |
| TXT-TIMESTAMP        | Timestamp of item. Equivalent to DateReceived for incoming items or to | ✓      | Timestamp: Date              | Date   | Date    | Date  |                 | Timestamp-Date | Timestamp-Date |       |                  |



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| Field Name         | Field Description                                                                                                                                                                                                                                                      | Mobile | Mobile Cellebrite Categories |         |           |         |                 |           |            |         |          |
|--------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|------------------------------|---------|-----------|---------|-----------------|-----------|------------|---------|----------|
|                    |                                                                                                                                                                                                                                                                        |        | Chats                        | MMS     | SMS       | Email   | Instant Message | Voicemail | Recordings | Notes   | Calendar |
|                    | DateSent for outgoing items.                                                                                                                                                                                                                                           |        |                              |         |           |         |                 |           |            |         |          |
| TXT-READDATE       | Date read                                                                                                                                                                                                                                                              | ✓      | Read: Date                   |         | Read-Date |         | Read-Date       |           |            |         |          |
| TXT-DELETED        | Indicates whether a message was deleted and recovered by Cellebrite.                                                                                                                                                                                                   | ✓      | Deleted - Chat               | Deleted |           | Deleted | Deleted         | Deleted   | Deleted    | Deleted | Deleted  |
| TXT-STARREDMESSAGE | Notes whether the message was flagged.                                                                                                                                                                                                                                 | ✓      | Starred message              |         |           |         | Starred message |           |            |         |          |
| TXT-THREAD-GROUP   | Populate with the DOCID of the first text in the chat conversation to allow the entire chat conversation to be grouped as a family. (Sort each device by Chat Number and then by Row Number to assign TXT-THREAD-GROUP identifier). This is NOT the BEGATTACH field or | ✓      | Chat #                       |         |           |         |                 |           |            |         |          |

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| Field Name | Field Description                                                                            | Mobile | Mobile Cellebrite Categories |           |           |           |                 |           |            |       |          |
|------------|----------------------------------------------------------------------------------------------|--------|------------------------------|-----------|-----------|-----------|-----------------|-----------|------------|-------|----------|
|            |                                                                                              |        | Chats                        | MMS       | SMS       | Email     | Instant Message | Voicemail | Recordings | Notes | Calendar |
|            | Relativity Group Identifier.                                                                 |        |                              |           |           |           |                 |           |            |       |          |
| TXT-SMSC   | Short Message Service Center (handles SMS text messages on behalf of phone service provider) | ✓      |                              |           | SMSC      |           |                 |           |            |       |          |
| DIRECTION  | Direction of communication ; Outgoing or Incoming.                                           | ✓      |                              | Direction | Direction | Direction | Direction       |           |            |       |          |
| IMPORTANCE |                                                                                              | ✓      |                              | Priority  |           | Priority  |                 |           |            |       | Priority |
| ACCOUNT    | Account identifier for device user: email address, phone number, account number.             | ✓      |                              | Name      |           | Account   |                 | Name      |            |       |          |
| DURATION   | Duration time of call, voice message, audio, video in HH:MM:SS format, e.g. 00:00:32         | ✓      |                              |           |           |           |                 | Duration  | Duration   |       |          |

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#### **14. Production of Social Media**

Prior to any production of responsive data from social media (e.g., Twitter, Facebook, LinkedIn, etc.), the producing party shall first discuss with the government the potential export formats before collecting the information, to ensure it is collected and produced in a way that preserves the original metadata, has a clear chain of custody, and provides as much information as possible regarding the source and history of each individual communication.

Social media platforms offer different functions, forms of content, and capability for downloading accounts. Because of these differences, prior to collection of social media data, the producing party must discuss with the government the available export and production methods and formats that the producing party is considering. Unless the government agrees to an alternative in writing, regardless of the social media platform, productions of social media content must meet the following general requirements: (1) separate (2) searchable (3) static images of (4) each responsive posting on the social media platform, (5) all related content (e.g., comments, likes, share or re-transmittal information, images, videos, linked documents and content), and (6) associated metadata (e.g., user name(s), date, and time of all posts, comments, likes, share or re-transmittals).

These general requirements are in addition to any more specific requirements in a particular request (e.g., geolocation data), and the producing party must ask the government about any perceived conflict between these requirements and another source of specifications or requirements. If available from the social media platform or through social media data processing software, files that facilitate interactive review of the data (i.e., html files) as well as load files in .csv format must be produced with the associated content.

#### **15. Production of Structured Data**

Prior to any production of responsive data from a structured database (e.g., Oracle, SAP, SQL, MySQL, QuickBooks, proprietary timekeeping, accounting, sales rep call notes, CRMs, SharePoint, etc.), the producing party shall first identify the database type and version number, discuss providing the database dictionary (in whole or part) and any user manuals, or any other documentation describing the structure and/or content of the database and a list of all reports that can be generated from the database. Upon consultation with and written consent of the government, if a report is provided, the standard format of that report provided should be in comma separated values (.csv) format. The information contained in any such report must be thoroughly explained to the government before production.

#### **16. Production of Photographs with Native File or Digitized ESI**

Photographs shall be produced as single-page JPEG files with a resolution equivalent to the original image as they were captured/created. All JPEG files shall have extracted metadata/database fields provided in a Concordance® load file format as outlined in section 3 for “Other ESI.”

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### **17. Production of Images from which Text Cannot be OCR Converted**

An exception report shall be provided when limitations of paper digitization software/hardware or attribute conversion do not allow for OCR text conversion of certain images. The report shall include the DOCID or Bates number(s) corresponding to each such image.

### **18. Production of Translated Text with Non-English Language ESI or Documents**

To the extent translated text is available to the producing party through machine language translation, such translations shall be provided to the government with the production. The producing party shall provide the original extracted text as well as the translated extracted text in load ready format. The translated text and images of translated documents shall be provided as a separate folder volume to the main production. The parties shall meet and confer regarding any required translated text redactions.

### **19. Production of Audio File Transcripts**

To the extent audio files are produced and transcripts are available to the producing party through machine transcription, such transcripts shall be provided to the government with the production. The producing party shall provide the audio file transcript as a text file in load ready format like any other text file named by the BEGDOC#. The parties shall meet and confer regarding any required audio file redactions.

### **20. Production of ESI from Non-PC or Non-Windows-based Systems**

If responsive ESI is in non-PC or non-Windows-based Systems (e.g., Apple, IBM mainframes, and UNIX machines, Android device, etc.), the ESI shall be produced after discussion with and written consent of the government about the format for the production of such data.

### **21. Production of Native Files (When Applicable Pursuant to These Specifications)**

Production of native files, as called for in these specifications, shall have extracted metadata/database fields provided in a Concordance® load file format as defined in the field specifications for “Other ESI” as outlined in section 3 as well as a placeholder image which indicates a native file is being produced.

ESI shall be produced in a manner which is functionally usable by the government. The following are examples:

- a. AutoCAD data, e.g., DWG and DXF files, shall be processed/converted and produced as single-page JPG image files and accompanied by a Concordance® Image formatted load file as described above. The native files shall be placed in a separate folder on the production media and linked by a hyperlink within the text load file.
- b. GIS data shall be produced in its native format and be accompanied by a viewer such that the mapping or other data can be reviewed in a manner that does not detract from its ability to be reasonably understood.

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- c. Audio and video recordings shall be produced in native format and be accompanied by a viewer if such recordings do not play in a generic application (e.g., Windows Media Player).

## 22. Bates Number Convention

All images should be assigned Bates numbers before production to the government. Each Bates number shall be a standard length, include leading zeros in the number, and be unique for each produced page. The numbers should be endorsed on the actual images at a location that does not obliterate, conceal, or interfere with any information from the source document. Native files should be assigned a single Bates number for the entire file which will represent the native document in the Opticon/ Concordance® Image Cross Reference file. The load file will include a reference to the native file path and utilize the NATIVELINK metadata field). The Bates number shall not exceed 30 characters in length and shall include leading zeros in the numeric portion. The Bates number shall be a unique number given sequentially (i.e. page one of document is PREFIX0000000001, page two of the same document is PREFIX0000000002) to each page (when assigned to an image) or to each document (when assigned to a native file). If the parties agree to a rolling production, the numbering convention shall remain consistent throughout the entire production. There shall be no spaces between the prefix and numeric value. If suffixes are required, please use “dot notation.” Below is a sample of dot notation:

|         | <u>Document #1</u>     | <u>Document #2</u>     |
|---------|------------------------|------------------------|
| Page #1 | PREFIX000000000001     | PREFIX000000000002     |
| Page #2 | PREFIX000000000001.002 | PREFIX000000000002.002 |
| Page #3 | PREFIX000000000001.003 | PREFIX000000000002.003 |

## 23. Media Formats for Storage and Delivery of Production Data

Electronic documents and data shall be delivered on any of the following media:

- a. CD-ROMs and/or DVD-R (+/-) formatted to ISO/IEC 13346 and Universal Disk Format 1.02 specifications; Blu-ray.
- b. External hard drives (USB 3.0 or higher, formatted to NTFS format specifications) or flash drives
- c. Government approved File Transfer Protocol (FTP) technologies.
- d. Storage media used to deliver ESI shall be appropriate to the size of the data in the production.
- e. Media should be labeled with the case name, production date, Bates range, and producing party.

## 24. Virus Protection and Security for Delivery of Production Data

Production data shall be free of computer viruses. Any files found to include a virus shall be quarantined by the producing party and noted in a log to be provided to the government. Password protected or encrypted files or media shall be provided with corresponding passwords and specific decryption instructions. All encryption software shall be used with approval by and with the written consent of the government.

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## **25. Privilege Logs**

- a. The name and title of the author (and if different, the preparer and signatory);
- b. The name(s) and title(s) of the individual(s) to whom the document was addressed;
- c. The name(s) and title(s) of the individuals to whom the document or a copy of the document was sent or to whom the document or a copy, or any part thereof, was shown;
- d. The date of the document;
- e. The number of pages;
- f. A brief description of the subject matter;
- g. A statement of the specific basis on which privilege is claimed; and
- h. The paragraph or subparagraph of the Subpoena to which it is responsive.

## **26. Compliance and Adherence to Generally Accepted Technical Standards**

Production shall be in conformance with standards and practices established by the National Institute of Standards and Technology (“NIST” at [www.nist.gov](http://www.nist.gov)), U.S. National Archives & Records Administration (“NARA” at [www.archives.gov](http://www.archives.gov)), American Records Management Association (“ARMA International” at [www.arma.org](http://www.arma.org)), American National Standards Institute (“ANSI” at [www.ansi.org](http://www.ansi.org)), International Organization for Standardization (“ISO” at [www.iso.org](http://www.iso.org)), and/or other U.S. Government or professional organizations.

## **27. Read Me Text File**

All deliverables shall include a “read me” text file at the root directory containing: total number of records, total number of images/pages or files, mapping of fields to plainly identify field names, types, lengths, and formats. The file shall also indicate the field name to which images will be linked for viewing, date and time format, and confirmation that the number of files in load files matches the number of files produced.

## **28. Exception Report**

An exception report, in .csv format, shall be included, documenting any production anomalies during the collection, processing, and production phases. The report shall provide all available BEGDOC# or DOCID values and metadata listed in section 3, including but not limited to file names and file paths for all affected files.

## **29. Transmittal Letter to Accompany Deliverables**

All deliverables should be accompanied by a transmittal letter including the production date, case name and number, producing party name, and Bates range produced. Technical instructions on how to decrypt media should be included in the transmittal letter but the password should be transmitted separately.

-XXX-

## DECLARATION OF LISA K. HSIAO

Pursuant to 28 U.S.C. § 1746, I, Lisa K. Hsiao, hereby declare as follows:

### GENERAL BACKGROUND

1. I am the Acting Director of the Enforcement and Affirmative Litigation Branch (“EALB”) of the Civil Division of the United States Department of Justice.
2. EALB’s Enforcement Section (“ES”) is the successor to the Consumer Protection Branch (“CPB”) and is vested with CPB’s legal authorities, including handling investigations and litigation arising under federal statutes that protect consumers’ health, safety, economic security, and identity integrity. ES, as the successor to CPB, is authorized to oversee and conduct all civil and criminal matters arising under the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301, et seq., and related matters. *See* 28 C.F.R. § 0.45(i) and Justice Manual 4-8.000, 4-1.313.
3. EALB-ES is currently conducting an investigation of potential violations of the Food, Drug, and Cosmetic Act (FDCA) relating to the on- or off-label use by manufacturers and distributors of drugs, including puberty blockers, sex hormones, or any other drug used to facilitate a child's so-called “gender transition.”
4. The Attorney General may authorize other officers of the Department of Justice to perform certain functions of the Attorney General. *See* 28 U.S.C. § 510. In any investigation of a federal health care offense, the Attorney General may issue in writing and cause to be served a subpoena requiring the production and testimony described in 18 U.S.C. § 3486(a)(1)(B). *See* 18 U.S.C. § 3486(a)(1)(A).

5. Pursuant to Attorney General Order Number 3591-2015, dated November 10, 2015, the Attorney General authorized the Assistant Attorney General for the Civil Division to issue and serve administrative subpoenas pursuant to 18 U.S.C. §§ 3486(a)(1)(A) and (a)(1)(B) to investigate violations of the FDCA that relate to a health care benefit program.

6. Under the authority of 18 U.S.C. § 3486 and the Attorney General's delegation of authority, on July 3, 2025, the Assistant Attorney General for the Civil Division, Brett A. Shumate, lawfully issued an administrative subpoena to Rhode Island Hospital ("RIH") in connection with an investigation being conducted in my office. The subpoena was served on RIH on July 11, 2025.

7. The facts in this Declaration come from my personal observations, my training and experience, and information obtained from other government personnel. This Declaration is intended to demonstrate that the administrative subpoena discussed herein was issued in the furtherance of an investigation authorized by law and that the records and other things the subpoena seeks are relevant to that investigation. Accordingly, this Declaration does not set forth all my knowledge about this matter.

#### **LEGAL BACKGROUND**

8. Among other statutory and regulatory authorities, EALB-ES investigates and brings actions to enforce the FDCA. The overriding purpose of the FDCA is to protect the public health. *United States v. Article of Drug ... Bacto-Unidisk*, 394 U.S. 784, 798 (1969). The FDCA's purpose should "infuse construction of the [FDCA]" so that courts give the FDCA a liberal construction that furthers protection of the public health,



including in criminal enforcement of the FDCA. *United States v. Dotterweich*, 320 U.S. 277, 280 (1943); *see also United States v. Park*, 421 U.S. 658, 672–73 (1975). This consideration applies even more strongly where the Government seeks to enforce the FDCA to protect the health of children.

9. A “Federal healthcare offense” for purposes of a subpoena issued under 18 U.S.C. § 3486 is defined by 18 U.S.C. § 24(a) as, *inter alia*, “a violation of, or a criminal conspiracy to violate ... section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 331) ... if the violation or conspiracy relates to a health benefit program.” 18 U.S.C. § 24(a). The statute defines “health care benefit program” to mean “any public or private plan or contract, affecting commerce, under which any medical benefit, item, or service is provided to any individual, and includes any individual or entity who is providing a medical benefit, item, or service for which payment may be made under the plan or contract.” 18 U.S.C. § 24(b). A subpoena issued under section 3486 (commonly referred to as a “HIPAA subpoena”) may be used to investigate both substantive violations of the FDCA, as well as conspiracies to violate the FDCA if the violation or conspiracy relates to products or services that might ultimately be paid for by a private or public health insurance program.

10. Administrative subpoenas issued under 18 U.S.C. § 3486 are routinely used to obtain categories of medical, billing, and related information in federal healthcare offense investigations. The materials requested by the subpoenas issued in this investigation fall within that framework and include the same kinds of records—patient files, insurance submissions, treatment documentation, and communications (such as emails)—that

federal investigators typically review to determine whether a federal health care offense may have occurred.

## FDA'S APPROVAL OF DRUGS

11. The FDCA regulates the development, manufacturing and distribution of drugs in the United States. For a “new drug” to enter interstate commerce, the manufacturer must first demonstrate to the United States Food and Drug Administration (“FDA”) that the drug is both safe and effective for each of its intended uses. 21 U.S.C. §§ 331(d), 355(a). The introduction into interstate commerce of an unapproved new drug violates the FDCA. 21 U.S.C. § 331(d).

12. A drug manufacturer obtains FDA approval for a new drug through a new drug application (“NDA”) that demonstrates its drug is safe and effective for each of its intended uses. 21 U.S.C. § 355(a). As part of the approval process, FDA reviews the proposed labeling for the drug in the NDA, which must include adequate directions for how to use the drug for each of its intended uses. 21 U.S.C. § 352(f); 21 C.F.R. § 201.5. When FDA approves an NDA, it determines that the drug is safe and effective **for the specific use or uses identified in the application**. As part of that approval, FDA also approves the product’s proposed labeling, including prescribing information, as providing adequate directions for use for those approved indications. FDA’s approval of a drug for one or more particular uses does **not** mean that the drug is safe and effective for unapproved uses, nor does approval mean that the labeling provides adequate directions for unapproved uses. While physicians are permitted to prescribe an FDA-approved drug for an unapproved use, such prescribing may warrant investigation because it may provide evidence of FDCA violations by others. *See, e.g., infra* ¶¶ 13–18. Also, depending on the circumstances, prescribing for unapproved uses can itself involve FDCA violations—for example, where the physician is engaged in the distribution or labeling of an unapproved drug.

## MISBRANDING OF DRUGS PRESCRIBED FOR UNAPPROVED USES THROUGH ILLEGAL LABELING

13. A drug is misbranded if its labeling does not have adequate directions for the use of the drug. 21 U.S.C. § 352(f). FDA-approved labeling contains directions only for the drug’s approved uses. If a drug manufacturer or other person distributes an approved drug for an unapproved use, the manufacturer or other person could be charged with misbranding the drug or distributing a misbranded drug with labeling that lacks adequate directions for its intended uses.<sup>1</sup> 21 U.S.C. §§ 331(a), 331(b), 331(c), 331(k), and 352(f)(1). Enforcement’s predecessor, CPB, participated in successful prosecutions of drug manufacturers for such illegal conduct. *See, e.g., United States v. Pharmacia & Upjohn Co.*, Case No. 09-CR-10258-DPW (D. Mass. 2009); *United States v. Eli Lilly & Co.*, Case No. 09-CR-00020-RK (E.D. Pa. 2009).

14. A drug is also misbranded if its labeling is false or misleading in any particular. 21 U.S.C. § 352(a).

15. Under the FDCA, drug labeling is broadly defined as any “written, printed, or graphic matter ... *accompanying*” the drug. 21 U.S.C. § 321(m) (emphasis added). The term “accompanying” is interpreted broadly and includes materials that are separate from the drug but nonetheless related to it, including any material that supplements, explains, or is designed for use with the drug. *See* 21 U.S.C. § 321(m); 21 C.F.R. § 1.3(a); *Kordel v. United States*, 335 U.S. 345 (1948); *United States v. Urbuteit*, 335 U.S. 355 (1948); *United States v. 47 Bottles ... Jenasol RJ Formula 60*, 320 F.2d 564, 569 (3d Cir. 1963) (literature shipped by company to sales agent and then stored in agent’s bedroom closet was labeling: “[I]t cannot be said that ...the Court promulgated or intended to promulgate a requirement that there be an actual use in order that the literature constitute labeling.”).

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<sup>1</sup> As noted above, it is possible for doctors to prescribe an approved drug for an unapproved use without violating the FDCA.

Labeling can include promotional materials, advertisements, brochures, flyers, instruction sheets, posters, and similar materials.

16. If a drug manufacturer or other person distributes (or causes the distribution of) an approved drug with false or misleading labeling for an unapproved use, the manufacturer or other person could possibly be charged with misbranding the drug or distributing a misbranded drug. 21 U.S.C. §§ 331(a), 331(b), 331(c), 331(k), and 352(a). Enforcement’s predecessor, CPB, participated in successful prosecutions of manufacturers for false and misleading labeling. *See, e.g., United States v. Avanos Medical, Inc.*, Case No. 21-CR-0307-E (N.D. Tex. 2021) (deferred prosecution agreement for false and misleading labeling for medical device).

#### **ILLEGAL DISTRIBUTION OF AN UNAPPROVED NEW DRUG**

17. A “new drug” is any drug that is “not generally recognized, among [qualified] experts . . . as safe and effective for use under the conditions prescribed, recommended, or suggested in the *labeling* thereof ....” 21 U.S.C. § 321(p)(1) (emphasis added). Even if a substance has been on the market for years, it can be a “new drug” if used for an indication that has not been approved by FDA and is not generally recognized as safe and effective for that indication.

18. If a drug manufacturer or other person distributes (or causes the distribution of) an approved drug for an unapproved use with labeling for that unapproved use, the manufacturer or other person could be charged with distributing an unapproved new drug in violation of the FDCA. 21 U.S.C. § 331(d).

#### **INTENT IN FDCA CRIMES**

19. A violation of 21 U.S.C. § 331 is a federal criminal offense that is punished as a strict liability misdemeanor without any proof of criminal intent. *See Park*, 421 U.S. at 672–73; *United States v. Wiesenfeld Warehouse Co.*, 376 U.S. 86, 91 (1964). Through its strict liability misdemeanor provision, the FDCA imposes rigorous criminal

accountability on companies and individuals involved with drugs that affect the health of consumers in circumstances where consumers realistically cannot protect themselves. *See Wiesenfeld*, 376 U.S. at 91; *Dotterweich*, 320 U.S. at 280–81. This heightened accountability is even more acute when the consumers at risk are children. Consequently, any violation of Section 331, including the causing of any prohibited act listed in Section 331, is a federal crime, even in the absence of any criminal intent.

20. A felony FDCA violation requires the same conduct as the strict liability misdemeanor, but with the added element of an intent to defraud or mislead. 21 U.S.C. § 333(a). Evidence of intent to defraud or mislead—whether directed at a government agency, a patient, or an insurance company—thus transforms a misdemeanor FDCA violation into a felony offense. Evidence of an intent to defraud or mislead a government agency or another third-party, such as a patient or insurer, in connection with an FDCA violation is sufficient to establish a felony FDCA offense. Efforts to conceal a violation or evade detection also can demonstrate the requisite intent to defraud or mislead.

### **THE DRUGS AT ISSUE IN THIS INVESTIGATION**

21. This investigation focuses on prescription drugs typically used in gender-related care for children and adolescents suffering from a recognized mental disorder known amongst clinicians as “gender identity disorder” or, as the most recent version of the DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS refers to it, “gender dysphoria.” Included in this group of prescription drugs are (1) drugs used to suppress the production of sex hormones to delay puberty—the most common being gonadotropin-releasing hormone agonists (“GnRH agonists”), commonly referred to as “puberty blockers;” and (2) cross-sex hormones meant to induce physical changes to alter the child’s secondary sexual characteristics to resemble those typically seen in the opposite

sex and less like the individual's biological sex. Testosterone, a Schedule III controlled substance under the Controlled Substances Act, is included in this latter group.

22. FDA has not determined these drugs to be either safe or effective for the treatment of gender dysphoria. Nor has FDA approved any of these drugs for the treatment of gender dysphoria or any other psychiatric disorder. While these prescription drugs are FDA-approved for other indications (*e.g.*, precocious puberty, prostate cancer, hypogonadism, etc.), FDA has not approved any NDA that establishes the safety and efficacy of these drugs for use in minors with gender dysphoria. As explained above, introducing a such "new drug" into interstate commerce without an FDA-approved indication is unlawful. Thus, to the extent these drugs are intended to treat gender dysphoria in minors, they constitute unapproved new drugs under federal law, and their distribution for that unapproved indication violates the FDCA and is a federal crime.

23. Some of these drugs, including puberty blockers, are not administered orally. Rather, they are typically administered by injection by a medical professional or through an outpatient surgical procedure to implant the drug. Puberty blockers are typically implants or injectables that require administration by a physician or nurse in a medical facility that must purchase, store, and administer the drug, placing healthcare providers in the chain of distribution of that drug. Similarly, testosterone may be, and often is, administered by injection.

24. The United States Government is aware of credible, publicly available evidence relating to the widespread practice of prescribing cross-sex hormones and puberty blockers to treat gender dysphoria in minors that casts doubt on the safety and efficacy of

this practice. The United States Department of Health and Human Services (“HHS”), of which FDA is a component agency, has determined that the evidence for the safety and efficacy of these drugs for the treatment of gender dysphoria in minors is weak. *See generally*, U.S. DEP’T OF HEALTH & HUMAN SERVS., TREATMENT FOR PEDIATRIC GENDER DYSPHORIA, REVIEW OF EVIDENCE AND BEST PRACTICES (Nov. 19, 2025) t <https://opa.hhs.gov/gender-dysphoria-report> (“HHS REVIEW”). Specifically, this report found that some of the pharmacologic interventions under investigation here “carry risk of significant harms including infertility/sterility, sexual dysfunction, impaired bone density accrual, adverse cognitive impacts, cardiovascular disease and metabolic disorders, [and] psychiatric disorders.” *Id.* at 10. HHS further determined that “the overall quality of [scientific] evidence concerning the effects of any intervention on psychological outcomes, quality of life, regret, or long-term health is **very low**.” *Id.* at 13 (emphasis added).

25. In December, 2025, the Assistant HHS Secretary for Health, Admiral Brian Christine, M.D., issued a public health message to healthcare providers stating that: “Current evidence does not support claims that puberty blockers, cross-sex hormones, and surgeries are safe and effective treatments for pediatric gender dysphoria ... Healthcare providers caring for children and adolescents with gender dysphoria should refuse to provide puberty blockers, cross-sex hormones, or surgical interventions to children and adolescents, as these treatments pose unnecessary and disproportionate risks of harm with insufficient evidence of benefit.” U.S. Dep’t of Health & Human Servs., *Evidence-Based Care for Children and Adolescents with Gender Dysphoria* (Dec. 18,

2025), [https://health.gov/sites/oash/files/Message\\_Pediatric\\_Gender\\_Dysphoria\\_Treatment.pdf](https://health.gov/sites/oash/files/Message_Pediatric_Gender_Dysphoria_Treatment.pdf).

26. The Government is also aware of other major scientific publications and national health authorities that have questioned the strength and quality of the evidence base for the efficacy of puberty blockers and other medical interventions to treat youth for gender dysphoria. In the United Kingdom, for example, the British National Health Service (“NHS”) commissioned an independent review led by Dr. Hilary Cass, a pediatrician and the former President of the Royal College of Paediatrics and Child Health, to evaluate how NHS was providing care for children experiencing gender-related distress. *See generally* NHS England, *Independent Review of Gender Identity Services for Children and Young People: Final Report* (Apr. 10, 2024), <https://cass.independent-review.uk/home/publications/final-report/> (“*Cass Review*”). Dr. Cass’s review concluded: “This is an area of remarkably weak evidence, and yet results of studies are exaggerated or misrepresented by people on all sides of the debate to support their viewpoint. The reality is that we have no good evidence on the long-term outcomes of interventions to manage gender-related distress.” *Cass Review* at 13.

27. With regard to puberty blockers, Dr. Cass reported that a systematic review conducted by the University of York “found no evidence that puberty blockers improve body image or dysphoria” while “a known side effect of puberty blockers on mood is that it may reduce psychological functioning.” *Id.* at 179. With regard to cross-sex hormones, the *Cass Review* agreed with another systematic review that concluded that: “There is a lack of high-quality research assessing the outcomes of hormone interventions in



adolescents with gender dysphoria/incongruence, and few studies that undertake long-term follow up. No conclusions can be drawn about the effect on gender dysphoria, body satisfaction, psychosocial health, cognitive development, or fertility. Uncertainty remains about the outcomes for height/growth, cardiometabolic and bone health.” *Id.* at 184.

28. As a result of the *Cass Review*’s findings, in December 2024, the United Kingdom banned puberty blocker treatment for gender dysphoria. *See* Press Release, U.K. Department of Health & Social Care, *Ban on Puberty Blockers to be Made Indefinite on Experts’ Advice* (Dec. 11, 2024), <https://www.gov.uk/government/news/ban-on-puberty-blockers-to-be-made-indefinite-on-experts-advice> (stating that “there is currently an unacceptable safety risk in the continued prescription of puberty blockers to children”). Press reports indicate that the U.K. is similarly considering banning cross-sex hormones for minors. *See* Alison Holt, *Cross-Sex Hormones for Under 18s Could be Restricted or Banned*, BBC News (May 22, 2025), <https://www.bbc.com/news/articles/cg711xevd89o>.

29. Several other countries have likewise enacted restrictions on the use of these pharmacologic interventions for treating gender-related disorders in minors, or are considering them. *See, e.g.,* Sweden Puts Brakes on Treatments for Trans Minors, FRANCE 24 (Aug. 2, 2023), <https://www.france24.com/en/live-news/20230208-sweden-puts-brakes-on-treatments-for-trans-minors>; Siobhan Harris, *Europe & the Puberty Blocker Debate*, MEDSCAPE MED. NEWS (Apr. 25, 2024), <https://www.medscape.com/viewarticle/europe-and-puberty-blocker-debate-2024a1000831> (reporting on European countries’ practices and findings including

France’s National Academy of Medicine recommendation that the “greatest reserve” be used in puberty blockers and/or hormones in children and adolescents; Sweden’s conclusion that the risks of puberty blockers and hormones currently outweigh the potential benefits); *New Zealand Halts New Puberty Blockers for Young Transgender People*, NBC NEWS, (Nov. 20, 2025), <https://www.nbcnews.com/world/asia/new-zealand-halts-new-puberty-blockers-young-transgender-people-rcna244925>.

30. Most recently, just last month researchers analyzed a large Finnish nationwide cohort (2,083 gender disordered individuals matched with 16,643 controls) and found that adolescents who were referred for gender-identity services (such as hormonal or surgical treatment) had substantially higher rates of severe psychiatric morbidity than matched peers—both before and after treatment. The study determined that these patients’ psychiatric needs not only persisted after undergoing sex-rejecting medical interventions, but even intensified. Those who underwent such procedures had elevated risks of psychiatric morbidity, “with hazard ratios approximately three times higher than female controls and five times higher than male controls.” Sami-Matti Ruuska et al., *Psychiatric Morbidity Among Adolescents Who Contacted Specialised Gender Identity Services in Finland in 1996–2019: A Register Study*, ACTA PAEDIATRICA (2026), <https://doi.org/10.1111/apa.70533>.

31. Both the HHS review and the UK’s independent *Cass Review*—along with numerous other systematic reviews of the evidence that the government is aware of—justify questioning the scientific foundation for prescribing puberty blockers and cross-sex hormones for minors. Not only has FDA not approved them for these purposes, but it

is far from certain, therefore, that prescribing these drugs would ever be considered by the agency as safe and effective for that indication. To the contrary, the available public record suggests there is serious potential for harm.

### **EVIDENCE OF FDCA AND HEALTH CARE FRAUD VIOLATIONS IN PEDIATRIC GENDER-RELATED CARE**

32. From testimonies of public whistleblowers and leading national medical experts on the subject matter, the Government is aware of potential violations of federal law in connection with the provision of gender-related treatments for minors occurring at healthcare providers across the country.

33. This includes allegations and evidence of fraudulent billing practices to secure insurance coverage/payment. Such practices include, but are not limited to, providers (i) using the incorrect diagnosis and/or billing code (*e.g.*, “endocrine disorder, unspecified” instead of “gender dysphoria” to prescribe cross-sex hormones, or “precocious puberty” instead of “gender dysphoria” to prescribe puberty blockers) because they know that certain insurance plans may not cover the off-label prescription of puberty blockers or cross-sex hormones for gender-related treatment<sup>2</sup>; (ii) changing or misrepresenting a patient’s sex in the medical records and coding and billing for “endocrine imbalance,” which is supported by accompanying bloodwork showing endocrine levels atypical of the incorrectly documented sex (but consistent with the patient’s actual sex); and (iii) fraudulently making a gender dysphoria diagnosis where patients do not meet the DSM-5

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<sup>2</sup> In fact, one nonprofit organization has published guidance to health care providers advising them of “coding alternatives for trans healthcare,” which detailed “codes that are commonly rejected by insurance providers” and “codes that are commonly accepted by insurance providers.”

diagnostic criteria, but the providers know that the carrier or plan will cover off-label prescription of cross-sex hormones or puberty blockers to treat gender dysphoria.

34. The Government also knows of evidence and allegations of many cases where providers failed to supply adequate labeling and to give the information necessary to obtain informed consent, actively deceived patients and parents with false claims and statements regarding the drugs' effectiveness or alternatives, and misrepresented to minor patients and their parents the risks associated with and the science claimed to support taking the drugs described herein for gender dysphoria.

35. The Government has also reviewed evidence (including transcripts and video recordings) from national conferences on treating patients with gender dysphoria, including minors, wherein presenters describe and encourage attendees to engage in the provision of purely patient-driven care (or "embodiment goals"), with little regard for gender dysphoria diagnoses, assessment, or clinical criteria. These recommendations include prescribing cross-sex hormones and puberty blockers to minors. The Government is concerned that such facially deficient care may be accompanied by facially deficient or misleading labelling.

36. The subpoena at issue here is one of several investigative tools the United States has been employing in its ongoing and legitimate investigation concerning the provision of medical sex trait modification services, including issues related to violations of the FDCA. The investigation has proceeded through multiple channels, including the analysis of insurance claims data, billing records, and other lawfully obtained material. Information developed through those efforts has raised questions concerning whether

puberty blockers and cross-sex hormones have been fraudulently distributed for unapproved uses involving RIH patients. For example, based on diagnosis codes, it appears that between 2020 and 2025, there were at least 4 minors first diagnosed at RIH with central precocious puberty at age 12 or older. This is well beyond the age at which children are typically diagnosed with precocious puberty. *See, e.g.*, Pediatric Endocrine Society, *Precocious Puberty: A Guide for Families*, <https://pedsendo.org/patient-recourse/precocious-puberty> (Apr. 29, 2026) (“Precocious puberty is usually defined as onset of puberty before age 8 in girls and before age 9 in boys.”).

37. Moreover, claims analysis shows that between 2020 and 2025, the number of RIH patients with claims bearing a diagnosis code for gender dysphoria more than doubled; the number of claims for “endocrine disorder” experienced similar growth.

38. In addition, the director of RIH’s pediatric “Gender and Sexuality Program” (and the principal author of the American Academy of Pediatrics’ gender policy statement) was responsible for at least 14 insurance claims for RIH patients bearing an “endocrine disorder” diagnosis code over the last decade—indeed more than his claims bearing a “gender dysphoria” diagnosis code over the same period.

39. As part of this investigation, the United States has also reviewed medical records obtained from other pediatric hospitals that have treated gender dysphoria with sex trait modification services, including through the use of pharmaceuticals. Those medical records reflect multiple instances in which diagnostic or billing codes for medical conditions such as “endocrine disorder, unspecified” notwithstanding clinical notes that reflect that the true disorder being treated with the drugs is gender

dysphoria/transsexualism. Some records further reflect that certain speech or vocal interventions are coded as treatment for vocal disorders even where the purpose is voice feminization or masculinization. These observations form part of the ongoing and developing factual basis for the Government's continuing investigation of similarly situated treatment centers, such as RIH.

## THE SUBPOENA SPECIFICATIONS SEEK INFORMATION RELEVANT TO THE INVESTIGATION

40. The fifteen requests in the investigative HIPAA subpoena issued to RIH seek to further the investigation described above. The requests can be broadly broken down into four main categories: (1) requests related to personnel and corporate oversight (Request 1); (2) requests related to billing, coding, and reimbursement practices (Requests 2–6); (3) requests related to the practice’s relationships with drug manufacturers, distributors, and pharmacies (Requests 7–10); and (4) requests regarding clinical practices and drug safety (Requests 11–15). All the subpoenaed records and documents are relevant to the federal healthcare investigation described herein. *See* 18 U.S.C. § 3486(a)(1).

41. Request 1 seeks information to identify who had authority to direct prescribing, billing, or marketing practices to determine liability. Under strict liability doctrines, including the responsible corporate officer doctrine, officers and responsible personnel can be held criminally liable for FDCA violations even without direct participation. Personnel files also show financial incentives, disciplinary history, and/or training which can establish knowledge and intent.

42. The requests in the second group (regarding billing, coding, and reimbursement practices) are necessary to determine whether the clinic disguised treatment for gender-

related mental disorders as another, physical illness (*e.g.*, endocrine disorder) to secure health benefit program reimbursement. Such practices are especially important to demonstrate an “intent to defraud or mislead” under 21 U.S.C. § 333(a)(2) if the clinic misrepresented the intended use of the drugs. Moreover, training materials and internal discussions can reveal whether improper coding was a deliberate strategy.

43. The third group of requests (relating to relationships with drug manufacturers, distributors, and pharmacies) are probative of an intent to market or promote drugs for unapproved uses. If RIH, or one of its affiliated healthcare providers, received promotional materials, “scientific exchange information,” or payments to encourage prescribing of puberty blockers or cross-sex hormones, such information would support a FDCA theory (including conspiracy) involving unlawful off-label promotion. Similarly, information regarding financial arrangements (consulting agreements, sponsorships, speaking honoraria) may suggest improper influence to reinforce a showing an intent to misbrand, including with intent to defraud or mislead.

44. The final group of requests (relating to patient-level clinical practices and drug safety) will permit the United States to evaluate the scope of prescribing the drugs described herein (including the number and age range of patients treated), and consistency of diagnoses. It also establishes the scope of interstate distribution and the scale of potential FDCA violations. Linking each patient’s clinical record to corresponding billing and insurance claims can demonstrate whether diagnoses were miscoded, which can prove fraudulent intent. Documentation of clinical justification, informed consent, and disclosure of off-label use is key to assessing whether the clinic

(and/or potential co-conspirators) concealed or downplayed risks associated with using these drugs in a manner not approved by FDA. Absence or minimization of such warnings could establish the intent to mislead. Patient charts also typically capture adverse outcomes, side effects, and complications of drug use. By reviewing multiple patient records, the investigative team may reveal systemic use of the same masking codes, fraudulent informed consent documents, etc. This enables investigators to distinguish between mere errors and an institutionalized practice. Finally, providing patient records can provide essential investigative leads. Parents may be witnesses about what disclosures were made. Patients (depending on age and circumstances) may provide information about the informed consent process, side effects, or other false or misleading information about the drugs conveyed during treatment. Health benefit programs tied to identified patients could provide additional information, including claim records, creating a triangulated evidentiary record. In sum, without this information, the Government cannot fully determine the scope of the violations, identify patterns of misbranding or fraudulent billing, or assess whether the conduct was undertaken with intent to defraud or mislead, as required for felony liability under 21 U.S.C. § 333(a)(2).

#### **GOVERNMENT INVESTIGATIVE RESOURCES**

45. This is a bona fide, high-priority, and substantial investigation of potential FDCA violations in the provision of gender-related care for minors. Substantial government resources have been assigned to it. It is being handled by several veteran, career prosecutors with many decades of experience in healthcare fraud and FDCA enforcement between them, supported by a team of document analysts and other forensic

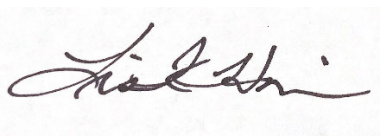


specialists. The Federal Bureau of Investigation (“FBI”) has assigned agents and analysts to assist with various field activities and is employing advanced data analytics to identify prescribing patterns, potential unlawful off-label promotion, and patterns in reimbursement. In addition to FBI, FDA has also assigned agents from its Office of Criminal Investigations. The scope and coordination of these efforts reflect the seriousness with which the Government is pursuing potential violations of federal law.

#### **RIH’S FAILURE TO COMPLY WITH THE SUBPOENA**

46. The return date on the subpoena was Thursday, August 7, 2025. In early conversations with counsel for RIH, the Government communicated that it would be willing to receive documents responsive to the subpoena past the return date but that it did not expect to extend that grace period beyond reason. Counsel for RIH has communicated several times that it intends to and would be producing responsive documents. However, the last such communication was on February 4, 2026, and to date, RIH has produced only one document totaling six pages. In other words, RIH has failed to comply in any meaningful way with the subpoena.

I declare under penalty of perjury that the foregoing is true and correct. Executed on this 30<sup>th</sup> day of April, 2026.



LISA K. HSIAO  
Acting Director  
Enforcement & Affirmative Litigation Branch  
Civil Division  
United States Department of Justice

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF RHODE ISLAND**

IN RE 2025 SUBPOENA TO RHODE  
ISLAND HOSPITAL

Case No. 26-mc-7-MSM-AEM

**MOTION TO STAY OR FOR TRANSFER OF VENUE**

The United States of America respectfully moves to stay this action, or to transfer venue of this action to the Northern District of Texas, under the “first-to-file” rule. Plaintiff has made clear that this action seeks to undo a valid order entered by a district judge in the Northern District of Texas enforcing this very same subpoena (25-1431-032) on the very same entity (Rhode Island Hospital). Doc. 1 at 2. In addition to other problems with the Plaintiff’s suit—addressed in the Government’s response filed later today—the first-filed rule counsels against this Court adjudicating this matter. Because the United States’ enforcement action was filed first and the lawsuits are functionally the same, the first-filed court—in this case, the Northern District of Texas—must determine which action should proceed. Therefore, this Court should stay or transfer this action in order to permit the Plaintiff to ask the Northern District of Texas to make that determination.

**BACKGROUND**

On July 3, 2025, the Government issued a subpoena pursuant to its 18 U.S.C. § 3486 subpoena authority to Rhode Island Hospital. Doc. 1-2 at 1. The subpoena listed a return date of August 7, 2025. *Id.* The Hospital chose not to move to quash the subpoena, and in

fact engaged with the Government and initially suggested that it would at least partially comply with the subpoena. However, the Hospital neither complied nor moved to quash by the response deadline.

On April 30, 2026—nearly ten months after the Hospital was served with the subpoena, and nine months after a motion to quash was due under the statute, *see* 18 U.S.C. § 3486(a)(5)—the Government moved to enforce the subpoena in the jurisdiction where this nationwide investigation is being carried on, which is the Northern District of Texas. 18 U.S.C. § 3486(c). On May 1, 2026, the district court enforced the subpoena. *In the Matter of Administrative Subpoena 25-1431-032* (N.D. Tex. 2026) (Doc. 2 at 1). On May 4, 2026, the Child Advocate for the State of Rhode Island filed this action in response to the Texas district court’s order. On May 6, 2026, Rhode Island Hospital appeared in the Northern District of Texas action, filing a notice of appeal and seeking a stay from the district judge. *In the Matter of Administrative Subpoena 25-1431-032* (N.D. Tex. 2026) (Docs. 6 & 7). Rhode Island Hospital’s arguments in its motion to stay cover much of the same ground as Plaintiff’s arguments in this suit. *Id.*

### **ARGUMENT**

The “first-filed rule” is “an equitable doctrine of venue selection followed universally[.]” *Feinstein v. Brown*, 304 F. Supp. 2d 279, 280 (D.R.I. 2004) (emphasis added). “Obvious concerns arise” when similar lawsuits proceed before two sister courts: “wasted resources because of piecemeal litigation, the possibility of conflicting judgments, and a general concern that the courts may unduly interfere with each other’s affairs.” *TPM Holdings, Inc. v. Intra-Gold Indus., Inc.*, 91 F.3d 1, 4 (1st Cir. 1996). “Where the overlap

between the two suits is nearly complete, the usual practice is for the court that first had jurisdiction to resolve the issues and the other court to defer.” *Id.*

Here, the first-filed rule directly applies on its own terms because there is complete legal and factual overlap between the two suits. The two lawsuits are precise mirror images of each other—the first lawsuit successfully sought enforcement under 18 U.S.C. § 3486 of the subpoena to Rhode Island Hospital, while the second lawsuit seeks to quash that same subpoena to the same entity based on the same statute—and the United States is a party in both suits. The suits are more than “substantially similar;” they are functionally the same suit over the same legal question, which is the enforceability of the subpoena. *Thakkar v. United States*, 389 F. Supp. 3d 160, 174 (D. Mass. 2019) (collecting cases on amount of similarity necessary for application of first-to-file rule).

Moreover, exceptions to the first-to-file rule do not apply because, among other things, the United States’ suit in Texas was not filed in order to deprive Rhode Island Hospital or the Child Advocate of its choice of venue—indeed, the Government waited patiently for nearly ten months for Rhode Island Hospital to comply with the subpoena before bringing the action, and Rhode Island Hospital could have filed a timely suit in this Court last year asserting these same arguments. The United States chose a natural venue permitted by statute, which is the venue where this nationwide investigation—which involves Rhode Island Hospital and numerous other actors—is being conducted. Moreover, the First Circuit’s concerns about wasted resources and conflicting judgments are especially acute here, where the first-filed court has already determined the matter at issue, the issues are on appeal, and the arguments being raised are essentially the same as the arguments here.

But this Court should not even determine whether the first-to-file rule definitively applies, because the Northern District of Texas must decide whether the doctrine applies and how to resolve the conflict. “The first-to-file rule has generally been interpreted to dictate not only which forum is appropriate, but also which forum should decide which forum is appropriate.” *EMC Corp. v. Parallel Iron, LLC*, 914 F. Supp. 2d 125, 129 (D. Mass. 2012); *see TPM*, 91 F.3d at 4. “Courts in nearly every circuit have held that the court in which the second action was filed should defer to courts in the first-filed action.” *EMC Corp.*, 914 F. Supp 2d at 129. Indeed, “[c]ase law indicates that the court in which the first-filed case was brought decides the question of whether or not the first-filed rule, or alternatively, an exception to the first-filed rule, applies.” *Cruz v. Hartford Cas. Ins. Co.*, No. 05-38S, 2005 WL 1231965, at \*3 (D.R.I. May 20, 2005); *Ontel Products, Inc. v. Project Strategies Corp.*, 899 F. Supp. 1144, 1150 n.9 (S.D.N.Y. 1995).

This is because “[w]here an action is brought in one federal district court and a later action embracing the same issue is brought in another federal court, the first court has jurisdiction to enjoin the prosecution of the second action.” *Meeropol v. Nizer*, 505 F.2d 232, 235 (2d Cir. 1974). “This rule is applicable even where the parties in the two actions are not identical.” *Id.*

### **CONCLUSION**

This Court should stay this action or transfer it to the Northern District of Texas so that the Child Advocate can ask that Court to permit this action—by either transferring this action back to this Court, or by considering the Child Advocate’s arguments in the Northern District of Texas.



**STATEMENT REGARDING NEED FOR HEARING UNDER LR Cv 7(c)**

The Government does not believe oral argument is necessary to determine this motion.

# CERTIFICATE OF SERVICE

I hereby certify that on May 7, 2026, I electronically filed the within Motion to and it is available for viewing and downloading from the Court's CM/ECF System, and that the participants in the case that are registered CM/ECF users will be served electronically by the CM/ECF system.

*/s/ Patrick R. Runkle*  
PATRICK R. RUNKLE  
Assistant Director

# Lifespan's Summary Notice Of Privacy Practices

***See the attached Privacy Notice for greater details***

Lifespan and its partners are required by federal law to provide a Privacy Notice that describes how medical and healthcare information we maintain about you may be used or disclosed. Your protected health information is confidential. The Notice describes each use and disclosure we are permitted to make, your rights and our obligations under the law.

### Use and Disclosures:

Under a variety of circumstances we may use your medical information without obtaining your prior authorization. For example we may use this information to:

- Provide you with treatment,
- Ensure the quality of your care,
- Bill and collect payment for the services you were provided, or
- Report a communicable disease, domestic violence or criminal activity.

In other scenarios we may use your medical information, but you have the opportunity to object. For example unless you object:

- The hospital directory will include limited information about you such as your hospital room number, or
- We may release information, as permitted under the law, about your condition to family and friends involved in or who help pay for your care.

These examples are merely illustrative. For full descriptions see the attached Notice.

## Your Rights:

While the records we maintain belong to us, you have a variety of rights with respect to the information in those records. For instance, you have the right to:

- Correct, but not delete, the information
- Choose where and how the information is sent to you, and
- Obtain a list of non-routine disclosures made of this information.

All of these rights are subject to some exceptions that are described in the attached Notice.





Effective Date – August 3, 2020

# Lifespan

## Joint Privacy Notice

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE READ IT CAREFULLY.

This Notice describes the types of medical information we gather about you (or your minor child or ward), with whom that information may be shared and the safeguards we have in place to protect it. You have the right to the confidentiality of your healthcare information. If you have any questions about this Notice, please contact the Lifespan Privacy Officer or one of the Lifespan Affiliate Privacy Officers at the telephone numbers and/or addresses listed at the end of this Notice.

### **1. Who We Are**

This Notice describes the privacy practices of the Lifespan Healthcare System (“Lifespan”) facilities, as well as health care professionals and other persons, such as doctors and nurses and their support personnel, who provide services at Lifespan facilities and have agreed to follow this Notice. We believe it is in the best interest of patient care to standardize privacy practices for all providers participating in the Lifespan organized health care arrangement, including the Lifespan entities identified below:

Rhode Island Hospital  
Hasbro Children’s Hospital, A Division of Rhode Island Hospital  
The Miriam Hospital  
Newport Hospital  
Emma Pendleton Bradley Hospital  
NHCC Medical Associates, Inc.  
Lifespan Physician Group, Inc.  
Gateway Health Care, Inc.  
Gateway Professional Group, Inc.  
The Autism Project  
RIH Ventures  
Lifespan Pharmacy, LLC

Radiosurgery Center of Rhode Island

**2. Our Pledge Regarding Protected Health Information**

We understand that protected health information, commonly referred to as medical and healthcare-related information, about you is personal and needs to be kept confidential. We are committed to protecting this information.

We create and maintain a record of the care and services you receive from us and from other organizations that participate in your care. This information includes medical information and personally identifiable information we use to bill for your care. Lifespan needs this record to provide you with quality care and to comply with certain legal requirements. We store and manage your protected health information primarily in our Electronic Health Record, although we may also store and manage some of your protected health information in paper format only.

This Notice will tell you about the ways Lifespan uses and discloses protected health information about you. It will also describe your rights and certain obligations we have regarding the use and disclosure of this information. Lifespan uses and discloses your protected health information in accordance with applicable state and federal laws. To the extent state laws are more restrictive than federal laws, we will comply with the more restrictive state laws.

We are required by law to:

- Keep protected health information about you private;
  - Give you this Notice of our legal duties and privacy practices;
  - Notify you if you are affected by a breach of unsecured health information; and
- Abide by the terms of the Notice that is currently in effect.

**3. How We May Use And Disclose Protected Health Information About You**

The following categories describe and give examples of the different ways we are permitted or required to use and disclose your protected health information without first asking for your permission or offering you the opportunity to agree or object. In addition, if you participate in one of Lifespan's federally assisted substance use disorder programs, your patient identifying information may receive some further protections.

- A. De-Identified Health Information** – We can release your protected health information without your permission if we first “de-identify” it such that the person looking at it will not know it refers to you.

- B. For Treatment** – We use your protected health information to provide, coordinate and manage your healthcare. This will include disclosing protected health information about you to doctors, nurses, technicians, or other healthcare professionals who care for you, whether or not they are employed by Lifespan. For example, a doctor treating you for a broken leg may need to know if you have diabetes because diabetes may slow the healing process.
- C. For Payment** – We use your protected health information in order to bill and collect payment from you, your insurance company, or a third party for the services you receive. For example, your insurance company may need to know about the type of surgery you received in order to pay us appropriately. If you elect to take full financial responsibility for services you receive, and you pay your bill in a timely manner, your request that we do not bill your insurer will be honored.
- D. For Health Care Operations Purposes** – We may use and disclose your protected health information to support the operations of our organization, such as to conduct quality assessment activities, train healthcare professionals or arrange for legal services. This is necessary to make sure all our patients receive quality care. For example, we may use your protected health information to evaluate the performance of our staff.
- E. Business Associates** – We may disclose your protected health information to business associates who provide services or activities on our behalf. For example, we may contract with accreditation agencies, management consultants, quality assurance reviewers, billing and collection services, and accountants. To protect your health information, we require our business associates to sign a written agreement regarding the safeguards they will implement to protect the privacy of our records in their possession.
- F. As Required by Law** – We disclose protected health information about you when required to do so by federal, state, or local law.
- G. Appointment Reminders** – We may use and disclose your protected health information to contact and remind you of your healthcare appointments with any of our Lifespan entities.
- H. Treatment Alternatives, Benefits and Services** – In the course of providing treatment for you, we may use your health information to contact you about health promotion activities, disease awareness or case management. We may also use your protected health information to tell you about or recommend possible treatment options, health related benefits, or services that may be of interest to you. However, if a third party provides financial remuneration to us in exchange for making these types of communications to you, we will ask you for your authorization in advance.
- I. Fundraising** – We may use or disclose your demographic information and the dates you receive treatment in order to contact you for our fundraising purposes. Each of

our hospital affiliates has established an institutionally-related fundraising foundation that solicits gifts. You have a right to opt-out of these types of communications in the future by following the instructions on fundraising communications from us.

- J. To Avert a Serious Threat to Health or Safety** – We may disclose protected health information about you when necessary to prevent a serious and imminent threat to your health and safety or to the health and safety of the public or another person. We may also release protected health information to the police in certain cases.
- K. Public Health Activities** – We may release your protected health information to appropriate authorities for public health purposes including, but not limited to, preventing or controlling disease, injury or disability; to report child abuse or neglect; to the Food and Drug Administration (FDA) for activities relating to quality, safety or effectiveness of FDA regulated products or activity. We may also release your protected health information for the public health purpose of alerting a person who may be at risk of contracting or spreading a communicable disease.
- L. Disclosures About Victims of Abuse, Neglect, or Domestic Violence** – We may release your protected health information in a situation where we believe you have been a victim of abuse, neglect, or domestic violence. In some cases, we may be required by law to release such information. In other cases, we may not be required to release the information, but we may choose to release it to appropriate authorities or social service providers in order to prevent harm to you or another person. If possible, we will ask you for your permission before we make the disclosure, or tell you as soon as possible after we make it.
- M. Organ and Tissue Donation** – If you are an organ donor, we may release your protected health information to organizations that obtain organ, eye or tissue for donation and transplantation.
- N. Limited Disclosures for Research Purposes or For Purposes Leading Up to Research** – We may use and disclose your protected health information within Lifespan as necessary to prepare for research studies. For example, a researcher might review your protected health information while he or she is thinking about how to design a research study. Also, after a patient's death, it is possible that his or her protected health information would be used for research purposes if at least fifty years have passed since the patient's death. In most other cases, we will not use your protected health information for research purposes unless we first explain the research to you and you consent to participate in the research and you give us permission to use your protected health information for the research. In some cases, though, we may use your protected health information for research without your permission. In order for this to happen, your information would have to be partially de-identified, or a committee of people who know about research, privacy and

medical ethics would have to decide that use of your information was necessary and that it would be of low risk to you and your privacy.

- O. National Security and Military** – We may disclose your protected health information to authorized federal officials for conducting national security and other intelligence activities, including providing protective services to the President and other officials. If you are a member of the armed forces, we may release information about you as required by military command authorities.
- P. Workers' Compensation** – We may release protected health information about you for workers' compensation or similar programs that provide benefits for work-related injuries or illness.
- Q. Legal Proceedings** – We may release protected health information about you during the course of legal proceedings if we are ordered to release the information by a court or judge, or in response to a valid subpoena or warrant issued by a court, administrative tribunal or an officer of a court.
- R. Law Enforcement** – We may release your protected health information to a law enforcement official for a law enforcement purpose under the following circumstances: (1) as permitted or required by law, or in response to certain types of court orders, warrants, subpoenas, demands, requests or other legal process; (2) if the law enforcement official needs limited information about you because of a reasonable belief that you pose a danger to yourself, a particular person or people, or if you are trying to obtain narcotics illegally; (3) if it is believed you have been the victim of a crime, although we will try to discuss with you before making the disclosure; (4) for the purpose of identifying or locating a suspect, fugitive, material witness, or missing person; (5) if you have died and we think your death involved a criminal act; (6) if a crime occurs at Lifespan and we think your protected health information is evidence of the crime and (7) in an emergency health care situation if necessary to report a crime.
- S. Coroners, Medical Examiners and Funeral Directors** – We may release protected health information to a coroner or medical examiner. This may be necessary, for example, to identify a deceased person when determining the cause of death. Following the patient's death, we may also be required to furnish funeral directors with a standard death certificate that includes certain protected health information.
- T. Health Oversight** – We may disclose your protected health information to governmental agencies authorized by law to audit, inspect, or investigate the health care system, government benefit programs, other government programs and civil rights laws.

**U. Inmates** – If you are an inmate of a correctional institution or under the custody of a law enforcement official, we will release your protected health information only as permitted by law.

**V. Questions of Capacity to Consent** – In situations where you lack capacity to consent, we may use and disclose your protected health information as permitted by applicable Lifespan policies and by law.

**W. Health Information Exchange(s)** – We may participate in certain health information exchanges whereby we may share, request and receive your health information, as permitted by law, with or from other health care providers or entities for treatment, payment, or health care operations purposes.

#### **4. Other Uses or Disclosures of Your Protected Health Information**

All other uses or disclosures of your protected health information will be made only with your written authorization, consent, or after you have been given the opportunity to object and you have decided not to object. If you authorize or agree to a use and disclosure now, you can change your mind later. If you do change your mind, you must let us know in writing. If and when you revoke your permission, we will stop using or disclosing your protected health information pursuant to your written authorization to the greatest extent practical. You understand that we are unable to revoke any disclosures we have already made and that we are required to retain our records of the care that we provide to you.

**For certain health information, you can tell us your choices about what we share.** If you have a clear preference for how we share your information in the situations described below, please let us know and we will follow your instructions.

**A. Hospital Directory** – Except for patients receiving mental health services, unless you object we will include certain limited information about you in the hospital directory while you are in the hospital. This information may include your name, location in the hospital, your general condition (e.g., fair, stable, etc.) and your religious affiliation. The directory information may also be released to individuals, such as your family, friends, a member of the clergy, who ask for you by your full name. This is so your family, friends and clergy can visit you in the hospital and generally know how you are doing. However, for patients receiving mental health services, we will not disclose that the patient is receiving care at the hospital, unless an official at the hospital determines that the release of such information to any of the following persons is in the patient's best interest: (1) members of the patient's family; (2) the patient's lawyer; or (3) the patient's guardian or conservator.



**B. Individuals Involved in Your Care or Payment for Your Care** – Unless you object in writing, we may release the fact of your admission and a general description of your condition to another person, such as a relative or friend, who is involved in your care, or who helps pay for your care. Also, we may use or disclose your protected health information to an authorized public or private entity to assist in disaster relief efforts and to coordinate permitted uses and disclosures to family or other individuals involved in your healthcare. In cases where you are not present or able to agree or object, the healthcare providers will use their professional judgment to determine whether it is in your best interest for them to make disclosures permitted by law

Below, we have provided a few examples of situations where we need to ask you before we can use or share your medical information.

**C. Research** – Except for research described in Section 3 of this Notice, we may not use or disclose your protected health information for research purposes unless you authorize us to do so.

**D. Psychotherapy Notes** – In general, we will not use or disclose psychotherapy notes (notes recorded by a mental health professional to document or analyze conversations with you and/or your family and stored separately from your medical record), unless you authorize us to do so. However, we can use or disclose such protected health information without your authorization for the following purposes: (1) the health professional who recorded the information can use it to treat you; (2) in limited situations, Lifespan can use or disclose the information in connection with mental health counseling training that occurs at Lifespan; and (3) Lifespan can use a patient's psychotherapy notes to defend against any legal proceeding brought by a patient.

**E. Marketing** – Marketing communications are communications about a product or service that encourage you to purchase or use the product or service. We must get your authorization before we use or disclose your protected health information for marketing, with two exceptions. First, we may inform you about products or services during face-to-face communications with you without your authorization, including providing related written materials to you. Second, we may also, without your authorization, provide to you promotional gifts of nominal value that encourage you to purchase or use a product or service.

**F. Sale of Protected Health Information** – We will not sell your protected health information to a third party without your prior authorization, and the authorization must state that we will receive remuneration in exchange for the disclosure of your protected health information.



## **5. Your Rights Regarding Your Medical Information**

You have the following rights regarding the protected health information we maintain about you.

- A. The Right to Request Restrictions** – You have the right to request restrictions on uses and disclosures of your protected health information for treatment, payment and health care operations. We are not required to agree to your request unless you request restriction on disclosures to a health plan for purposes of payment or healthcare operations, and the protected health information relates to an item or service for which you, or another person on your behalf, have assumed full financial responsibility. If we do agree to your request for restrictions, we are bound by the restrictions, except in limited circumstances, such as if there is an emergency. In many cases, restricting a caregiver’s access to protected health information is not in the best interest of the patient and could impede Lifespan operations. For this reason, in many cases, Lifespan will not agree to your request.

You may also request that we not release any part of your protected health information to family members or friends who may be involved in your care, but we are not required to agree to your request.

To request restrictions, you must make your request in writing to the **Lifespan Privacy Officer, 245 Chapman Street, Suite 200, Providence, RI 02905, or one of the Affiliate Privacy Officers at the addresses listed at the end of this Notice.**

- B. The Right to Request to Receive Confidential Communication** – We will accommodate reasonable requests to communicate protected health information to you at a certain location or in a certain way. For example, you may ask us to contact you at work, or at a location other than your home address. If possible, please make alternative location requests at your first contact or at the time of registration. However, you may make such requests anytime thereafter. Requests for alternative means of communication made after the first contact or registration must be made in writing to our Privacy Officers at the address listed above.
- C. Right to Inspect and Copy** – You have the right to inspect and obtain, in a timely manner, a copy of your protected health information used to make decisions about your care, known as a “designated record set.” Usually, this includes medical and billing records, but does not include psychotherapy notes, information gathered for research purposes, information compiled in reasonable anticipation of or use in a legal proceeding, and protected health information subject to any law that prohibits your access.

To inspect and copy your protected health information in a designated record set, you must submit your request in writing to our Privacy Officer at the address above or Affiliated Privacy Officer at the addresses listed at the end of this Notice. If you request a copy of the information, we may charge a fee for the costs of copying,

mailing or other supplies associated with your request. If we maintain the protected health information you request in an electronic format, you have the right to request a copy of your information in electronic format, and we will provide the information to you in the format you request so long as it is readily producible in that format. If the information is not readily producible in the electronic format you request, we will reach an agreement with you as to an alternative readable electronic format. We will not charge you more than our labor costs of responding to your request for an electronic copy of your protected health information.

We may deny your request to inspect and receive a copy your protected health information in certain very limited circumstances. If you are denied access to your medical information, you may request that the denial be reviewed by another Lifespan healthcare professional. Under some circumstances, however, we are not required to offer you such review. If we do comply with your request for review of a denial, we will comply with the outcome of this review.

**D. Right to Amend** – If you feel that protected health information we have about you is incorrect or incomplete, you may ask us to amend the information. You have the right to request an amendment for as long as the information is kept.

To request an amendment, your request must be made in writing and submitted to the Lifespan Privacy Officer or Lifespan Affiliated Privacy Officers at the address listed at the end of this Notice. In addition, you must provide a reason that supports your request.

We may deny your request for an amendment if it is not in writing or does not include a reason to support the request. In addition, we may deny your request if you ask us to amend information that:

- Was not created by us, unless the person or entity that created the information is no longer available to make the amendment;
- Is not part of the protected health information kept by Lifespan;
- Is accurate and complete.

**E. Accounting of Certain Disclosures** – In general, you have the right to receive an accounting of disclosures we made of your protected health information in the six (6) years prior to the date the accounting is requested. However, many exceptions apply to this general rule. For instance, you do not have a right to receive an accounting for disclosures made: (1) for treatment, payment or health care operations; (2) to you or your personal representative; (3) that you authorized in writing; (4) for the hospital's directory ; (5) to family and friends involved in your care or payment for your care or certain other notification purposes; (6) to federal officials for national security or intelligence activities; (7) to correctional institutions or law enforcement officers regarding inmates; (8) as part of a limited data set; or (9) to health oversight officials in certain situations. The scope of your

right to request an accounting may be modified by changes in federal law from time to time.

You have the right to receive specific information about those disclosures for which you do have a right to an accounting. The right to receive this information is subject to certain exceptions, restrictions and limitations. Your request must be submitted in writing to either the Lifespan Privacy Officer or the appropriate Lifespan Affiliate Privacy Officer at the address listed at the end of this Notice. The first disclosure list you request within a 12-month period will be free. For additional lists, we may charge you the cost of providing such lists.

**F. Right to a Paper Copy of This Notice** – You have the right to request a paper copy of this Notice at any time, even if you have agreed to receive this Notice electronically. Requests for paper copies may be obtained when registering at a Lifespan affiliate or can be requested, in writing, from either the Lifespan Privacy Officer, or the appropriate Lifespan Affiliate Privacy Officer listed at the end of this Notice.

**G. Right to Notification** – If we determine that your medical records have been improperly used or accessed, we will notify you of the improper use or access as required by law.

## **6. Minors and Personal Representatives**

In most situations, parents, guardians, and/or others with legal responsibilities for minors (children under 18 years of age) may exercise the rights described in this Notice on behalf of the minor. However, there are situations where minors may themselves exercise the rights described in the Notice.

## **7. Changing This Notice**

We reserve the right to change this Notice. We reserve the right to make the revised or changed Notice effective for protected health information we already have about you as well as any information we receive in the future. We will prominently post a copy of this Notice at each Lifespan affiliate and on the Web at

<http://www.lifespan.org/lifespan-joint-privacy-notice.html>

The effective date will be printed on the first page of the Notice in the top right hand corner.

It should also be noted that in the event Lifespan or any of its affiliates are sold or merge with another organization, your medical information/medical record would become the property of the new owner.

## **8. Complaints/Informational Inquiries**

If you believe your privacy rights have been violated, you may file a complaint with the Secretary of the Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Avenue, SW, Washington, DC 20201. You may also file a complaint with the Lifespan Privacy Officer at the address and phone number below.

You will not be penalized for filing a complaint, nor will you be asked to waive your rights as a condition of treatment.

Lifespan Privacy Officer  
245 Chapman Street, Suite 200  
Providence, RI 02905

401-444-4728 or [privacyofficer@lifespan.org](mailto:privacyofficer@lifespan.org)

We recognize that our patients may have questions about, or may wish to make inquiries about, their protected health information, this Notice or our privacy practices. Lifespan has appointed Lifespan Affiliate Privacy Officers who work closely with the Lifespan Privacy Office. The Lifespan Affiliate Privacy Officers, who work primarily in the Health Information Services area, are ready to assist you with your questions and inquiries and can be reached at the addresses and telephone numbers listed on the following page.

## **Contact Information for Affiliate Privacy Officers**

Rhode Island Hospital  
Health Information Services  
Affiliate Privacy Officer  
593 Eddy Street  
Providence, RI 02903  
401-444-4560

The Miriam Hospital/Lifespan Physician Group  
Health Information Services  
Affiliate Privacy Officer  
164 Summit Avenue  
Providence, RI 02906  
401-793-2910

Newport Hospital/ NHCC Medical Associates, Inc  
Affiliate Privacy Officer  
11 Friendship Street  
Newport, RI 02840  
401-845-1545  
401-845-1152

Emma Pendleton Bradley Hospital  
Affiliate Privacy Officer  
1011 Veterans Memorial Parkway  
East Providence, RI 02915  
401-432-1129

Gateway Healthcare, Inc./ Gateway Professional  
Group, Inc./ The Autism Project  
Affiliate Privacy Officer  
249 Roosevelt Ave. Suite 250  
Pawtucket, RI 02860  
401-724-8400

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF RHODE ISLAND**

In Re: Administrative Subpoena  
25-1431-032 to Rhode Island Hospital

Misc. Action No. 1:26-mc-00007-MSM-AEM

**EMERGENCY MOTION TO QUASH  
SUBPOENA DUCES TECUM**

**REQUEST FOR EXPEDITED RELIEF  
PURSUANT TO LR CV 9**

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## INTRODUCTION

After months of negotiations over an expansive administrative subpoena that demands production of full patient files for an entire class of vulnerable minor patients, the Government, without warning, sought to compel compliance by going to court in Texas—almost 2,000 miles from Rhode Island Hospital (RIH) and the community it serves. This gamesmanship worked. RIH now faces an imminent compliance obligation under the Northern District of Texas’s order, which it signed hours after the Government filed its motion and before RIH had any opportunity to respond—a clear due process violation that invalidates the order. Even though the Government has voluntarily agreed to accept a narrower set of records from other hospitals that received identical subpoenas, here it sought, and the Northern District of Texas has ordered, full production by Thursday, May 14, 2026. If it does not fully comply, RIH faces immediate threat of sanctions and contempt.

Compliance would be impossible on this timetable. The Government knows this full well. It is especially egregious to demand when the Government’s conduct led RIH to believe that the pace of negotiations was acceptable and never indicated that RIH would face the draconian relief the Government blind-sided it with in securing the Texas order. At all times, RIH proceeded in good faith in its discussions with the Government—which routinely went dark for weeks or months at a time—in seeking to find a path to appropriate compliance. RIH’s good faith has been repaid with the threat of sanctions and contempt. As such, it has no choice but to pursue relief from the subpoena and the Texas order, which has no binding effect on this Court because both the subpoena and the order itself are unlawful. This Court should thus quash the subpoena in its entirety and order relief to RIH by **May 14, 2026**.

## BACKGROUND

### I. Factual Background

#### A. RIH lawfully provides gender-affirming care.

Rhode Island Hospital is an acute care hospital and academic medical center. Ex. 9 ¶¶ 4-5. At RIH, physicians and other providers administer comprehensive, multi-disciplinary gender-affirming care through the Gender and Sexuality Program at Hasbro's Children's Hospital, located on RIH's main campus in Providence. *Id.* ¶ 6; Exs. 10 ¶ 2, 11 ¶ 2. RIH's gender-affirming care services for minors include "medical and psychosocial evaluations, initiation and continuation of gender care and hormone therapy, and referrals to other providers and community resources." Ex. 11 ¶ 3. RIH provides this care only with the knowledge and consent of the patients and their parents or legal guardians. *Id.* ¶¶ 6, 9.

When minor patients receive gender-affirming care at RIH, they disclose private medical information about a range of topics, such as mental health, sexual health, fertility, relationships in school, their parents' occupations, the names of their friends and family members, family medical history, and more. *Id.* ¶ 6. RIH receives this information for purposes of diagnosing and treating its patients. *Id.* Physicians use this information to develop tailored care plans for each patient. *See id.* ¶ 7. In consultation with patients and their families, RIH physicians determine which medications will best serve each patient. *Id.* ¶ 10.

Although patients disclose highly sensitive and private information to RIH providers during the course of treatment, including intimate and personal details about their lives and their bodies, they do so with the understanding that RIH will maintain that information's confidentiality. Exs. 10 ¶ 5, 11 ¶ 11. Patient trust is critical to the physician-patient relationships at the core of RIH's operations—especially for minors seeking gender-affirming care. Ex. 10 ¶ 6. That trust

allows the physicians, patients, and the families of patients to engage in open, honest, and thorough discussions of medical history and needs to assess and deliver the best possible treatment plan for each patient. *Id.*

**B. The Government issued an expansive subpoena targeting gender-affirming care.**

On July 9, 2025, the Department of Justice served an administrative subpoena on RIH at its principal place of business in Providence, Rhode Island. *See* ECF No. 1-2; Ex. 3-C. The Government set a return date of August 7 and requested production at its Consumer Protection Branch office (now the Enforcement and Affirmative Litigation Branch) in Washington, D.C. *See* ECF No. 1-2 at 1. The subpoena enumerates fifteen requests for information that RIH must produce, including three for sensitive patient information:

11. Documents sufficient to identify each patient (by name, date of birth, social security number, address, and parent/guardian information) who was prescribed puberty blockers or hormone therapy.
12. For each such patient identified in Subpoena specification 11, *supra*, documents relating to the clinical indications, diagnoses, or assessments that formed the basis for prescribing puberty blockers or hormone therapy.
13. All documents relating to informed consent, patient intake, and parent or guardian authorization for minor patients identified in Subpoena specification 11, *supra*, including any disclosures about off-label use (*i.e.*, uses not approved by the United States Food and Drug Administration) and potential risks.

*Id.* at 8.

The Government issued this subpoena as part of a sweeping nationwide investigation targeted at hospitals and other medical facilities that provide gender-affirming care. To date, the Government has issued at least two dozen of these subpoenas across the country. The Government has purported to issue the subpoenas under the Health Insurance Portability and Accountability Act (HIPAA), 18 U.S.C. § 3486, citing its authority to “investigate Federal health care offenses.”

ECF No. 1-2 at 1. Specifically, the Government has asserted that its subpoenas further an investigation into potential criminal offenses under the Food, Drug, and Cosmetic Act (FDCA).

**C. RIH worked with the Government to negotiate compliance.**

Following service of the subpoena, counsel for RIH and the Government began to discuss RIH's compliance efforts. Ex. 9 ¶ 8; ECF No. 1-3 ¶ 46. At the very outset, counsel for the Government informed Glenn Friedemann, Associate General Counsel for Brown Health (RIH's parent organization), that the Government did not believe that RIH had engaged in any criminal wrongdoing and was instead only subpoenaed in its capacity as a potential witness. Ex. 9 ¶ 8.

RIH communicated to the Government that it would strive to reasonably comply with the Government's subpoena, but that compliance by the August 7, 2025 return date (less than a month after service occurred) would be impracticable, if not impossible.

For the time being, the Government appeared to understand that the month-long period before the return date would be far too short for any meaningful compliance with the subpoena's requests for production. The Government informed RIH that partial compliance by that date would be sufficient and that it was "willing to receive documents responsive to the subpoena past the return date." ECF No. 1-3 ¶ 46. Accordingly, RIH produced a responsive, six-page document by the subpoena's August 7 return date.

As part of this production, RIH noted that its "agreement to produce information and records responsive to the subpoena did not constitute a waiver of any objection that RIH may have to the subpoena or to any of its requests." Ex. 9 ¶ 9. Specifically, RIH expressly reserved, and did not waive:

- (1) its right to object to certain of the government's requests as unduly burdensome, irrelevant, or otherwise requiring the production of material or information protected from disclosure under federal or state law or
- (2) its right to seek a

protective order or any other judicial relief in any litigation arising in connection with the subpoena.

*Id.* The Government did not object to RIH’s reservation of rights. *Id.* Nor did it raise objections to the letter’s content at any time.

RIH continued to take steps to reasonably comply with the subpoena, including by collecting and reviewing certain responsive email communications. Throughout that process, RIH maintained open lines of communication with the Government about its ongoing compliance efforts, engaging in almost monthly calls through counsel for the first five months after the subpoena was served.

In late January 2026, counsel for RIH notified the Government that it was prepared to produce additional responsive documents in the weeks to come, and that it would send the Government proposed search terms for review relevant to RIH’s efforts to identify certain responsive emails—which had been the topic of the parties’ discussions in recent months and, again, without any objection from the Government as to this area of focus. RIH sent the Government the proposed search terms in early February. *See* Ex. 12 at 3. RIH anticipated making a production upon the Government’s confirmation of the search terms. The Government did not respond, even to confirm receipt. *See id.*

RIH did not hear back from the Government for nearly 12 weeks. Then, on April 28, the Government contacted counsel for RIH by email, observing that it “does not appear we have received any productions . . . in light of [the] search terms” proposed, but without expressing any expectation that document production should have commenced while the Government was presumably reviewing the terms. *Id.* The Government asked whether counsel could “conference this week regarding status.” *Id.* Although counsel for RIH responded the following day to propose a conference date, the Government sent no response. *Id.* at 2.

Instead, on Thursday, April 30, the Government filed a petition to enforce the subpoena in the U.S. District Court for the Northern District of Texas, Fort Worth Division. *See* Ex. 3.<sup>1</sup> The Government provided RIH no notice of its filing and did not confer with RIH about it, despite having been in email communication the day before.

The Northern District of Texas granted the Government's petition the same day it was filed, executing the Government's proposed order exactly as drafted. *See* Ex. 3-D; Ex. 4. The order summarily states:

The Court finds that the subpoena was issued within the Department of Justice's statutory authority, the subpoena seeks documents reasonably relevant to the investigation, and the subpoena's demands are reasonable. The Court further finds that the witness, Rhode Island Hospital, was served with the subpoena on July 3, 2025,<sup>2</sup> and has failed to fully comply with the subpoena by providing records to the government on or before the original due date of August 7, 2025, or the date of the Government's filing of its petition to enforce of April 30, 2026. The Court further finds that the witness has neither filed a motion to quash nor shown just cause for noncompliance.

Ex. 4 at 2.

RIH received no opportunity to respond to the Government's petition. The Northern District of Texas granted the petition mere hours after it was filed. RIH promptly appealed to the Fifth Circuit and has moved both the Northern District of Texas and the Fifth Circuit for a stay pending appeal. Ex. 5.

Full compliance with the subpoena at this stage would be impossible. In particular, RIH would need to explore ways in which it could comply with the subpoena while maintaining its patients' privacy. *See* Ex. 9 ¶ 13. The anonymization process that RIH would employ, to the extent true anonymization is even possible, is burdensome and takes several months to complete. *Id.*

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<sup>1</sup> This Court may take judicial notice of the filings in this proceeding, which are attached as exhibits for reference. *Medtronic Med. CR SRL v. Feliciano-Soto*, 59 F.4th 51, 53 n.2 (1st Cir. 2023).

<sup>2</sup> This date is incorrect. RIH was served on July 9, 2025. Ex. 3-C.



And many of the document custodians are actively practicing medical providers; reviewing documents for production thus comes at the expense of time spent caring for their patients. *Id.* ¶ 12. Compliance with the Government’s subpoena would therefore require a substantial amount of time and *millions* of dollars. *Id.* ¶ 14.

Additionally, even though the Government has voluntarily agreed to accept a narrower set of records—namely de-identified medical records—from other hospitals that received identical subpoenas, here it sought, and the Northern District of Texas has ordered, full production by Thursday, May 14, 2026.<sup>3</sup> Not only does this demand jeopardize the privacy rights of RIH’s patients, but this disparate treatment renders compliance inequitable and underscores the arbitrary and unreasonable nature of the Government’s enforcement posture toward RIH.

## II. Legal Background

The Government’s enforcement petition against RIH asserts that its investigation concerns “misbranding” under the Food, Drug, and Cosmetic Act (FDCA) and that its subpoena is tailored to uncovering information about potential misbranding offenses. Ex. 3. Under the FDCA, “misbranding” occurs when a drug’s “labeling” is “false or misleading” or—most relevant to the Government’s liability theory here—when it does not bear “adequate directions for use.” 21 U.S.C. § 352(a), (f); *see* Ex. 3 at 2. The term “labeling” refers broadly to the written materials that manufacturers and distributors of a drug associate it with to identify the drug and its uses. 21 U.S.C. § 321(m).

Food and Drug Administration (FDA) regulations implementing the FDCA provide that the adequacy of a prescription drug’s labeling depends on the drug’s “intended use.” *See* 21 C.F.R.

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<sup>3</sup> The Government has agreed to accept de-identified medical records from the Children’s Hospital of Philadelphia (Ex. 14-A at 12), the University of Pittsburgh Medical Center (Ex. 14-B at 17), and the Children’s Hospital of Los Angeles (Ex. 14-C at 36).

§ 201.100(d). Those regulations explain that a prescription drug’s labeling must contain “adequate information for [ ] use” of the drug. *Id.* A prescription drug’s directions for use may be “inadequate” if the labeling omits or incorrectly states “adequate information . . . under which practitioners licensed by law to administer the drug can use the drug safely and for the purposes for which it is intended.” *Id.* § 201.100(d)(1). The FDA defines “intended use” as “the objective intent of the persons legally responsible for the labeling of an article (or their representatives).” *Id.* § 201.128.

These provisions governing labeling apply to the manufacturers and distributors that place FDA-approved drugs into the stream of commerce, eventually reaching the physicians that prescribe the drugs and then the patients they care for and treat. Once a drug reaches a physician, however, the FDCA leaves the decisions about its appropriate use to the physician in the exercise of her medical judgment. Critically, the FDCA does not restrict off-label use by a physician—that is, use “for some other purpose than that for which it has been approved” by the FDA. *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 350 (2001). Instead, in enacting the FDCA, Congress preserved physicians’ authority to prescribe drugs for off-label uses and otherwise engage in the practice of medicine. *See* 21 U.S.C. § 396 (“Nothing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship.”).

Given these statutory parameters and in line with core federalism principles, the regulation of the practice of medicine—and specifically physicians’ decisions about how to treat their patients, including by prescribing drugs—thus remains the States’ prerogative. In Rhode Island,

gender-affirming care is a lawful and protected medical practice. *See* R.I. Gen. Laws §§ 5-37.8-1, 23-101, 23-101-2.

## LEGAL STANDARD

To defend its subpoena, the Government must establish that the “(1) the subpoena is issued for a congressionally authorized purpose, the information sought is (2) relevant to the authorized purpose and (3) adequately described, and (4) proper procedures have been employed in issuing the subpoena.” *U.S. Dep’t of Just. v. Ricco Jonas*, 24 F.4th 718, 726 (1st Cir. 2022).

## ARGUMENT

As similar litigation has laid bare in courts across the country, the Government has weaponized a slew of subpoenas to pressure hospitals and clinics that provide gender-affirming care to stop doing so. That effort cannot stand. The Government’s investigation has no sound statutory basis. And even if peripheral elements of its requests could conceivably be relevant to some legitimate investigation (none exists), the Government’s improper intrusion into the physician-patient relationship confirms that the subpoena is unacceptably broad and unduly burdensome. Thus, as the subpoenaed party, RIH moves to quash the subpoena in its entirety.

### **I. This challenge is timely.**

Although 18 U.S.C. § 3486 permits the subpoenaed party to move to quash the subpoena “[a]t any time before the return date specified in the summons,” 18 U.S.C. § 3486(a)(5), that language is permissive, not preclusive, and it does not override or displace this Court’s “discretion” to consider motions to quash filed after that date. *See, e.g., Michalski v. Little*, No. 1:22-CV-00262-SPB, 2025 WL 2108202, at \*1 (W.D. Pa. July 28, 2025); *see also In re Keebaugh*, No. MISC 19-163, 2019 WL 5802703, at \*3 (E.D. Pa. Nov. 6, 2019) (“‘Good cause’ or other circumstances may excuse an untimely motion.”). Courts evaluating good cause consider whether the moving party

acted in good faith and whether any delay caused prejudice to the opposing party. *See Concord Boat Corp. v. Brunswick Corp.*, 169 F.R.D. 44, 48 (S.D.N.Y. 1996); *Michalski*, 2025 WL 2108202, at \*2. Even if filing by the return date were *required*, not just allowed, RIH has good cause for seeking to quash the subpoena now.

Until the Government's April 30 petition in Texas, the Government led RIH to believe that it was satisfied with the pace of production and the parties' ongoing negotiations regarding compliance to date.<sup>4</sup> RIH relied on the Government's conduct to its detriment. RIH received no advance notice of the Government's intention to seek judicial enforcement of the subpoena (much less its intention to seek enforcement in Texas) and was instead led to understand, based on Government counsel's communications, that further negotiations regarding compliance with the subpoena would continue. RIH provided the Government search terms for approval and input months prior; and after an extended delay, the Government re-engaged and asked to schedule a conference to discuss status. *See* Ex. 12. While RIH was attempting to coordinate dates for that conference, the Government secretly filed its enforcement petition in the Northern District of Texas. Only after that filing occurred on April 30 was RIH made aware of any sense of urgency on the Government's part—and even then, the Government did not request expedited or *ex parte*

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<sup>4</sup> The Government's argument that RIH had ten months to seek quashal is disingenuous, Ex. 6 at 6, where it led RIH to believe that it was acting in good faith, was satisfied with the pace of production and discussions, and was not likely to seek full compliance without warning via a motion to compel in a far-flung district. In other words, RIH relied on the Government's conduct up until April 30 to conclude that a motion to quash was not yet necessary to protect the paramount interests at stake in this matter.

relief from that district court. Yet, that is what the Government received, with the Texas court granting the exact relief sought before RIH had an opportunity to respond.

Despite the Government's nearly 10-month delay in seeking judicial enforcement, and the absence of any mention of any need for immediate or emergency relief, the Northern District of Texas dropped its enforcement order on a dime. RIH had no opportunity to respond to the Government's petition. And given the Northern District of Texas's impending deadline of May 14 for full compliance with the subpoena, RIH has necessarily had to spend time since that order assessing avenues for redress from the erroneous (and untested) order. Despite RIH's reservations of rights in its dealings with the Government, including its ability to seek judicial recourse from enforcement, *see supra* n.2, RIH did not even receive the bare minimum due process that should be given any litigant in an enforcement proceeding.

Meanwhile, the Child Advocate initiated proceedings in this Court to adjudicate the lawfulness of the Government's subpoena to RIH.<sup>5</sup> RIH seeks to quash the subpoena in full to protect its patients' privacy and avoid the threatened sanctions and contempt for non-compliance with the Northern District of Texas's May 14 deadline. The timing of RIH's motion to quash is the direct result of the Government's bait and switch actions—representing an intent to continue negotiations about the subpoena's scope while secretly filing and securing an enforcement from an improper jurisdiction with an impossible response date. RIH has therefore shown the necessary good cause for any delay in its filing.

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<sup>5</sup> As the Child Advocate explains, the Administrative Procedure Act also provides a cause of action against the Government that would support the requested relief. *See* ECF No. 812 at 8-9.

## **II. The subpoena is unlawful.**

### **A. Criminal liability under the FDCA does not justify the subpoena.**

Through HIPAA, Congress delegated the Executive Branch the authority to issue subpoenas in connection with an investigation of a “Federal health care offense.” 18 U.S.C. § 3486(a)(1)(A)(i)(I). The Government attempts to justify its subpoena based on its authority to investigate violations of the FDCA; specifically, its prohibition on misbranding. *See, e.g.*, 21 U.S.C. § 352(f). That claimed statutory authority does not exist, laying bare the Government’s true purpose: harassing medical facilities and patients until they submit to its policy aims and cease gender-affirming care.

In its response to the Child Advocate, the Government says it seeks RIH records on two grounds. First, the Government claims that RIH may itself have “engaged in conduct that implicates the FDCA.” ECF No. 9 at 14. Second, the Government claims that RIH could be a witness to the FDCA violations of manufacturers and distributors. *Id.* Neither theory supports the subpoena. Indeed, both suffer from the same flaw because, at bottom, they seek to attach criminal liability to the lawful practice of off-label prescribing. No court has ever stretched the FDCA this far.

The FDCA ensures that manufacturers and distributors are accountable for drug labeling and the representations they make about drug products placed into the stream of commerce. FDCA misbranding liability attaches only to those who manufacture and distribute a drug. *See* 21 U.S.C. § 352(f); *In re Subpoena No. 25-1431-014*, 810 F. Supp. 3d 555, 569 (E.D. Pa. 2025).

As to physicians, in contrast, the FDCA protects rather than constrains their authority to prescribe drugs for various uses as they find appropriate in the exercise of their medical judgment. The FDCA explicitly states that it is not to “be construed” as “limit[ing] or interfer[ing] with the

authority of a health care practitioner to prescribe or administer *any* legally marketed device to a patient for *any* condition or disease within a legitimate health care practitioner-patient relationship.” 21 U.S.C. § 396 (emphasis added).

The Government accepts—at least superficially—that the FDCA does not regulate (let alone criminally prohibit) “merely writing prescriptions for off-label use,” in accordance with widespread Circuit precedent. ECF No. 9 at 19; *see, e.g., In re Celexa & Lexapro Mktg. & Sales Pracs. Litig.*, 915 F.3d 1, 5 (1st Cir. 2019); *In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 240 (3d Cir. 2012); *Ass’n of Am. Physicians & Surgeons v. FDA*, 13 F.4th 531, 544 (6th Cir. 2021); *Wash. Legal Found. v. Henney*, 202 F.3d 331, 332-33 (D.C. Cir. 2000). Yet the Government’s various apparent theories of criminal “misbranding” liability depend entirely on that lawful conduct. And while the Government may not admit directly that it seeks to punish providers for off-label use (because it must concede the FDCA does not do so), its implausible statutory contortions and focus on hospitals, rather than manufacturers or distributors, support no other conclusion.

Consider the Government’s purported justification for requiring patient records. The Government says that by comparing patient records to billing information, it can uncover “patterns of misbranding or false billing.” ECF No. 9 at 15. The Government then says that a mismatch between treatments and codes “suggest[s] concealment of off-label use of puberty blockers and hormones.” *Id.* But the FDCA does not prohibit “off-label use of puberty blockers and hormones.” So the Government seeks evidence of concealment of conduct that it admits is not a crime.

Although the Government facially asserts that it may view RIH as only a witness to off-label promotion by others, that assertion is belied by the Government’s repeated categorization of RIH as an entity that can be held criminally liable in relation to off-label prescribing by RIH

providers. That is, in the Government’s view, off-label use can still be dispositive as to whether RIH committed a criminal violation of the FDCA.

For instance, the Government asserts in its enforcement petition that a drug is “misbranded” in violation of the FDCA if “its labeling does not bear adequate directions for its intended use.” Ex. 3 at 2. The term “intended use” comes from a regulation stating that “intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer.” 21 C.F.R. § 201.128. The Government’s apparent theory is that if a drug’s “intended use” changes as it makes its way from manufacturer to patient—*i.e.*, when a physician prescribes it for “off-label use”—then the drug becomes “misbranded,” because its original labeling will no longer match the physician’s “intended use” in prescribing it. *See* Ex 3 at 2, 4. In this way, the Government contends, a physician’s “off-label use” violates the FDCA because it changes the drug’s “intended use.” *Id.* at 4. But that is not the law. Prescription drugs are *exempt* from the adequate directions for use requirement if they are prescribed by a licensed provider through a prescription. 21 U.S.C. § 353(b)(2).<sup>6</sup> Consequently, the misbranding theory proffered by the Government—criminal liability predicated on a lack of “adequate directions for use”—can apply only to those who manufacture and distribute a drug. It does not apply to hospitals or physicians.

The Government does everything it can to get at the off-label use of drugs (but only those associated with gender-affirming care), short of saying that the mere act of off-label use itself is

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<sup>6</sup> “Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of section 352 of this title, except paragraphs (a), (i)(2) and (3), (k), and (l), and the packaging requirements of paragraphs (g), (h), and (p), if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber, and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription.” 21 U.S.C. § 353(b)(2).



illegal. Notably, the Government would impose criminal liability on physicians for their participation in a chain of distribution that facilitates off-label prescribing. But off-label prescribing by physicians is lawful; it is logically impossible for a physician to facilitate, conspire, or aid and abet an FDCA violation predicated on the physician's own lawful ability to prescribe a drug off-label. The Government's labyrinthine FDCA theories collapse on themselves.

Indeed, because the FDCA is a strict-liability statute that imposes criminal liability for misbranding "without any proof of criminal intent" or "direct participation," under the Government's reading of the statute, anyone in the supply chain or peripherally involved could be held criminally liable for a doctor's lawful off-label prescription, based solely on the doctor's supposed lawful decision to prescribe a drug off-label. *See* 21 U.S.C. §§ 331, 333(a)(1). As explained above, that theory misreads the FDCA and cannot justify the Government's investigation into RIH.

At base, the Government asserts sweeping authority to criminally punish anyone in the stream of distribution for "misbranding" based solely on whether a physician has engaged in the lawful practice of off-label prescribing. The Government also erroneously treats medical care providers as "distributors" and says that they participate in "misbranding" through off-label prescribing or by dispensing drugs to patients. *See* Proposed Amicus Br. of Rhode Island, *et al.*, ECF No. 10-1 at 14. The Government claims that RIH may have itself "violated the FDCA by causing distribution of misbranded drugs"—even though, through its filing, the Government recognizes that RIH prescribes drugs and does not distribute them.<sup>7</sup> ECF No. 9 at 17, 28. But no matter how the Government attempts to contort the law it cannot escape first principles: a doctor's

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<sup>7</sup> The Government's assertion here is inconsistent with its initial statement that RIH had not engaged in any wrongdoing. Ex. 9 ¶ 8.

prescription of drugs to a patient for purposes of providing medical care to that patient is not drug distribution, it is the lawful practice of medicine and does not violate the FDCA.

**B. The Government has no proper purpose.**

When the Government’s purported statutory rationale falls out of the picture, its true motive is clear. The Government seeks to use its subpoena not to investigate crime or uncover wrongdoing, but to burden entities that have engaged in gender-affirming care—in hopes that those like RIH that maintain active programs will suspend them and to punish those that have previously provided such care.<sup>8</sup>

The only off-label use that appears to matter to the Government is that which relates to gender-affirming care because the Government seeks to stifle that care. That motive is indisputable (and undisputed). The records developed in litigation over these identical subpoenas issued to hospitals and clinics around the country could provide “no clearer evidence of improper purpose”; in declarations filed in cases just like this one, Government officials repeatedly attest that the Administration “seeks to end the very practice it claims to be merely investigating.” *See QueerDoc, PLLC v. U.S. Dep’t of Just.*, 807 F. Supp. 3d 1295, 1303 (W.D. Wash. 2025), *appeal pending*, No. 25-7384 (9th Cir.).

The White House prioritized these care-related investigations at the starting line of President Trump’s second Term. In April 2025, the White House issued a press release for National Child Abuse Prevention Month that claimed that gender-affirming care—including hormone therapy and puberty blockers—constitutes “one of the most prevalent forms of child abuse facing our country today.” Then-Attorney General Bondi issued a memorandum directing the

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<sup>8</sup> *See* The White House, *President Trump Promised to End Sexual Mutilation – And He Delivered* (July 25, 2025) (celebrating the announcement that Yale New Haven Health and Connecticut Children’s Medical Center are “ending their so-called ‘gender-affirming care services’”).

Department of Justice to investigate potential violations by manufacturers and distributors of puberty blockers and sex hormones. Shortly after, RIH, along with more than twenty other hospitals and clinics, received a subpoena investigating its gender-affirming care practices.

These statements are directly relevant to the Court's inquiry in evaluating whether the subpoena was issued for a congressionally authorized purpose or an improper one. They reflect the Government's plain aims in pursuing this investigation. Indeed, because the subpoena was issued at the Attorney General's direction (ECF No. 1-2), "[n]o clearer evidence of improper purpose could exist than the Government's own repeated declarations that it seeks to end the very practice it claims to be merely investigating." *QueerDoc*, 807 F. Supp. 3d at 1303.

Given this context and the faulty statutory basis on which the Government rests its investigation, district courts around the country have held that the Government lacks authority to enforce identical subpoenas, and that it issued those subpoenas for an improper purpose. *See QueerDoc*, 807 F. Supp. 3d at 1303-04; *In re Admin. Subpoena*, No. 25-1431-019, 800 F. Supp. 3d 229, 239 (D. Mass. 2025), *appeal pending*, No. 26-1093 (1st Cir.); *In re Subpoena Duces Tecum No. 25-1431-016*, No. 25-mc-41, 2025 WL 3562151, at \*12-13 (W.D. Wash. Sept. 3, 2025); *see In re Dep't of Just. Admin. Subpoena No. 25-1431-030*, No. 25-mc-63, 2026 WL 33398, at \*1, 11 (D. Colo. Jan. 5, 2026) (Report & Recommendation).

And when those district courts began siding against the Government on that very basis, the Government appears to have devised a new plan: shift its investigation away from its D.C. hub—specifically, almost 2,000 miles away from both RIH and the officials who have been conducting the investigation of it—to a specific division of a judicial district in Texas. Once there, the Government secured its first victory in its pursuit of the most sensitive patient records of a group of vulnerable children, without RIH having uttered a word in opposition. This cannot stand.

**C. The subpoena is unduly broad and burdensome.**

Along with serving an improper purpose, the subpoena is also overly broad and burdensome. *See In re Children's Nat'l Hosp.*, No.: 1:25-cv-03780-JRR, 2026 WL 160792, at \*8 (D. Md. Jan. 21, 2026); *QueerDoc*, 807 F. Supp. 3d at 1304; *In re Administrative Subpoena No. 25-1431-019*, 800 F. Supp. 3d at 238. Even if the Government were properly investigating potential FDCA violations (it is not), the subpoena is overbroad in its intrusive request for adolescent patient records, including sensitive personally identifiable information (names, dates of birth, social security numbers, home addresses, medical diagnoses, and other sensitive medical documents).

These requests are not relevant to any inquiry into potential FDCA violations. And the burdens they impose on RIH and its patients cannot possibly justify any benefit to the Government's investigation. *In re 2025 UPMC Subpoena, No. 2:25-MC-01069-CB*, 2026 WL 570419, at \*2 (W.D. Pa. Mar. 2, 2026) (initially limiting the subpoena to strike requests that pertain to patient records but then quashing the entire subpoena as invalid); *In re Subpoena No. 25-1431-014*, 810 F. Supp. 3d at 578-81. Concluding otherwise would again stretch the FDCA's text beyond recognition. As noted, that statute regulates "the introduction, labeling, and distribution of drugs in interstate commerce; it does not govern how physicians diagnose patients, obtain consent, document treatment, or communicate" with patients. *In re Subpoena No. 25-1431-014*, 810 F. Supp. 3d at 579; *see In re Children's Nat'l Hosp.*, 2026 WL 160792, at \*8.

In addition, contrary to the Government's assertion in its effectively *ex parte* petition before the Northern District of Texas, producing these records absolutely "threatens to unduly disrupt or seriously hinder" RIH's operations. *Contra* Ex. 3 at 11 (citation omitted). The Government faults RIH for not "present[ing] to the Department any evidence demonstrating that compliance with the

subpoena would cause such a disruption or hindrance.” *Id.* But RIH does not have to present that evidence “to the Department”—the time and place to present such evidence would have been to *the Northern District of Texas*, in opposition to the petition for enforcement. And RIH now takes the opportunity to do so here. The attached declarations detail the burden on RIH and its employees, including the threats that the ordered full production would pose to RIH patient relationships at the core of the hospital’s operations. Exs. 9 ¶¶ 11-14, 10 ¶¶ 7-11, 11 ¶¶ 12-14.

As another court in this Circuit has already concluded: the subpoena’s intrusive requests seek “an astonishingly broad array of documents and information that are virtually unlimited in scope.” *In re Admin. Subpoena No. 25-1431-019*, 800 F. Supp. 3d at 238. The scope of the Government’s inquiry dwarfs any investigative benefit it could conceivably receive by focusing only on actors peripherally involved in the misbranding conspiracy that the Government alleges exists. *See id.* The Government “seeks all this while not offering one iota of suspicion” that RIH and similarly situated providers are actually engaging in the promotion of off-label drugs that the FDCA does prohibit. *Id.* Nor does the Government articulate how RIH or its clinicians possibly could engage in that covered conduct in their capacity as prescribers. *Id.* Overbreadth and burden both establish independent bases for this Court to quash the subpoena in full.

### **III. The Northern District of Texas’s order does not prevent relief here.**

In responding to the Child Advocate, the Government attempts to avoid defending its subpoena here by relying on the Texas court’s decision. *See* ECF No. 9. That invalid order has no binding effect and does not control this Court’s assessment of the merits of RIH’s challenge.

#### **A. The first-to-file rule does not apply.**

The Government invokes the first-to-file rule in an effort to avoid this Court’s adjudication of the subpoena. As this Court has already decided, that rule does not apply here. The Texas

litigation is no longer pending in that district court. In fact, it was finished before this action even began. The Northern District of Texas’s decision enforcing the subpoena was—as the Government’s appeals in the First and Ninth Circuits reflect—an appealable, final order under 28 U.S.C. § 1291. So, as this Court correctly recognized in denying the Government’s motion to transfer or stay the Child Advocate’s motion to quash, there is no pending district court action to which this Court could defer. *See* ECF No. 8.

Even if the first-to-file rule could apply here, the Court would be well-justified in exercising its discretion to reject it. Courts “may [] decline to apply the first-to-file rule when ‘special circumstances’ warrant giving priority to the second suit.” *EMC Corp. v. Parallel Iron, LLC*, 914 F. Supp. 2d 125, 128 (D. Mass. 2012). Those “special circumstances” include forum shopping, which plainly occurred here. *Id.*

The Government’s forum shopping is obvious. The Government could have filed its enforcement petition in this District, where RIH is located and carries on business. 18 U.S.C. § 3486(c) (jurisdiction in the district where the “subpoenaed person is an inhabitant, or in which he carries on business or may be found”). Or the Government could have filed in the District of Columbia, the central hub of its nationwide investigation, where the relevant DOJ office is located. *Id.* (jurisdiction where “the investigation is carried on”). Instead, the Government chose to file in the Northern District of Texas, where the D.C.-based Government officials who have participated in ongoing conversations with RIH regarding the subpoena do not work, and where RIH itself has no ties. The Government clearly filed there in hopes of finding a more favorable forum. And in doing so, it flouted § 3486(c)’s venue restrictions. Given this improper forum-shopping, and even if the Texas action were ongoing and continuing concurrently with this one, the first-to-file rule would not apply.

**B. The Northern District of Texas proceeding has no preclusive effect.**

Because the Texas litigation has ended, the relevant doctrine for this Court to consider when assessing the effect of the Northern District of Texas's order is preclusion. Preclusion doctrines bar re-litigation, not litigation in the first instance. But a prior judgment has no preclusive effect when the party purportedly bound by it did not, or never had the opportunity to, litigate the issue or claim. *See* Restatement (Second) of Judgments § 28(3) (permitting re-litigation when the party “did not have an adequate opportunity or incentive to obtain a full and fair adjudication in the initial action”).<sup>9</sup> On that basis, the Northern District of Texas's judgment cannot have any preclusive effect here.

RIH had *no* opportunity to litigate in the Northern District of Texas, let alone a full and fair one. Again, that court entered its order granting the Government's petition the same day it was filed, without allowing RIH any opportunity to respond. And it summarily entered the Government's proposed order as drafted without giving RIH any time to submit briefing, present evidence, or otherwise be heard. That procedure deprived RIH of due process, as discussed below and as RIH will demonstrate in its pending appeal in the Fifth Circuit. *See Tex. Keystone, Inc. v. Prime Nat'l Res., Inc.*, 694 F.3d 548, 549, 552, 556 n.5 (5th Cir. 2012) (holding that procedural due process requires “an opportunity to respond in opposition” in administrative-subpoena enforcement proceedings).

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<sup>9</sup> Res judicata bars relitigation of a claim where a court has reached a final judgment on the merits between the parties. *Gonzalez-Pina v. Rodriguez*, 407 F.3d 425, 429 (1st Cir. 2005). Collateral estoppel, or issue preclusion, bars relitigation only where the same issue was actually litigated, determined by a valid and binding final judgment, and essential to that judgment. *Id.* at 430; *Keystone Shipping Co. v. New England Power Co.*, 109 F.3d 46, 51 (1st Cir. 1997). Both share the criterion that a party bound by a prior judgment litigated—or at least had the opportunity to litigate—in the earlier litigation.

Meanwhile, nothing precludes this Court from considering the petition’s enforceability, just as nothing bars RIH from fully litigating the issue for the *first* time. RIH seeks the opportunity to raise its objections to the subpoena in this proceeding, as it was denied that chance in the Northern District of Texas. It should not have to face the threat of contempt and sanctions for violating an order against which it never had the opportunity to even attempt to defend itself.

**C. The Norther District of Texas court’s order is void for lack of due process.**

Finally, the Government maintains in opposition to the Child Advocate’s filing that the Northern District of Texas’s order ties this Court’s hands under the collateral-attack doctrine. ECF No. 9 at 5–6. To be sure, the appellate process is the ordinary avenue for redress of judicial errors. But the collateral-attack doctrine does not protect all judgments. When a judgment is “void,” it can be challenged collaterally as well as on appeal. *See Celotex Corp. v. Edwards*, 514 U.S. 300, 306 (1995) (recognizing exception to collateral-attack rule for orders with only a “frivolous pretense to validity”). That rule applies here.

The Texas order is void because the Northern District of Texas violated due process by entering it.<sup>10</sup> *See Taylor v. Sturgell*, 553 U.S. 880, 884-85 (2008); *see also Ashe v. McNamara*, 355 F.2d 277, 282 (1st Cir. 1965) (when a prior proceeding was constitutionally defective, the later decisionmaker had a duty comparable to that of “a court empowered to entertain a collateral attack” to treat the resulting sentence as void); 11 Wright & Miller, *Federal Practice & Procedure* § 2862 (judgment is “void” when “the court that rendered it . . . acted in a manner inconsistent with due

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<sup>10</sup> The judgment may also be void on other grounds, including due to jurisdictional flaws. *See* 11 Wright & Miller, *Federal Practice & Procedure* § 2862 (3d ed. 2026) (judgment is “void” if a court “lacked jurisdiction of the subject matter or of the parties”); 18 U.S.C. § 3486(c) (permitting enforcement of an administrative subpoena in “any court of the United States within the jurisdiction of which the investigation is carried on or of which the subpoenaed person is an inhabitant, or in which he carries on business or may be found”); *see also U.S. Int’l Trade Comm’n v. ASAT, Inc.*, 411 F.3d 245, 248 (D.C. Cir. 2005).



process of law”). That court discarded due process entirely when it entered its enforcement order without affording RIH any “opportunity to respond.” *Castille v. Port Arthur ISD*, 168 F.4th 240, 252 (5th Cir. 2026) (quoting *Cleveland Bd. of Educ. v. Loudermill*, 470 U.S. 532, 546 (1985)).

The precedent that binds that district court makes its due process violation abundantly clear. In *Sandsend Financial Consultants, Ltd. v. Federal Home Loan Bank Board*, the Fifth Circuit held that, by ruling on a motion to quash an administrative subpoena before receiving a response, the district court “robb[ed]” the subpoena’s issuer of “its right to be heard.” 878 F.2d 875, 881 (5th Cir. 1989). And again, in *Texas Keystone, Inc. v. Prime Natural Resources, Inc.*, that court held that the district court violated procedural due process by granting a motion to quash the day after it was filed, without giving the issuer “an opportunity to respond in opposition.” 694 F.3d 549, 552, 556 n.5. Under these precedents and others, due process requires that a subpoena’s recipient receive the opportunity to be heard *before* enforcement. See *Okla. Press Publ’g. Co. v. Walling*, 327 U.S. 186, 195 (1946) (describing administrative subpoenas enforced “pursuant to orders of court authorized by law and made after adequate opportunity to present objections”); *U.S. v. Sturm, Ruger & Co.*, 84 F.3d at 3 (“[T]he subject of an administrative subpoena has an opportunity to challenge the subpoena before yielding the information.”); *Shotkin v. Nelson*, 146 F.2d 402, 405 (10th Cir. 1944) (“[T]he trial court should have given . . . notice and an opportunity to be heard before the enforcement order was issued.”).

The Court’s refusal to give RIH an opportunity to respond in opposition to the Government’s petition is a due-process error that justifies a collateral challenge to its order. An order entered in violation of foundational due process protections cannot bind the party denied the right to be heard. And it certainly cannot preclude that party from seeking to assert its interests elsewhere. This Court may thus validly decide RIH’s motion.

## CONCLUSION

For these reasons, the Court should quash the subpoena in full by **Thursday, May 14, 2026.**

Dated: May 9, 2026

Respectfully submitted,

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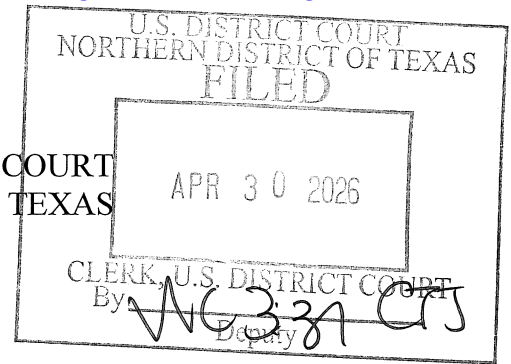
**CERTIFICATE OF SERVICE**

I hereby certify that on May 9, 2026, I electronically filed the foregoing document with the Clerk of Court using the CM/ECF system, which will send notification of such filing to all counsel of record registered to receive electronic notice in this matter.

Dated: May 9, 2026

/s/ Stacey P. Nakasian

IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF TEXAS  
FORT WORTH DIVISION



IN THE MATTER OF  
ADMINISTRATIVE SUBPOENA 25-  
1431-032

NO **4-26MC-006-0**

**GOVERNMENT'S PETITION FOR ENFORCEMENT OF ADMINISTRATIVE  
SUBPOENA PURSUANT TO 18 U.S.C. § 3486(c)**

On July 3, 2025, the Department of Justice (Department) served a Health Insurance Portability and Accountability Act (HIPAA) administrative subpoena on Rhode Island Hospital (RI Hospital), with a return date of Thursday, August 7, 2025. The subpoena is within the Department's statutory authority to investigate violations of the Federal Food, Drug, and Cosmetic Act (FDCA), the information requested is relevant to the Department's inquiry, and the subpoena is neither overbroad nor unduly burdensome. Yet, over ten months after service, RI Hospital has not complied with the subpoena. In fact, it has produced only one six-page document in response to the Department's fifteen document requests. The Department therefore moves for an order compelling RI Hospital to fully comply.

**BACKGROUND**

This case concerns an investigation into the distribution of certain prescription drugs to minors with gender dysphoria and related disorders—intended uses for which the Food

and Drug Administration (FDA) has determined neither their safety nor effectiveness. These include drugs that suppress the production of sex hormones to delay puberty (commonly referred to as “puberty blockers”) and cross-sex hormones meant to induce physical changes to alter the child’s secondary sexual characteristics to resemble those typically seen in the opposite sex and less like the individual’s biological sex. *See United States v. Skrametti*, 605 U.S. 495 503-04 (2025) (describing use of these drugs). Although these drugs are approved by FDA for some uses, the agency has not determined that any of these drugs are safe or effective for the treatment of gender dysphoria, nor has FDA approved them for the treatment of gender dysphoria or any other psychiatric disorder.

A primary focus of the Department’s investigation—which is being carried out in the Northern District of Texas, *see* 18 U.S.C. § 3486(c)—is potential violations of the FDCA. The FDCA generally prohibits “misbranding” a drug. *See* 21 U.S.C. § 352; *id.* § 331(a)-(c), (k). A drug may be misbranded if, among other things, its labeling is false or misleading, *id.* § 352(a), or if its labeling does not bear adequate directions for its intended use, *id.* § 352(f)(1). “Intended use” means the “objective intent of the persons legally responsible for the labeling of an article (or their representatives).” 21 C.F.R. § 201.128. Such intent “may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives.” *Id.* And the “intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer.” *Id.* If, for example, a seller “intends an article for different uses than those intended by the person from whom he or she received the article,” then the “seller is required to supply adequate labeling in accordance with the new intended uses.” *Id.*

Under the FDCA, drug labeling is broadly defined to include any “written, printed, or graphic matter . . . accompanying” the drug. 21 U.S.C. § 321(m). The term “accompanying” includes materials that are separate from but related to the drug and any material that supplements, explains, or is designed for use with the drug. *See id.* § 321(m); 21 C.F.R. § 1.3(a); *Kordel v. United States*, 335 U.S. 345, 349-50 (1948); *United States v. Urbuteit*, 335 U.S. 355, 357 (1948); *United States v. 47 Bottles, More or Less, Etc.*, 320 F.2d 564, 569 (3d Cir. 1963). Labeling can include promotional materials, advertisements, brochures, flyers, instruction sheets, posters, and similar materials.

Misdemeanor violations of the FDCA are punishable on a strict liability basis, without any proof of criminal intent. *See* 21 U.S.C. § 331, § 333(a)(1); *United States v. Wiesenfeld Warehouse Co.*, 376 U.S. 86, 91 (1964). For example, if a drug manufacturer or other person causes the distribution of an approved drug for an unapproved use, the manufacturer or other person could be charged with misbranding the drug by distributing it with labeling that lacks adequate directions for its intended uses. 21 U.S.C. §§ 331(a)-(c), (k), 352(f)(1). Where a violator has an intent to defraud or mislead, an FDCA violation may be punishable as a felony. *Id.* § 333(a)(2).

In the investigation of a “Federal health care offense,” HIPAA permits the Attorney General to issue a subpoena. 18 U.S.C. § 3486(a)(1)(A)(i)(I). A federal health care offense includes a “violation of, or a criminal conspiracy to violate” 21 U.S.C. § 331, “if the violation or conspiracy relates to a health care benefit program,” 18 U.S.C. § 24(a)(2). And a “health care benefit program” is “any public or private plan or contract, affecting commerce, under which any medical benefit, item, or service is provided to any individual,

and includes any individual or entity who is providing a medical benefit, item, or service for which payment may be made under the plan or contract.” *Id.* § 24(b).

Because public or private insurance plans were presented with claims related to off-label use of puberty blockers and cross-sex hormones, such a violation of the FDCA could constitute a “federal health care offense” as defined by 18 U.S.C. § 24. *See* Ex. A (Hsiao Decl.). Accordingly, the Assistant Attorney General signed a HIPAA subpoena, which was served on RI Hospital on July 11, 2025. *See* Ex. B (Subpoena); Ex. C (Proof of Service). After the review of claims data and billing records, the Department is investigating whether RI Hospital patients have received misbranded drugs. Hsiao Decl. ¶ 36. Also, the Department has reason to suspect that RI Hospital employees might have engaged in false billing concerning patients suffering from gender dysphoria. *Id.* ¶¶ 37–38. Medical records from other pediatric hospitals suggest that RI Hospital is not unique in this regard. *Id.* ¶ 39. The return date specified in the subpoena was reasonable and was set as August 7, 2025. Hsiao Decl. ¶ 46; Ex. B. But, to date, RI Hospital remains non-complaint. Indeed, over the past ten months, RI Hospital has provided only *one* document totaling *six* pages. Hsiao Decl. ¶ 46.<sup>1</sup>

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<sup>1</sup> Partial compliance does not foreclose a petition to enforce. *See, e.g., Equal Emp. Opportunity Comm’n v. MTV Food, Inc.*, No. 23-MC-278, 2024 WL 4164507, at \*1 (S.D.N.Y. Sept. 12, 2024) (granting petition to enforce in the absence of full compliance); *United States v. Sysco Corp.*, 25 F. Supp. 2d 684, 685 (D. Md. 1998) (granting a motion to enforce after the recipient “only partially complied with the subpoenas”); *see also United States v. Transocean Deepwater Drilling, Inc.*, 767 F.3d 485, 488 (5th Cir. 2014) (affirming judgment granting petition to enforce after the recipient “failed to comply fully” with the subpoenas”).

## **ARGUMENT**

The Fifth Circuit “has consistently recognized the summary nature of administrative subpoena enforcement proceedings,” *Burlington N. R. Co. v. Off. of Inspector Gen., R.R. Ret. Bd.*, 983 F.2d 631, 637 (5th Cir. 1993), and said that “when reviewing an administrative subpoena, the court plays a strictly limited role,” *Sandsend Fin. Consultants, Ltd. v. Fed. Home Loan Bank Bd.*, 878 F.2d 875, 879 (5th Cir. 1989). The requirements for enforcement are “minimal”—“courts will enforce an administrative subpoena if: (1) the subpoena is within the statutory authority of the agency; (2) the information sought is reasonably relevant to the inquiry; and (3) the demand is not unreasonably broad or burdensome.” *Burlington N. R. Co.*, 983 F.2d at 637-38; *see United States v. Zadeh*, 820 F.3d 746, 756 (5th Cir. 2016) (applying this standard “in the context of an administrative subpoena seeking an individual’s medical records”). Here, all three prerequisites are met. *See United States v. Transocean Deepwater Drilling, Inc.*, 767 F.3d 485, 489 (5th Cir. 2014) (explaining that the Government has the “minimal” burden of making a “prima facie case”).<sup>2</sup>

### **I. The Subpoena Is Within the Department’s Statutory Authority.**

An agency’s subpoena must be enforced unless it is “plainly incompetent or irrelevant to any lawful purpose.” *Fed. Election Comm’n v. Lance*, 617 F.2d 365, 368 (5th Cir. 1980) (quoting *Endicott Johnson Corp. v. Perkins*, 317 U.S. 501, 509 (1943)); *accord*,

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<sup>2</sup> To the extent the Fifth Circuit also requires a showing that “the required administrative steps have been followed,” *Burlington N. R. Co.*, 983 F.2d at 637 n.2, the Department meets that requirement too. The subpoena was signed by the Assistant Attorney General, properly served on RI Hospital, and calls for the production of nonprivileged documents relevant to the investigation within 500 miles of RI Hospital. *See Subpoena*; 18 U.S.C. § 3486(a)(3).



*e.g.*, *United States v. Sturm, Ruger & Co.*, 84 F.3d 1, 5–6 (1st Cir. 1996) (“As long as the agency’s assertion of authority is not obviously apocryphal, a procedurally sound subpoena must be enforced.”).

The subpoena at issue is plainly relevant to a lawful purpose. Congress has expressly authorized the Attorney General to issue subpoenas to investigate potential “Federal health care offense[s],” including qualifying offenses in the FDCA. 18 U.S.C. § 3486(a)(1)(A)(i)(I). The subpoena in this case was issued for that very purpose, as described above. The subpoena to RI Hospital will assist the Department’s efforts to “investigate Federal health care offenses,” Subpoena at 1. Accordingly, the subpoena issued to RI Hospital plainly comes within the Department’s statutory authority. *See Burlington N. R. Co.*, 983 F.2d at 637-38.

## **II. The Subpoena Seeks Documents Reasonably Relevant to the Investigation.**

The subpoena seeks information “reasonably relevant” to the Department’s investigation in two different ways. *Burlington N. R. Co.*, 983 F.2d at 638; *see FTC v. Texaco, Inc.*, 555 F.2d 862, 874 (D.C. Cir. 1977) (en banc) (“[I]n the pre-complaint stage, . . . the relevance of the agency’s subpoena requests may be measured only against the general purposes of its investigation.”). First, the Department seeks records to determine whether RI Hospital itself may have engaged in conduct that implicates the FDCA. Second, the Department seeks records from RI Hospital to determine whether manufacturers and distributors of the drugs at issue may have violated the FDCA.

In the subpoena are 15 Requests, all of which extend from January 1, 2020, to the present. *See* Subpoena at 4, 7-9. The fifteen requests can be broadly broken down into four

main categories: (1) requests related to personnel and corporate oversight (Request 1); (2) requests related to billing, coding, and reimbursement practices (Requests 2–6); (3) requests related to the practice’s relationships with drug manufacturers, distributors, and pharmacies (Requests 7–10); and (4) requests regarding clinical practices and drug safety (Requests 11–15). As the Hsiao Declaration explains, all 15 requests—and all four categories—are reasonably related to identifying evidence that could be used to shed light on the Government’s lawful investigation. *See* Hsiao Decl. ¶¶ 40–44.

Request 1 seeks information to identify who had authority to direct prescribing, billing, or marketing practices to determine liability. Subpoena at 7. Under strict liability doctrines, including the responsible corporate officer doctrine, officers and responsible personnel can be held criminally liable for FDCA violations even without direct participation. Hsiao Decl. ¶ 41. Personnel files also show financial incentives, disciplinary history, and/or training which can establish knowledge and intent. *Id.*

Requests 2 through 6 (regarding billing, coding, and reimbursement practices) are necessary to determine whether the clinic disguised treatment for gender-related mental disorders as another, physical illness (e.g., endocrine disorder) to disguise or hide potential FDCA violations and potentially secure health care benefit program reimbursements through fraud. Subpoena at 7-8; Hsiao Decl. ¶ 42. Such practices are especially important to demonstrate an “intent to defraud or mislead” under 21 U.S.C. § 333(a)(2) if the clinic misrepresented the intended use of the drugs. Hsiao Decl. ¶ 42. Moreover, training materials and internal discussions can reveal whether improper coding was a deliberate strategy. *Id.*

Requests 7 through 10 (relating to relationships with drug manufacturers, distributors, and pharmacies) seek evidence of an intent to market or promote drugs for unapproved uses in violation of the FDCA. Subpoena at 8; Hsiao Decl. ¶ 43. Communications between pharmaceutical sales representatives and prescribing physicians can provide evidence of off-label promotion, which would be relevant to an FDCA prosecution for misbranding drugs. *See, e.g.*, Information at 4-5, ¶¶ 12-18, *United States v. Cephalon, Inc.*, No. 2:08-cr-598 (E.D. Pa. Sep. 29, 2008), Dkt. No. 1; Press Release, U.S. Dep’t of Just., *Eli Lilly and Company to Pay U.S. \$36 Million Relating to Off-Label Promotion* (Dec. 21, 2005), <https://perma.cc/2Y64-FUK5> (announcing guilty plea of drug manufacturer involving illegal off-label promotion and highlighting evidence that the defendant “[e]ncourag[ed] sales representatives . . . to send unsolicited medical letters to promote the drug for an unapproved use to doctors”).<sup>3</sup> If RI Hospital, or one of its affiliated health care providers, received promotional materials, “scientific exchange information,” or payments to encourage prescribing of puberty blockers or cross-sex hormones, such information would support a FDCA theory (including conspiracy) involving the illegal misbranding of drugs and distribution of misbranded drugs or unapproved new drugs.

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<sup>3</sup> There are many similar examples. *See, e.g.*, Press Release, U.S. Dep’t of Just., *Genzyme Corporation to Pay \$32.5 Million to Resolve Criminal Liability Relating to Seprafilm* (Sep. 3, 2015), <https://perma.cc/P7AT-MUVT> (highlighting evidence that manufacturer encouraged off-label uses by distributing promotional materials citing a misleading scientific study); *United States v. Endo Pharms., Inc.*, No. 1:14-CR-66 (N.D.N.Y. Feb. 21, 2014), Dkt. 2 (deferred prosecution agreement regarding drug manufacturer’s off-label promotion of drug, highlighting evidence that manufacturer distributed a misleading scientific study and promoted off-label uses at educational presentations for physicians); Press Release, U.S. Dep’t of Just., *Wyeth Pharmaceutical Agrees to Pay \$490.9 Million for Marketing the Prescription Drug Rapamune for Unapproved Uses* (July 30, 2013), <https://archives.fbi.gov/archives/oklahomacity/press-releases/2013/wyeth-pharmaceutical-agrees-to-pay-490.9-million-for-marketing-the-prescription-drug-rapamune-for-unapproved-uses> (highlighting evidence that manufacturer paid bonuses to incentivize off-label sales).

Hsiao Decl. ¶ 43. Similarly, information regarding financial arrangements (consulting agreements, sponsorships, speaking honoraria) may suggest improper influence to reinforce a showing of an intent to misbrand the drugs, including with an intent to defraud or mislead. *Id.*

Requests 11 through 15 (relating to patient-level clinical practices and drug safety) will permit the United States to evaluate the scope of prescribing (including the number and age range of patients treated), and consistency of diagnoses. Subpoena at 8-9; *see* Hsiao Decl. ¶ 44. Such information also establishes the scope of interstate distribution and the scale of potential FDCA violations. Hsiao Decl. ¶ 44. Linking each patient's clinical record to corresponding billing and insurance claims can demonstrate whether diagnoses were miscoded, which can prove fraudulent intent. *Id.* Documentation of clinical justification, informed consent, and disclosure of unapproved use is key to assessing whether the clinic (and/or potential co-conspirators) concealed or downplayed risks associated with the unapproved use of these drugs. *Id.* Absence or minimization of such warnings could establish the intent to mislead. *Id.* Patient charts also typically capture adverse outcomes, side effects, and complications of drug use. *Id.* By reviewing multiple patient records, the investigative team may reveal systemic use of the same masking codes and fraudulent informed consent documents. *Id.* This enables investigators to distinguish between mere errors and an institutionalized practice.

Providing patient records including patient identities can also provide essential investigative leads. *Id.* Parents may be witnesses about what disclosures were made. Patients (depending on age and circumstances) may provide information about the

informed consent process, side effects, or other false or misleading information about the drugs conveyed during treatment. *Id.* Health benefit programs tied to identified patients could provide additional information including claim records, creating a reinforced evidentiary record. *Id.* In sum, without this information, the Government cannot fully determine the scope of the violations, identify patterns of misbranding or fraudulent billing, or assess whether the conduct was undertaken with intent to defraud or mislead, as required for felony liability under 21 U.S.C. § 333(a)(2).

For these reasons, the information sought is “reasonably relevant,” *Morton Salt*, 338 U.S. at 652, to the “general purposes of the agency’s investigation,” *Dow Chem. Co. v. Allen*, 672 F.2d 1262, 1268 (7th Cir. 1982) (alteration adopted and quotation omitted)). Accordingly, the Court should enforce the subpoena. *See United States v. Zadeh*, No. 4:14-CV-105-O, 2015 WL 418090, at \*7 (N.D. Tex. Jan. 31, 2015) (O’Connor, J.) (“For the purposes of administrative subpoenas, the notion of relevancy is a broad one, and so long as the material requested touches a matter under investigation, the subpoena will survive a challenge that it is not relevant.”).

### **III. The Subpoena’s Demands Are Reasonable.**

Finally, the subpoena’s demands are “not unreasonably broad or burdensome.” *Burlington N. R. Co.*, 983 F.2d at 638.

Because the Department’s “inquiry” is “a relatively broad one,” “the permissible scope of materials that [can] reasonably be sought [is] necessarily equally broad.” *McPhaul v. United States*, 364 U.S. 372, 382 (1960); *see Securities & Exch. Comm’n v. McGoff*, 647 F.2d 185, 192-93 (D.C. Cir. 1981) (“We agree that the demands are broad.

But the nature of the inquiry precludes a trim list of requests.” (footnote omitted)). And the Department’s requests are not atypical in this area. *See, e.g., In re Subpoena Duces Tecum*, 228 F.3d 341, 350 (4th Cir. 2000) (“[I]f Bailey had treated 15,000 patients over a period of seven years and all of them were reimbursed on claims he submitted, a suspicion of fraud on these claims would justify a review of Bailey’s documentation of services to these patients, of the claims submitted on their behalf, and of the reimbursements collected.”); *cf. Zadeh*, 820 F.3d at 758 (agreeing that “the subpoena was not unduly broad or burdensome albeit implicating privacy interests of patients whose records are produced but are not parties to this litigation”). The Department’s requests are also limited in “time and scope,” asking only for records since January 1, 2020. *Zadeh*, 2015 WL 418090 at \*5.

The subpoena is also not unduly burdensome. The information sought is relevant and not otherwise available, meaning that the subpoena is “unreasonably burdensome” only if “compliance threatens to unduly disrupt or seriously hinder normal operations of a business.” *F.T.C. v. Jim Walter Corp.*, 651 F.2d 251, 258 (5th Cir. 1981) (quotation omitted), *abrogated on other grounds as recognized by Republic of Panama v. BCCI Holdings (Luxembourg) S.A.*, 119 F.3d 935, 943 (11th Cir. 1997). RI Hospital has not presented to the Department any evidence demonstrating that compliance with the subpoena would cause such a disruption or hindrance. *Id.* (“The subpoenaed party may not merely utter the claim; it must persuade us.”). Notably, other hospitals to whom the

Department issued similar subpoenas have complied with the subpoena without any disruption or hindrance. The Court therefore should enforce the subpoena in its entirety.<sup>4</sup>

### **CONCLUSION**

The Government respectfully requests an order from the Court compelling Rhode Island Hospital to comply with the subpoena.

Dated: April 30, 2026

Respectfully submitted,

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<sup>4</sup> The Fifth Circuit has provided that “[c]ourts will not enforce an administrative subpoena . . . if the subpoena was issued for an improper purpose, such as harassment.” *Burlington N. R. Co.*, 983 F.2d at 638. The Department acknowledges that a handful of mistaken district judges have found “improper purpose” given the administration’s policy positions and priorities. *See, e.g., QueerDoc, PLLC v. U.S. Dep’t of Just.*, 807 F. Supp. 3d 1295, 1303-04 (W.D. Wash. 2025); *In re Admin. Subpoena No. 25-1431-019*, 800 F. Supp. 3d 229, 239 (D. Mass. 2025). These decisions are wrong and currently on appeal. There is no basis in law or logic to conclude that an administration’s policy positions prevent it from enforcing existing federal law. And, given that existing federal law, even if an administration’s policy views might be treated as an improper purpose, this is no reason to deny the Department’s motion. Denial is only warranted when the sole purpose behind a subpoena’s issuance is an improper one. *See Donaldson v. United States*, 400 U.S. 517, 533 (1971) (inquiring whether “the sole objective of the investigation is to” impermissibly use a civil subpoena to “obtain evidence for use in a criminal prosecution”); *Lynn v. Biderman*, 536 F.2d 820, 826 (9th Cir. 1976) (“It is not . . . a ground to deny enforcement of a subpoena that it is being employed for a wrongful purpose if there is also a legitimate purpose for the subpoena.”).



/s/ Patrick R. Runkle

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**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF TEXAS  
FORT WORTH DIVISION**

**IN THE MATTER OF  
ADMINISTRATIVE SUBPOENA 25-  
1431-032**

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**Civil Action No. 4:26-MC-00006-O**

**ORDER**

Before the Court is the government's petition to enforce compliance with the above captioned subpoena (ECF No. 1). The Court finds that the subpoena was issued within the Department of Justice's statutory authority, the subpoena seeks documents reasonably relevant to the investigation, and the subpoena's demands are reasonable. The Court further finds that the witness, Rhode Island Hospital, was served with the subpoena on July 3, 2025, and has failed to fully comply with the subpoena by providing records to the government on or before the original due date of August 7, 2025, or the date of the Government's filing of its petition to enforce of April 30, 2026. The Court further finds that the witness has neither filed a motion to quash nor shown just cause for noncompliance. The Court determines that the government's petition to enforce should be and is hereby **GRANTED**.

Therefore, the Court hereby **ORDERS** the following:

1. That the witness, Rhode Island Hospital, provide all records responsive to each request in the subpoena within 14 days of the entry of this order; and

2. That failure to fully comply with the subpoena or show just cause for continued noncompliance may result in sanctions up to and including this Court holding the witness in contempt.

**SO ORDERED** on this **30th day** of **April, 2026**.

  
\_\_\_\_\_  
Reed O'Connor  
CHIEF UNITED STATES DISTRICT JUDGE

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF TEXAS  
FORT WORTH DIVISION**

IN THE MATTER OF  
ADMINISTRATIVE SUBPOENA 25-  
1431-032

Civil Action No. 4:26-MC-0006-O

**EMERGENCY MOTION FOR STAY PENDING APPEAL**

Rhode Island Hospital moves the Court for a stay pending appeal of its April 30, 2026, Order enforcing the above-captioned administrative subpoena. RIH requests that this Court rule on its motion for a stay pending appeal by **Friday, May 8, 2026, at 12:00 p.m.** Counsel for RIH conferred with counsel for the Government, who stated that the Government opposes the requested relief.

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## INTRODUCTION

Last Thursday evening, without any notice to Rhode Island Hospital, the Government petitioned this Court to enforce a ten-month-old administrative subpoena. That same day, without giving RIH any opportunity to respond, this Court entered an Order enforcing the subpoena and giving RIH only 14 days to comply. That Order is legally and procedurally unsound. RIH has promptly appealed it. Given that RIH is likely to succeed on appeal and will suffer irreparable harm if the Order is enforced in the meantime, this Court should stay its Order for the duration of the appeal.

## BACKGROUND

On July 9, 2025, the Department of Justice served an administrative subpoena on RIH at its principal place of business in Providence, Rhode Island. *See* Pet. Ex. B, ECF No. 1-2, at 2, 4;<sup>1</sup> Pet. Ex. C, ECF No. 1-3, at 2 (proof of service).<sup>2</sup> The Government set a return date of August 7 and requested production at the office of the DOJ's Consumer Protection Branch (now the Enforcement and Affirmative Litigation Branch), which is located in Washington, D.C. ECF No. 1-2 at 2. The Government purported to issue the subpoena under the Health Insurance Portability and Accountability Act (HIPAA), 18 U.S.C. § 3486, to "investigate Federal health care offenses." ECF No. 1-2 at 2.

The subpoena contains fifteen requests for documents, including three that explicitly call for sensitive patient information:

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<sup>1</sup> Citations to public record pages are to the page numbers that appear in the header generated by the Court's ECF system.

<sup>2</sup> The Court's Order mistakenly states that service occurred on July 3, 2025. *See* Order, ECF No. 2, at 1. The Government's petition mistakenly (and contradictorily) states that service occurred on July 3, 2025, and on July 11, 2025. *See* Pet., ECF No. 1, at 1, 4. The Government's own exhibit reflects that service occurred on July 9, 2025. *See* ECF No. 1-3 at 2.



11. Documents sufficient to identify each patient (by name, date of birth, social security number, address, and parent/guardian information) who was prescribed puberty blockers or hormone therapy.
12. For each such patient identified in Subpoena specification 11, *supra*, documents relating to the clinical indications, diagnoses, or assessments that formed the basis for prescribing puberty blockers or hormone therapy.
13. All documents relating to informed consent, patient intake, and parent or guardian authorization for minor patients identified in Subpoena specification 11, *supra*, including any disclosures about off-label use (*i.e.*, uses not approved by the United States Food and Drug Administration) and potential risks.

*Id.* at 9.

Following service of the subpoena, counsel for RIH and the Government began to discuss RIH's compliance efforts. Ex. 1 at App. 6, ¶ 8 ; *see* Declaration of Lisa K. Hsiao ("Hsiao Decl."), ECF No. 1-1, at 20, ¶ 46. Counsel for the Government informed Glenn Friedemann, Associate General Counsel for Brown Health (the parent organization of RIH), that the Government did not believe that RIH had engaged in any criminal wrongdoing. Ex. 1 at App. 6, ¶ 8. The Government also "communicated that it would be willing to receive documents responsive to the subpoena past the return date." Hsiao Decl. at 20, ¶ 46.

On January 29, 2026, RIH, through undersigned counsel Eric Olshan, notified the Government that it was prepared to produce additional responsive documents in the weeks to come, and that it would first send the Government proposed search terms for review. *See* Ex. 2 at App. 10. RIH sent the Government the proposed search terms on February 4, 2026. *See id.* RIH anticipated making a production upon the Government's confirmation of the search terms, but the Government did not respond, even to confirm receipt. *See id.*

RIH did not hear from the Government again until April 28, requesting that counsel "conference this week regarding status." *Id.* Although counsel for RIH responded the next day,

the next communication RIH received from the Government was not about scheduling; rather, it was an email sent after the close of business at 6:10 p.m. Eastern Time on Thursday, April 30, informing RIH that the Government had filed a petition to enforce the subpoena in this Court. *Id.* at 9. The Government did not confer with RIH in advance of the filing of the petition.

The Court granted the petition the same day it was filed and executed the Government's proposed order, requiring that RIH "provide all records responsive to each request in the subpoena within 14 days of the entry of this order"—by May 14, 2026—and stating that "failure to fully comply with the subpoena or show just cause for continued noncompliance may result in sanctions up to and including this Court holding [RIH] in contempt." *See* Order, ECF No. 2, at 1-2. RIH received no opportunity to respond to the petition.

The Court's Order enforcing the administrative subpoena is an appealable final judgment. *See Cobbledick v. United States*, 309 U.S. 323, 330 (1940); 28 U.S.C. § 1291. RIH seeks a stay of the Court's Order pending resolution of its appeal to the Fifth Circuit.

### **LEGAL STANDARD**

In deciding whether to enter a stay pending appeal, courts consider "(1) whether the stay applicant has made a strong showing that he or she is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies." *Veasy v. Perry*, 769 F.3d 890, 892 (5th Cir. 2014) (quoting *Nken v. Holder*, 559 U.S. 418, 426 (2009)). "The first two factors of the traditional standard are the most critical." *Id.* (quoting *Nken*, 559 U.S. at 434).

## ARGUMENT

This Court denied RIH due process and erroneously ordered enforcement of a legally improper subpoena. RIH is appealing this decision. While the appeal is pending, this Court should stay its Order. The Court's refusal to give RIH an opportunity to respond in opposition to the Government's petition is reversible error, and the subpoena is otherwise legally unsound. The remaining stay factors also support a stay.

### **I. Rhode Island Hospital is likely to succeed on the merits.**

RIH has multiple grounds for its appeal on which it is highly likely to succeed. Because the Court refused to allow adversarial testing of the Government's petition, the Fifth Circuit is likely to reverse. That error also meant that RIH had no chance to raise its other arguments against the subpoena's enforcement, which buttress its likely success on appeal.

#### **A. The Court erroneously denied Rhode Island Hospital an opportunity to respond to the petition.**

This Court impermissibly denied RIH due process by issuing its Order without allowing RIH to be heard. Procedural due process requires that a recipient of an administrative subpoena have both "notice and an opportunity to respond" before enforcement. *Castille v. Port Arthur ISD*, 168 F.4th 240, 252 (5th Cir. 2026) (quoting *Cleveland Bd. of Educ. v. Loudermill*, 470 U.S. 532, 546 (1985)). RIH received neither. It will thus prevail in its appeal.

The Fifth Circuit has repeatedly confirmed this due process requirement in administrative subpoena enforcement proceedings. In *Sandsend Financial Consultants, Ltd. v. Federal Home Loan Bank Board*, the Fifth Circuit held that, by ruling on a motion to quash an administrative subpoena before receiving a response, the district court "robb[ed]" the subpoena's issuer of "its right to be heard." 878 F.2d 875, 881 (5th Cir. 1989). And again, in *Texas Keystone, Inc. v. Prime Natural Resources, Inc.*, the Fifth Circuit held that the district court violated procedural due process

by granting a motion to quash the day after it was filed, without giving the issuer “an opportunity to respond in opposition.” 694 F.3d 548, 549, 552, 556 n.5 (5th Cir. 2012).

This right to respond applies in proceedings to quash administrative subpoenas and to enforce them alike. “An administrative subpoena is not self-executing”; enforcing one thus requires “judicial review and enforcement.” *United States v. Sturm, Ruger & Co., Inc.*, 84 F.3d 1, 3 (1st Cir. 1996). Indeed, the “enforcement process for administrative subpoenas” is designed to give the “subpoenaed party . . . an opportunity to be heard during the enforcement proceeding itself.” *In re Anthony Marano Co.*, 51 F.4th 722, 734 (7th Cir. 2022). More precisely, due process requires the opportunity to be heard *before* enforcement. See *Okla. Press Pub. Co. v. Walling*, 327 U.S. 186, 195 (1946) (describing administrative subpoenas enforced “pursuant to orders of court authorized by law and made after adequate opportunity to present objections”); *Sturm*, 84 F.3d at 3 (“[T]he subject of an administrative subpoena has an opportunity to challenge the subpoena before yielding the information.”); *Shotkin v. Nelson*, 146 F.2d 402, 405 (10th Cir. 1944) (“[T]he trial court should have given . . . notice and an opportunity to be heard before the enforcement order was issued.”).

This right to respond is critical, not just to a participant’s due process rights, but also to ensure adversarial “testing [of] the subpoena in federal court.” *First Choice Women’s Res. Ctrs., Inc. v. Davenport*, No. 24-781, slip. op. at 18 (U.S. Apr. 29, 2026) (internal quotation marks omitted). The standards for judicial enforcement of administrative subpoenas confirm the need for a fulsome adversarial process. Again, these subpoenas are not self-enforcing—a court must decide whether to enforce one by evaluating whether “(1) the subpoena is within the statutory authority of the agency; (2) the information sought is reasonably relevant to the inquiry; and (3) the demand is not unreasonably broad or burdensome.” *United States v. Transocean Deepwater*

*Drilling, Inc.*, 767 F.3d 485, 488 (5th Cir. 2014). “The Government bears the initial burden to show that these criteria have been met,” and “[o]nce the Government has made a prima facie case, *the burden of going forward shifts to the party opposing the subpoenas.*” *Id.* at 489 (emphasis added). That burden-shifting cannot happen if the opposing party has no chance to respond. Nor can a court adequately assess the controlling factors without hearing from both sides.

The Court’s refusal to give RIH an opportunity to respond in opposition to the Government’s petition is a procedural error that will result in reversal on appeal. *See Tex. Keystone*, 694 F.3d at 555; *Sandsend*, 878 F.2d at 881 (explaining that this “procedural error[] . . . would be dispositive”).

**B. Venue is improper in this District.**

The Court’s Order is also erroneous because the Government improperly filed its petition in this District. This Court is not the proper venue to adjudicate the Government’s petition. Title 18 U.S.C. § 3486(c) permits enforcement of an administrative subpoena in “any court of the United States within the jurisdiction of which the investigation is carried on or of which the subpoenaed person is an inhabitant, or in which he carries on business or may be found.” The Government’s petition conclusorily asserts that the investigation “is being carried out in the Northern District of Texas.”<sup>3</sup> Pet., ECF No. 1, at 2. The lack of evidentiary support for that assertion is fatal to the Government’s enforcement effort in this District.

Neither the Government’s petition nor its accompanying exhibits identify any nexus between its investigation and this District. The administrative subpoena demanded production at the Consumer Protection Branch office in Washington, D.C. ECF No. 1-2 at 1. The DOJ officials

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<sup>3</sup> The Government does not assert any other basis for venue, and RIH’s principal place of business is in Rhode Island. *See* ECF No. 1-2 at 4.

who have communicated with RIH about the subpoena have done so from that office in Washington, D.C. *See* ECF No. 1-3 at 3; *see also* Pet. 13; Ex. 2 at App. 9-10. The Government has not identified any target of the investigation based in the Northern District of Texas. RIH itself has no ties there. And the declaration of Lisa Hsiao, Acting Director of EALB, makes no mention of any investigative activities in the Northern District of Texas, as opposed to Washington D.C., where the EALB's office is located. *See generally* Hsiao Decl.; *see also* Pet. 13; Ex. 3 at App. 12.

The record contains no support for the Government's claim that its investigation is being carried on in the Northern District of Texas, let alone that it is being carried out here "to any substantial degree." *FTC v. Jim Walter Corp.*, 651 F.2d 251, 254 (5th Cir. 1981), *abrogated on other grounds as recognized by Republic of Pan. v. BCCI Holdings (Luxembourg) S.A.*, 119 F.3d 935, 943 (11th Cir. 1997).<sup>4</sup> Nothing supports enforcement in a district with such a tenuous and unproven connection to the underlying investigation.<sup>5</sup> Indeed, even when an investigation is "nationwide in scope," venue cannot be simply based on the Government's "choice of any forum it like[s]." *NLRB v. Cooper Tire & Robber Co.*, 438 F.3d 1198, 1200, 1202 (D.C. Cir. 2006). Venue then lies in the "command center" or "hub" of the investigation—here, the entirety of the investigative contact between RIH and the Government prior to the petition's filing makes clear that that would be the District of Columbia, not the Northern District of Texas. *Id.* at 1202; *see*

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<sup>4</sup> The Fifth Circuit has expressed "grave misgivings" regarding the assertion of personal jurisdiction over a party that lacks minimum contacts with the forum. *Bellaire Gen. Hosp. v. Blue Cross Blue Shield of Mich.*, 97 F.3d 822, 826 (5th Cir. 1996). RIH's lack of contacts with the Northern District of Texas further shows that the Government's "choice of forum" is "unreasonable" for purposes of the venue analysis. *Jim Walter*, 651 F.2d at 254; *NLRB v. Cooper Tire & Robber Co.*, 438 F.3d 1198, 1202 (D.C. Cir. 2006) (also assessing reasonableness).

<sup>5</sup> *See NLRB v. Line*, 50 F.3d 311, 313-14 (5th Cir. 1995) (district where the underlying labor practices under investigation occurred); *Jim Walter*, 651 F.2d at 254 (district where "[m]any of the building and marketing practices under investigation" occurred and where the agency managed the investigation).

*FEC v. Comm. to Elect Lyndon La Rouche*, 613 F.2d 849, 857 (D.C. Cir. 1979); *see also* *Jim Walter*, 651 F.2d at 254 (considering where the agency “managed [its] investigation”).

**C. The subpoena is unlawful.**

Even if venue were proper in this District, this Court should have denied the Government’s petition.

To start, the subpoena lacks a congressionally authorized and legitimate investigatory purpose. *See Transocean*, 767 F.3d at 488-89. Through HIPAA, Congress delegated the authority to issue subpoenas in connection with an investigation of a “Federal health care offense.” 18 U.S.C. § 3486(a)(1)(A)(i)(I). The Government’s authority is limited to seeking items that are “relevant to the investigation” of such an offense. *Id.* § 3486(a)(1)(B)(i).

The Government bases the subpoena on its authority to investigate violations of the Food, Drug, and Cosmetic Act (FDCA). *See* Pet. 2. The Government’s proffered theory of criminal FDCA liability is that “off-label use of puberty blockers and cross-sex hormones” is “a violation of the FDCA.” *Id.* at 4. That theory is wrong.

The Government arrives at that liability theory through a series of convoluted steps that lack support in the FDCA’s text. The Government asserts that a drug is “misbranded” if “its labeling does not bear adequate directions for its intended use.” *Id.* at 2. The term “intended use” comes from a regulation of the Food and Drug Administration, which states that the “intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer.” 21 C.F.R. § 201.128. The Government’s apparent theory is that if a drug’s “intended use” changes as it makes its way from manufacturer to patient—including even when a physician prescribes the drug for an “off-label use”—then the drug becomes “misbranded” in violation of the FDCA,

because its labeling will no longer match the “intended use” of the physician. *See* Pet. 2, 4. In this respect, the Government asserts, “off-label use” by physicians violates the FDCA. *Id.* at 4.

The Government’s theory is contrary to the statute and cannot stand. The federal government lacks authority to regulate the practice of medicine, including a physician’s off-label prescription of drugs, under the FDCA. The FDCA’s text explicitly confirms that. *See* 21 U.S.C. § 396 (“Nothing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship.”). As is well recognized, the FDCA “regulates how manufacturers label medical devices and drugs”—not “the practice of medicine.” *Conger v. Danek Med., Inc.*, 27 F. Supp. 2d 717, 720 (N.D. Tex. 1998). “Physicians routinely use products for ‘off-label’ purposes,” and “[s]uch off-label use is appropriate, rational, and accepted medical practice and can be of great value.” *Id.*; *see In re Celexa & Lexapro Mktg. & Sales Pracs. Litig.*, 915 F.3d 1, 5 (1st Cir. 2019); *In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 240 (3d Cir. 2012); *Wash. Legal Found. v. Henney*, 202 F.3d 331, 332-33 (D.C. Cir. 2000).<sup>6</sup>

Because physicians can lawfully prescribe drugs off-label, the concept of “intended use” (and misbranding predicated on intended use) is not applicable to physicians’ treatment decisions. Misbranding liability predicated on the lack of “adequate directions for use” attaches only to those who manufacture and distribute a drug. 21 U.S.C. § 352(f); *see In re Subpoena No. 25-1431-014*, 810 F. Supp. 3d 555, 568 (E.D. Pa. 2025). The FDCA thus ensures that manufacturers and distributors are accountable for drug labeling and the representations they make about drug

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<sup>6</sup> *See also Understanding Unapproved Use of Approved Drugs “Off Label,”* U.S. Food & Drug Admin. (Feb. 5, 2018), <https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label>.



products placed into the stream of commerce. But misbranding liability does not attach to physicians based on off-label prescribing. *See Ass’n of Am. Physicians & Surgeons v. FDA*, 13 F.4th 531, 544 (6th Cir. 2021) (“The Act regulates drug distribution; it does not bar doctors from prescribing an approved drug (like hydroxychloroquine) for an off-label use (like COVID-19).”).

The Government’s theory would turn the FDCA on its head by imposing criminal liability based on off-label prescribing—a lawful practice. The Government seeks to impose criminal liability on everyone up the supply chain from a doctor who engages in off-label prescribing (*e.g.*, drug manufacturers and distributors) based on the doctor’s own lawful decision to prescribe a drug off-label. And because the FDCA is a strict-liability statute that imposes criminal liability for misbranding “without any proof of criminal intent” or “direct participation,” Pet. 3 (citing 21 U.S.C. §§ 331, 333(a)(1)); *id.* at 7, under the Government’s reading of the statute, anyone in the supply chain or peripherally involved could be held criminally liable for a doctor’s subsequent and lawful off-label prescription. That theory badly misreads the FDCA and cannot support the Government’s investigation into RIH or any other entity.

In short, the Government asserts sweeping authority to criminally punish anyone in the stream of distribution for “misbranding” solely based on whether a physician has intended to engage in the lawful practice of off-label prescribing.<sup>7</sup> No such authority exists, and the Government therefore lacks statutory authority to investigate that lawful practice.

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<sup>7</sup> In addition to targeting “manufacturers and distributors,” the Government states without elaboration that it “seeks records to determine whether RI Hospital itself may have engaged in conduct that implicates the FDCA.” Pet. 6. Under the FDA’s own understanding of the Act, however, “misbranding” through false or misleading “labeling” occurs in materials “supplied by the manufacturer, packer, or distributor of the drug”—not the downstream provider. *See* 21 C.F.R. § 202.1(l)(2); *In re Subpoena No. 25-1431-014*, 810 F. Supp. 3d at 567, 586. This position is also inconsistent with representations made by Government counsel to RIH. Ex. 1 at App. 6, ¶ 8.

Given the faulty statutory basis on which the Government rests its investigation, district courts around the country have correctly held that the Government lacks authority to enforce identical subpoenas, and in turn has issued those subpoenas for an improper purpose. *See In re Child. 's Nat'l Hosp.*, No. 25-cv-3780, 2026 WL 160792, at \*8 (D. Md. Jan. 21, 2026); *QueerDoc, PLLC v. U.S. Dep't of Just.*, 807 F. Supp. 3d 1295, 1302-03 (W.D. Wash. 2025), *appeal pending*, No. 25-7384 (9th Cir.); *In re Administrative Subpoena No. 25-1431-019*, 800 F. Supp. 3d 229, 237-38 (D. Mass. 2025), *appeal pending*, No. 26-1093 (1st Cir.); *In re Subpoena Duces Tecum No. 25-1431-016*, No. 25-mc-41, 2025 WL 3562151, at \*8-12 (W.D. Wash. Sept. 3, 2025). RIH is likely to succeed in demonstrating the same.

RIH is also likely to succeed in showing that, as multiple courts have concluded, the subpoena is overly broad and burdensome. *See In re Child. 's Nat'l Hosp.*, 2026 WL 160792, at \*8; *QueerDoc*, 807 F. Supp. 3d at 1304; *In re Administrative Subpoena No. 25-1431-019*, 800 F. Supp. 3d at 238. Even if the Government were properly investigating potential FDCA violations (it is not), the subpoena overreaches with its intrusive request for patient records that include sensitive personally identifiable information (names, dates of birth, Social Security numbers, and home addresses), medical diagnoses, and other sensitive medical documents. *See* ECF No. 1-2 at 9-10 (requests 11-13).

These requests for patient records are not relevant to any inquiry into potential FDCA violations, even under the Government's untenable reading of the law. *See In re 2025 UPMC Subpoena*, No. 25-mc-1069, 2025 WL 3724705, at \*3 (W.D. Pa. Dec. 24, 2025) (limiting subpoena to strike requests that pertain to patient records); *In re Subpoena No. 25-1431-014*, 810 F. Supp. 3d at 578-81 (same). Concluding otherwise would again stretch the FDCA's text beyond recognition. The FDCA regulates "the introduction, labeling, and distribution of drugs in interstate

commerce; it does not govern how physicians diagnose patients, obtain consent, document treatment, or communicate” with patients. *In re Subpoena No. 25-1431-014*, 810 F. Supp. 3d at 579; see *In re Child. ’s Nat’l Hosp.*, 2026 WL 160792, at \*8.

In addition, contrary to the Government’s assertion, producing these records “threatens to unduly disrupt or seriously hinder” RIH’s operations. *Contra* Pet. 11 (citation omitted). The Government faults RIH for not “present[ing] to the Department any evidence demonstrating that compliance with the subpoena would cause such a disruption or hindrance.” *Id.* But RIH does not have to present that evidence “to the Department”—the time and place to present such evidence would have been to *this Court*, in opposition to the petition for enforcement. The attached declarations detail the burden on RIH and its employees, including the threats that the ordered full production would pose to RIH patient relationships at the core of the hospital’s operations. Ex. 1 at App. 6-7, ¶¶ 10-13; Ex. 4 at App. 15-16, ¶¶ 4-11; Ex. 5 at App. 20, ¶¶ 12-14.

In sum, RIH’s appeal will raise multiple challenges to the subpoena’s enforcement and is likely to succeed on the merits of those challenges. This factor weighs strongly in favor of a stay.

## **II. Rhode Island Hospital will suffer irreparable harm without a stay.**

The irreparable constitutional and monetary injuries RIH will suffer without a stay also support the requested relief.

For one, if RIH must comply with the subpoena with no opportunity to respond, this litigation will become moot without RIH ever receiving an opportunity to be heard. Its resulting deprivation of its due process right would constitute irreparable harm. See *Book People, Inc. v. Wong*, 91 F.4th 318, 340-41 (5th Cir. 2024).

Moreover, compliance with a subpoena later held unlawful produces irreparable monetary harm. See *id.* at 341. Any production will involve collecting information from disparate platforms

and then processing, de-duplicating, anonymizing, and reviewing these documents for privilege and confidentiality. This process takes time and costs money—upwards of millions of dollars. Ex. 1 at App. 6-7, ¶¶ 10-13. Any such compliance will thus cause expenses that RIH can never recoup. *Id.* at 7, ¶ 13.

RIH will also suffer irreparable harm to its patient relationships without a stay. Among other things, RIH will have to turn over highly sensitive medical records that contain comprehensive psychosocial evaluations and deeply personal disclosures by children about their bodies, sexuality, trauma, family dynamics, self-harm, mental-health history, and cognitive and emotional functioning. Ex. 5 at 19, ¶¶ 6-8.

Patients rely on RIH to maintain the confidentiality of exactly this information. *Id.* at 20, ¶ 11; Ex. 4 at 14-15, ¶¶ 5-6. But as the Supreme Court recently confirmed, disclosure pursuant to a subpoena produces real risks of that “information becoming public,” even when the Government promises confidentiality (and even if a court enters a protective order). *First Choice*, slip op. at 21. The information “might wind up in the public domain due to a hack or leak,” creating a “risk of harassment and reprisals” of RIH employees and patients. *Id.* Forced compliance thus threatens irreparable harm to those patients and, in turn, their relationships with their providers at RIH and RIH’s overall operations.

Indeed, just as a subpoena “is enough to discourage reasonable individuals from associating,” it can also discourage patients from consulting their medical providers and seeking the medical care they need. *Id.*; see Ex. 4 at App. 15, ¶¶ 8-9; Ex. 5 at 20, ¶ 12. Enforcement of this subpoena therefore risks irreparable harm to RIH’s ability to provide sound medical treatment by intruding upon its private records. See *Harbor Healthcare Sys., L.P. v. United States*, 5 F.4th

593, 600 (5th Cir. 2021) (“The government’s ongoing intrusion on . . . privacy constitutes an irreparable injury.”). This factor also warrants a stay.

### **III. The public interest and balance of equities favor a stay.**

Finally, the last two factors—the harm to the opposing party and the public interest—weigh heavily in favor of a stay. These two factors “merge when the Government is the opposing party.” *Nken*, 556 U.S. at 435. Any potential harm to the Government from a stay would be minimal. The Government allowed ten months to pass before seeking to enforce its subpoena without warning. Up to the filing of the enforcement petition, the Government communicated no objection to delayed production. The Government did not seek immediate or emergency relief in its petition and has identified no basis for urgency. Meanwhile, RIH will retain and protect responsive documents. Ex. 1 at App. 7, ¶ 14. As a result, the additional time needed to remedy the Court’s due process violation and address the unlawful subpoena will not substantially prejudice the Government’s investigation.

The privacy interests at stake further tip the balance of the equities away from the Government. *See First Choice*, slip op. at 21. The Government seeks vast swaths of private patient information untethered to its investigative authority. The Government’s purported investigatory interest therefore cannot outweigh the harm to RIH and its patients.

In sum, all four stay factors strongly justify a stay.

## CONCLUSION

For these reasons, the Court should stay the Court's April 30, 2026, order pending resolution of RIH's appeal to the Fifth Circuit.<sup>8</sup>

Dated: May 6, 2026

Respectfully submitted,

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<sup>8</sup> Should the Court decline to enter a full stay pending appeal, RIH requests that the Court enter a temporary administrative stay pending the Fifth Circuit's decision on RIH's motion for a stay pending appeal, which RIH will file in the Fifth Circuit if this Court denies the requested stay. *See Garcia v. Posada*, No. 24-cv-360, 2024 WL 4415280, at \*1 (N.D. Tex. Apr. 9, 2024) (entering an administrative stay of one week to permit sufficient time for review on appeal).

### CERTIFICATE OF CONFERENCE

On May 3 and May 4, 2026, counsel for Rhode Island Hospital, Eric Olshan, corresponded by email with counsel of record for the Government (Ross Goldstein, Patrick Runkle, Scott Dahlquist, and Ethan Womble) regarding this Motion for Stay Pending Appeal. The Government does not consent to the requested relief, and the parties therefore could not reach agreement. Accordingly, pursuant to Local Rule 7.1(b), the undersigned states that this motion is opposed.

Dated: May 6, 2026

Respectfully submitted,

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### CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing Emergency Motion for Stay Pending Appeal was filed electronically with the clerk of court via ECF, which will provide electronic service on all counsel of record.

Dated: May 6, 2026

Respectfully submitted,

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*Attorneys for Rhode Island Hospital*



**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF TEXAS  
FORT WORTH DIVISION**

IN THE MATTER OF  
ADMINISTRATIVE SUBPOENA 25-  
1431-032

Civil Action No. 4:26-MC-0006-O

**[PROPOSED] ORDER**

Before this Court is Rhode Island Hospital's Emergency Motion for Stay Pending Appeal (ECF No. 7). Upon consideration of the Motion, the Court determines that Rhode Island Hospital's Emergency Motion for Stay Pending Appeal should be and is **GRANTED**.

Therefore, the Court **ORDERS** that its Order dated April 30, 2026 (ECF No. 2) is **STAYED** pending resolution of the appeal.

**SO ORDERED** on this \_\_\_\_ day of May, 2026.

---

**Reed O'Connor**  
**UNITED STATES CHIEF DISTRICT JUDGE**

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF TEXAS  
FORT WORTH DIVISION**

IN THE MATTER OF  
ADMINISTRATIVE SUBPOENA 25-  
1431-032

Civil Action No. 4:26-MC-0006-O

**APPENDIX IN SUPPORT OF EMERGENCY MOTION FOR STAY PENDING APPEAL**

| <b>Exhibit No.</b> | <b>Description</b>                                                | <b>Appendix No.</b> |
|--------------------|-------------------------------------------------------------------|---------------------|
| 1                  | Declaration of Glenn R. Friedemann, Esq.                          | App. 4 – App. 7     |
| 2                  | Email Exchange Related to Administrative Subpoena                 | App. 8 – App. 10    |
| 3                  | Location of Enforcement & Affirmative Litigation<br>Branch Office | App. 11 – App. 12   |
| 4                  | Declaration of Dr. Phyllis Dennerly, M.D.                         | App. 13 – App. 16   |
| 5                  | Declaration of Dr. Abigail Donaldson, M.D.                        | App. 17 – App 21    |

Dated: May 6, 2026

Respectfully submitted,

/s/ Mindy M. Sauter

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**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that a true and correct copy of the Appendix in Support of Emergency Motion for Stay Pending Appeal was filed electronically with the clerk of court via ECF, which will provide electronic service on all counsel of record.

Dated: May 6, 2026

/s/ Mindy M. Sauter  
Mindy M. Sauter

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF TEXAS  
FORT WORTH DIVISION**

IN THE MATTER OF  
ADMINISTRATIVE SUBPOENA 25-  
1431-032

Civil Action No. 4:26-MC-0006-O

**DECLARATION OF GLENN R. FRIEDEMANN, ESQ.**

I, Glenn R. Friedemann, declare as follows:

1. I am the Associate General Counsel in the Office of the General Counsel for Brown University Health (“Brown Health”). I have been in this role for 20 years. In this role, I have supervised matters related to the Health Insurance Portability and Accountability Act Subpoena No. 25-1431-032 (“the Subpoena”) issued to Rhode Island Hospital (“RIH”).

2. Brown Health is a not-for-profit health system based in Providence, Rhode Island. Brown Health is organized as a Rhode Island nonprofit corporation (IRS 501(c)(3)) and has been domiciled in the state of Rhode Island since its formation. Brown Health is the parent organization of RIH.

3. Brown Health’s corporate offices are located at 15 Lasalle Sq., Providence, Rhode Island, 02903.

4. RIH’s principal place of business is 593 Eddy Street, Providence, RI 02903. The vast majority of RIH’s hospitals, clinics, and patient care sites are located in Rhode Island. RIH has two community hospital affiliates that operate in Fall River, Massachusetts, and Taunton, Massachusetts.

5. All of Brown Health's and RIH's corporate functions—such as legal, communications, human resources, and finance operations—are carried out from Providence, Rhode Island.

6. RIH provides gender-affirming care through the Gender and Sexuality Program at Hasbro Children's Hospital, which is the pediatric division of RIH. Hasbro Children's Hospital primary place of business is 593 Eddy St, Providence, RI 02903.

7. On July 9, 2025, RIH was served with the Subpoena by the Department of Justice. The Subpoena included request for production with a return date of August 7, 2025, at the Department of Justice's office in Washington, D.C.

8. On July 9, 2025, counsel for the Government contacted me by phone about the Subpoena. On that call, counsel for the Government informed me that it did not believe that RIH had engaged in any criminal wrongdoing.

9. The Court's April 30, 2026, Order requires compliance with the Subpoena within a 14-day period, by May 14, 2026.

10. Full compliance with the Subpoena by May 14 is not possible. The data is not hosted in a manner that can be easily collected or reviewed. The data must be collected from disparate platforms (including legacy platforms) and hard copy sources, processed, de-duplicated, and reviewed for privilege and confidentiality. This process alone will take several months.

11. Moreover, many of the custodians whose documents are required are actively practicing medical providers who care for patients daily. Every hour they spend identifying documents, reviewing materials, meeting with counsel, and engaging in other activities necessary to comply with the Subpoena detracts from their ability to administer patient care.

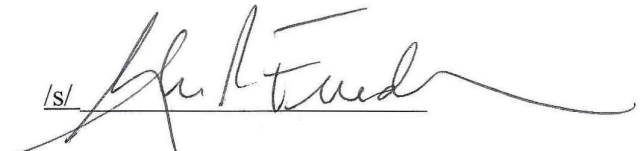
12. Finally, to protect its patients' privacy, RIH is exploring ways in which it can anonymize its patient records before any production. The Department of Justice has agreed to accept anonymized patient records in other litigation involving similar subpoenas. However, the process of anonymization is burdensome and will take several months to complete.

13. Accordingly, full compliance with the Subpoena will carry an irreparable monetary harm of millions of dollars that RIH will be unable to recover if the Subpoena is found invalid.

14. RIH will retain and protect all responsive materials pending a determination in this matter.

15. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: MAY 6, 2026

/s/   
Glenn R. Friedemann, Esq.

**From:** [Gunn, David L \(CRM\)](#)  
**To:** [Narver, Clint](#)  
**Cc:** [Olshan, Eric G.](#); [Shahane, Rhea T.](#); [Dahlquist, Scott B \(CIV\)](#); [Campbell, Jordan C \(CIV\)](#); [Goldstein, Ross \(CRM\)](#); [Runkle, Patrick](#); [Scott, Steven R \(CRM\)](#)  
**Subject:** RE: Rhode Island Hospital / Production of Search Terms  
**Date:** Thursday, April 30, 2026 6:10:21 PM  
**Attachments:** [2026.04.30 - Rhode Island - USA Petition for Enforcement \(FILED\).pdf](#)  
[2026.04.30 - Rhode Island - Ex. A.pdf](#)  
[2026.04.30 - Rhode Island - Ex. B.pdf](#)  
[2026.04.30 - Rhode Island - Ex. C.pdf](#)  
[2026.04.30 - Rhode Island - Proposed Order.pdf](#)

**\*\*EXTERNAL EMAIL; use caution with links and attachments\*\***

Clint,

No immediate need to connect now. I had hoped to talk before we filed the attached. I'm sure we will discuss soon.

Best,  
David

---

**From:** Narver, Clint <[cnarver@mcguirewoods.com](mailto:cnarver@mcguirewoods.com)>  
**Sent:** Wednesday, April 29, 2026 5:11 PM  
**To:** Gunn, David L (CRM) <[David.L.Gunn@usdoj.gov](mailto:David.L.Gunn@usdoj.gov)>; Dahlquist, Scott (CIV) <[Scott.Dahlquist2@usdoj.gov](mailto:Scott.Dahlquist2@usdoj.gov)>  
**Cc:** Olshan, Eric G. <[eolshan@mcguirewoods.com](mailto:eolshan@mcguirewoods.com)>; Shahane, Rhea T. <[rshahane@mcguirewoods.com](mailto:rshahane@mcguirewoods.com)>  
**Subject:** [EXTERNAL] RE: Rhode Island Hospital / Production of Search Terms

David,

We are happy to connect. Would Monday of next week work?

Thanks.

Clint

## Clint Narver

Partner  
McGuireWoods LLP  
T: +1 202 857 2481 | M: +1 703 403 0618  
[cnarver@mcguirewoods.com](mailto:cnarver@mcguirewoods.com)

---

**From:** Gunn, David L (CRM) <[David.L.Gunn@usdoj.gov](mailto:David.L.Gunn@usdoj.gov)>  
**Sent:** Tuesday, April 28, 2026 10:36 AM



**To:** Narver, Clint <[cnarver@mcguirewoods.com](mailto:cnarver@mcguirewoods.com)>; Dahlquist, Scott B (CIV) <[Scott.Dahlquist@usdoj.gov](mailto:Scott.Dahlquist@usdoj.gov)>  
**Cc:** Olshan, Eric G. <[eolshan@mcguirewoods.com](mailto:eolshan@mcguirewoods.com)>; Shahane, Rhea T. <[rshahane@mcguirewoods.com](mailto:rshahane@mcguirewoods.com)>  
**Subject:** RE: Rhode Island Hospital / Production of Search Terms

**\*\*EXTERNAL EMAIL; use caution with links and attachments\*\***

Good morning Clint and Eric,

I've been out a few weeks and hope all is well. In reviewing our production charts, it does not appear we have received any productions from your client in light of your search terms below. (In fact, it appears the one and only production was in August 2025). Can we conference this week regarding status?

---

**From:** Narver, Clint <[cnarver@mcguirewoods.com](mailto:cnarver@mcguirewoods.com)>  
**Sent:** Wednesday, February 4, 2026 10:52 AM  
**To:** Gunn, David L (CRM) <[David.L.Gunn@usdoj.gov](mailto:David.L.Gunn@usdoj.gov)>; Dahlquist, Scott B (CRM) <[Scott.B.Dahlquist@usdoj.gov](mailto:Scott.B.Dahlquist@usdoj.gov)>  
**Cc:** Olshan, Eric G. <[eolshan@mcguirewoods.com](mailto:eolshan@mcguirewoods.com)>; Shahane, Rhea T. <[rshahane@mcguirewoods.com](mailto:rshahane@mcguirewoods.com)>  
**Subject:** [EXTERNAL] Rhode Island Hospital / Production of Search Terms

David and Scott,

Following up on our recent call, please see the attached correspondence.

Best,

Clint

**Clint Narver**

Partner

McGuireWoods LLP

T: +1 202 857 2481 | M: +1 703 403 0618

[cnarver@mcguirewoods.com](mailto:cnarver@mcguirewoods.com)

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# Contact Enforcement & Affirmative Litigation Branch

By U.S. Postal Service:

Enforcement & Affirmative Litigation Branch  
U.S. Department of Justice  
Civil Division  
950 Pennsylvania Avenue, N.W.  
Washington, DC 20530-0001

*Note: Electronic media should not be sent to the Enforcement & Affirmative Litigation Branch using the U.S. Postal Service.*

To make alternate arrangements for the delivery of electronic media or other items, please contact the attorney assigned to your case.

*Updated October 1, 2025*



U.S. Department of Justice  
Civil Division  
950 Pennsylvania Avenue NW  
Washington DC 20530-0001  
  
Civil.Feedback@usdoj.gov



Phone: 202-514-2000

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF TEXAS  
FORT WORTH DIVISION**

IN THE MATTER OF  
ADMINISTRATIVE SUBPOENA 25-  
1431-032

Civil Action No. 4:26-MC-0006-O

**DECLARATION OF DR. PHYLLIS DENNERY, M.D.**

I, Dr. Phyllis Dennery, declare as follows:

1. I am the chief of pediatrics for Brown University Health (“Brown Health”) and pediatrician-in-chief for Rhode Island Hospital. I have served in this role for 11 years.
2. RIH provides comprehensive, multi-disciplinary gender-affirming care in Rhode Island, including through the Gender and Sexuality Program at Hasbro Children’s Hospital, which is the pediatric division of RIH. Hasbro Children’s Hospital’s primary place of business is 593 Eddy St, Providence, RI 02903.
3. I understand that the Department of Justice (the “Government”) issued a subpoena (the “Subpoena”) to RIH in July 2025, and that the Subpoena requests production of medical records and confidential personal information concerning minor patients who received gender-affirming care at RIH.
4. The Government’s request for patient information will have detrimental effects that will impact the entire RIH patient population, their families, and the broader community.
5. The patient-physician relationship is essential in helping people to live healthy, productive lives. The cornerstone of that relationship is confidentiality. Patients seek medical care from RIH with the understanding that RIH will maintain the confidentiality of their highly sensitive and private medical records and personal information.

6. Trust is critical to the patient-physician relationship, especially for minor patients seeking gender-affirming care, who may experience harassment, bullying, and other traumatic events if private information about their care were to be disclosed outside the patient-physician relationship. Trust between a physician, patient, and the patient's family members allows for open, honest, and thorough discussion of a patient's medical conditions, questions, concerns, and potential treatment plans.

7. Production of a patient's medical records, name, Social Security number, and/or home address in response to the Subpoena will result in identification of the patient and disclosure of the patient's most intimate and personal details to the Government. Such disclosure could cause severe emotional distress for the patient and their family and could expose the patient and their family to the possibility of harassment, discrimination, and violence, especially if that information was leaked to the public.

8. Disclosure of minor patients' highly sensitive and private medical could have a chilling effect on these patients, decreasing the likelihood that an already vulnerable class of patients will continue to seek medical care. Moreover, any patients who do continue to seek medical care are likely to be reluctant to disclose sensitive information out of fear of similar government requests.

9. The disclosure of patient records to the Government, accordingly, would undermine the trust that patients have in their doctors, eroding the patient-physician relationship and making it more difficult for medical providers to accurately diagnose and provide effective medical care to patients.

10. The patient's privacy would not be protected by simply redacting the patient's name or address from records, as patients typically disclose other personally identifiable information to

their providers—such as their relationships in school, parents’ occupations, and extra-curricular activities—during their care.

11. For all the reasons above, I believe that disclosure of the patients’ medical records pursuant to the Subpoena would cause irreparable harm to the patients. I also believe that disclosure of patients’ medical records pursuant to the Subpoena will irreparably harm the relationship between patients and medical care providers at RIH, which is based on trust and confidentiality.

12. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: 05/06/2026

  
/s/ \_\_\_\_\_

Dr. Phyllis Dennerly, M.D.

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF TEXAS  
FORT WORTH DIVISION**

IN THE MATTER OF  
ADMINISTRATIVE SUBPOENA 25-  
1431-032

Civil Action No. 4:26-MC-0006-O

**DECLARATION OF DR. ABIGAIL DONALDSON, M.D.**

I, Dr. Abigail Donaldson, declare as follows:

1. I am the division director of the Adolescent Medicine Division of Hasbro Children's at Rhode Island Hospital (RIH). I have served in this role for 5 years.
2. RIH provides comprehensive, multi-disciplinary gender-affirming care in Rhode Island, including through the Gender and Sexuality Program at Hasbro Children's Hospital, which is in the pediatric division of RIH. Hasbro Children's Hospital's primary place of business is 593 Eddy St, Providence, RI 02903.
3. As part of its gender-affirming care services for minors, RIH uses a patient-centered, consent-based process to better understand its patients' gender and sexual health care needs and goals. The range of services it provides includes thorough medical and psychosocial evaluations, initiation and continuation of gender care and hormone therapy, and referrals to other providers and community resources.
4. I understand that the Department of Justice (the "Government") issued a subpoena (the "Subpoena") to RIH in July 2025, and that the Subpoena requests production of medical records and confidential personal information concerning minor patients who received gender-affirming care at RIH.

5. A minor patient who receives gender-affirming care at RIH, along with that patient's parents or guardian, typically meet with one or more RIH providers and collaborating medical professionals over the course of multiple visits. No minor is seen at RIH for gender-affirming care without the knowledge and consent of their parent or legal guardian.

6. Throughout those visits and in related communications, the patient discloses private information about their mental health, sexual health, and fertility; information about relationships in school, parents' occupations, and neighborhood; names of families and friends, family medical history, any involvement with Rhode Island Department of Children, Youth, and Families or other state agencies; and more. All such disclosures are made to RIH for purposes of diagnosing and treating the patient.

7. During the course of the patient's care, the patient, along with the patient's parents, typically discuss a recommended treatment plan and any concerns about the treatment plan privately with the patient's provider. Each patient has a uniquely tailored care plan based on their mental health and medical assessments.

8. If medical treatment is being considered, and especially gender affirming hormone treatment, the assessment process includes a thorough medical and psychosocial evaluation of the patient, which includes (but is not limited to) evaluating the patient's physical function, cognitive abilities, communication skills, emotional functioning, and capacity for decision-making.

9. No medical treatments will begin until after informed consent is obtained from the parent(s)/legal guardian(s) with medical decision-making authority over the minor patient, and the minor patient provides their consent.

10. Part of a patient's medical treatment plan may include taking hormonal medications. A provider, in consultation with the patients and their families, will determine which medications best serve the medical needs of the patient.

11. The patient-physician relationship is sacred and fundamental. Confidentiality is central to that relationship. Patients seek medical care from RIH with the understanding that RIH will keep their highly sensitive and private medical records and personal information confidential.

12. Production of a patient's medical records, name, Social Security number, and/or home address in response to the Subpoena will result in identification of the patient and disclosure of the patient's most intimate and personal details to the Government. Any such disclosure could cause severe emotional distress for the patient and family members and expose the patient and family members to the possibility of bullying, harassment, discrimination, and violence. Moreover, disclosure of this information will curtail the likelihood that an already vulnerable population of individuals will receive the care they need. The chilling effect caused by disclosure of patient records could also extend beyond gender-affirming care treatment to other aspects of medical care, such as mental health treatment, preventative care, emergency care, and other subspecialty care.

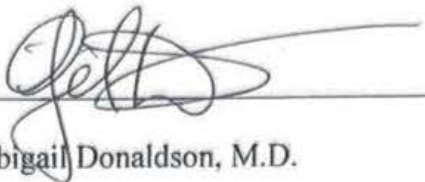
13. The patient's privacy would not be protected by simply redacting the patient's name or address from records, as patients typically disclose other personally identifiable information to their providers—such as their relationships in school, parents' occupations, and extra-curricular activities—during their care.

14. For all the reasons above, I believe that disclosure of the patients' medical records would cause irreparable harm to the patients. I also believe that disclosure of patients' medical records will irreparably harm the relationship between patients and medical care providers at RIH, which is based on trust and confidentiality.



15. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: 5/6/26

/s/   
Dr. Abigail Donaldson, M.D.

IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF TEXAS  
FORT WORTH DIVISION

IN THE MATTER OF  
ADMINISTRATIVE SUBPOENA  
25-1431-032

Case No. 4:26-mc-006-O

**GOVERNMENT’S RESPONSE IN OPPOSITION TO EMERGENCY  
MOTION FOR STAY PENDING APPEAL**

Less than a week ago, but about ten months after the issuance of the subpoena in question, this Court ordered Rhode Island Hospital (“RIH”) to comply with the subpoena. RIH now seeks a stay pending appeal. For the reasons described herein, RIH has not met its burden to demonstrate entitlement to the “extraordinary relief” of a stay, and its motion should be denied.

**BACKGROUND**

On July 3, 2026, the Government issued a subpoena pursuant to its 18 U.S.C. § 3486 subpoena authority to RIH. Doc. 1-2. The subpoena’s return date was August 7, 2025. *Id.* at 1. RIH did not move to quash the subpoena within the statutory deadline to do so. In fact, it engaged with the Government and represented to the Government that it would at least partially comply with the subpoena. However, over the ensuing roughly nine months, the Hospital produced one six-page document, and it never moved to quash.

On April 30, 2026—nearly ten months after the Hospital was served with the subpoena, and nearly nine months after a motion to quash was due under the statute, *see*

18 U.S.C. § 3486(a)(5)—the Government moved to enforce the subpoena in the in this Court, which is where this nationwide investigation is being carried on. 18 U.S.C. § 3486(c). That same day, this Court signed an order enforcing the subpoena. *In the Matter of Administrative Subpoena 25-1431-032* (N.D. Tex. 2026 Apr. 30, 2026) (Doc. 2 at 1). RIH appealed and moved this Court to stay its order.

## **ARGUMENT**

A stay pending appeal is “extraordinary relief” for which the movant bears a “heavy burden.” *Plaquemines Par. v. Chevron USA, Inc.*, 84 F.4th 362, 373 (5th Cir. 2023). In determining whether RIH has met its burden, the Court considers “four factors”: “(1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure other parties interested in the proceeding; and (4) where the public interest lies.” *United States v. Texas*, 97 F.4th 268, 274 (5th Cir. 2024) (quoting *Nken v. Holder*, 556 U.S. 418, 426 (2009)). “The first two factors of the traditional standard are the most critical.” *Id.* (quoting *Nken*, 556 U.S. at 434). But “[a] stay pending appeal ‘is not a matter of right, even if irreparable injury might otherwise result.’” *Id.* (quoting *Nken*, 556 U.S. at 427).

### **I. RIH Is Unlikely to Prevail on Appeal**

#### **a. RIH’s Procedural Argument Is Unlikely to Prevail**

RIH first claims a likelihood of success on the merits because it did not receive “notice and an opportunity to respond before enforcement.” Doc. 7 at 4–6 (quotation omitted). But this Court’s procedure in enforcing the subpoena was proper, and RIH is

unlikely to prevail on appeal. An administrative subpoena enforcement proceeding is designed to be summary in nature and to employ flexible procedures to ensure a speedy resolution of the matter. “The great discretion afforded by motion rules is appropriate when regulating the form of opposition to subpoena enforcement because . . . subpoena enforcement is meant to be a summary proceeding.” *EEOC v. Bay Shipbuilding Corp.*, 668 F.2d 304, 310 (7th Cir. 1981).

RIH asserts that a response from a nonmovant is *required* prior to a district court deciding a motion. But the Fifth Circuit has said the opposite. A “district court does not abuse its discretion or violate a non-movant’s due process rights by deciding a motion to dismiss before the non-movant has responded if ‘the response would [not] have affected the outcome of the decision.’” *Vodicka v. Ermatinger*, No. 3:19-CV-0056-B, 2022 WL 992600, at \*10 (N.D. Tex. Apr. 1, 2022) (alteration adopted) (quoting *United States v. Rand*, 924 F.3d 140, 144–45 (5th Cir. 2019)). So too here. Even though a nonmovant is obviously permitted to *attempt* to surmount its “heavy burden” to resist an administrative subpoena, *United States v. Zadeh*, 820 F.3d 746, 757 (5th Cir. 2016), a district court need not wait for a response if the district court reasonably believes that the response will not change the outcome. *See Vodicka*, 2022 WL 992600 at \*10.<sup>1</sup> In such a circumstance, the “central question” is “whether the response would have affected the outcome of the district court’s decision.” *Rand*, 924 F.3d at 145.

Here, given the fulsomeness of the Government’s application for enforcement, the presumption of regularity afforded prosecutorial activity, *United States v. Armstrong*, 517

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<sup>1</sup> Moreover, with RIH’s response now before it, the Court can and should make clear that it has considered and rejected RIH’s arguments against enforcement.

U.S. 456, 464 (1996), RIH’s long-term noncompliance with the instant subpoena, and the fact that Government made the Court aware of arguments made to other district courts that have misguidedly quashed nearly identical subpoenas, the Court could reasonably have determined that RIH’s opposition would not have affected the outcome of its decision. As explained *infra*, the merits arguments RIH now offers are meritless and do not go to the facial validity or procedural adequacy of the subpoena. Instead, RIH improperly challenges the legal theories the Government might ultimately use in a criminal prosecution, as well as Executive Branch officials’ statements about gender-related medical procedures performed on minors. These are not valid bases upon which a party may resist an administrative subpoena. Put simply, RIH’s arguments would not have changed the outcome of this Court’s decision.

RIH cites *Sendsend Financial Consultants, Ltd. v. Federal Home Loan Bank Board* for the proposition that the district court in that case “robb[ed]” the government of “its right to be heard” in opposition to a motion to quash. Doc. 7 at 4 (quoting 878 F.2d 875, 881 (5th Cir. 1989)). But *Sendsend* does not stand for the proposition that a nonmovant must be permitted a response in all administrative subpoena proceedings; in fact, the case involves a statute that *requires* the agency to respond to a motion to quash. *See* 878 F.2d at 881. Moreover, the Fifth Circuit has never said that subpoena enforcement proceedings are somehow exempted from the discretion afforded to district judges—recognized in *Rand*—to decide motions without responses in appropriate circumstances. And even in *Sendsend*, the Fifth Circuit did not “remand for reconsideration under the proper procedure.” *Id.* Instead, because the record permitted “only one resolution” of the issue

on appeal, the Fifth Circuit decided against “wast[ing] precious resources remanding the case,” and proceeded to reverse in order to uphold the subpoena’s validity. *Id.* The record here, too, only permits one resolution—enforcement of the subpoena. *See infra* at 7–12. A stay is therefore unwarranted.

In sum, the Government filed a fulsome enforcement application nearly ten months after it issued a subpoena to RIH and nine months after RIH could have filed a motion to quash that subpoena in its home district. The Court reviewed the application, was aware of arguments against enforcement, and found that the Government met the requirements for summary enforcement. Nothing more was required to grant the Government’s petition.

**b. Venue Is Proper in This District**

RIH is also unlikely to succeed on appeal in its venue argument. As described in the attached Declaration from the Acting Director of the Enforcement and Affirmative Litigation Branch, the “investigation is being carried on” in this district, and venue is therefore proper. *See generally* Hsiao Declaration (motion to file under seal and ex parte pending).

RIH’s arguments to the contrary are factually and legally incorrect. First, as discussed in the Declaration, there is substantial operational and decision-making control of the investigation being exercised at the U.S. Attorney’s Office in the Northern District of Texas, along with several subjects and potential targets of the investigation located here. Also as discussed in the Declaration, while the investigation is indeed nationwide in scope, the Government did not simply decide that it would park the investigation in this

District to bring enforcement petitions and nothing else. Rather, there are substantial investigative steps happening here.

Legally, RIH's venue arguments fare little better. RIH's case citations involve statutes authorizing civil investigative demands from various federal agencies that operate in a different way than the statute at issue here. *See* Doc. 7 at 7. Indeed, Section 3486 authorizes the *Attorney General* to issue subpoenas in support of *criminal* investigations and permits the Government to bring enforcement actions in “any court of the United States within the jurisdiction of which the [criminal] investigation is carried on.” Criminal charges do not spring forth from Government agencies in Washington, D.C.; rather, our Constitution requires that serious criminal charges be presented to grand juries in one of the 94 federal judicial districts of the United States. Hence, cases that parse different statutes and try to determine whether federal agency administrative investigations—which might not require court filings at all, let alone presentments to a grand jury—are being conducted in some amorphous sense in Washington, D.C., are not particularly relevant.

Similarly, 18 U.S.C. § 3486(c) uses purposefully capacious language, stating that the enforcement action can be brought in “any” district where the investigation is being “carried on.” This is inclusive, not exclusive, language, and RIH does not meaningfully engage with it. RIH essentially argues that, to interpret this language, this Court should determine the location of the “command center” (whatever that is) for the Government's investigation and/or the location of some Government personnel with whom RIH has interacted, and permit the Government to bring enforcement actions only in that place.

Doc. 7 at 7. But determining the location of the “command center” of the Government’s investigation has nothing to do with the statute that Congress passed.

In sum, this investigation is being “carried on” in the Northern District of Texas. RIH’s venue arguments are therefore contrary to both the facts and the law. RIH is unlikely to prevail on appeal on this issue.

**c. The Subpoena Is Proper**

RIH is also unlikely to prevail on appeal on its arguments about the lawfulness of the subpoena. RIH argues that the subpoena is “unlawful” because it claims that the Government is proceeding on a theory that “‘off label use of puberty blockers and cross sex hormones’ is ‘a violation of the FDCA.’” Doc. 7 at 8. But that is not what the Government argued in its Petition, nor is it what the Government is doing here. *See* Doc. 1 at 3–4 (explaining that when a drug is distributed for an intended use not approved by FDA—a potential FDCA violation—and an insurance plan pays for that drug, the FDCA violation becomes a “federal health care offense” under 18 U.S.C. § 24 and therefore may be investigated through a HIPAA subpoena). The Government does not contend that the mere act of off-label prescribing by a physician constitutes an FDCA offense.

While the FDCA does not generally regulate the practice of medicine, federal health care law obviously does proscribe many practices directly related to the practice of medicine, such as: the unlawful dispensing of unapproved drugs, prescription medications, and controlled substances, 21 U.S.C. §§ 331(a), 841; the making of false statements in relation to claims to public and private insurance payors, 18 U.S.C. § 1035; fraud on patients and insurance payors, 18 U.S.C. § 1347; and many others. A white coat



does not confer immunity from such laws. RIH's suggestion that the federal government has no role in ensuring that medical practitioners obey federal law while practicing medicine is absurd. HIPAA expressly grants authority to issue subpoenas in investigating potential violations of federal healthcare laws, including the FDCA.

But the larger problem with these arguments is that they are not cognizable in a subpoena enforcement action. A subpoena recipient "may not avoid an administrative subpoena on the ground that it has a valid defense to a potential subsequent lawsuit" and cannot raise "factual challenges based on a lack of statutory 'coverage'" of a recipient's activities. *EEOC v. Karuk Tribe Hous. Auth.*, 260 F.3d 1071, 1076–77 (9th Cir. 2001); *Donovan v. Shaw*, 668 F.2d 985, 989 (8th Cir. 1982) ("[A] subpoena enforcement proceeding is not the proper forum in which to litigate the question of coverage under a particular federal statute."); *United States v. Sturm, Ruger & Co.*, 84 F.3d 1, 5 (1st Cir. 1996) ("[Q]uestions concerning the scope of an agency's substantive authority to regulate are not to be resolved in subpoena enforcement proceedings."). That principle dates back over 80 years to Supreme Court decisions rejecting efforts to contest subpoenas based on claims that the investigating agency lacked authority over the matter. *Oklahoma Press Pub. Co. v. Walling*, 327 U.S. 186, 213–14 (1946); *Endicott Johnson Corp. v. Perkins*, 317 U.S. 501, 508–09 (1943).

That rule follows from the posture of such proceedings: "[s]ubpoena enforcement proceedings are designed to be summary in nature and an agency's investigations should not be bogged down by premature challenges to its regulatory jurisdiction." *Sturm*, 84 F.3d at 5 (citation and quotation omitted). Were it otherwise, every subpoena recipient

could seek to pre-litigate issues of potential liability or statutory coverage, which would “stop much if not all of investigation in the public interest at the threshold of inquiry.”

*Oklahoma Press*, 327 U.S. at 213. It is thus enough to say that “an administrative subpoena is to be enforced unless agency authority is plainly lacking.” *EEOC v. Federal Express Corp.*, 558 F.3d 842, 851 n.3 (9th Cir. 2009).

In short, RIH’s arguments sound in hypothesizing a possible Government enforcement action and trying to explain why RIH believes it will be meritless. But such arguments have no place in administrative subpoena enforcement proceedings. RIH’s protestations about its perception of the Government’s view of the FDCA is precisely the sort of argument based on statutory coverage that cannot be entertained at this stage.

RIH’s position would immunize all conduct even tangentially related to off-label prescribing from federal investigation, an incorrect and dangerous argument. FDA has not found that these drugs are safe and effective to treat gender dysphoria or any other mental disorder. Off-label use of drugs such as these can expose patients to unproven and potentially dangerous treatments without adequate evidence of safety and effectiveness. These risks are particularly acute where, as here, the patients involved are children, which makes them especially vulnerable. As the comprehensive, peer-reviewed November 2025 HHS report explains:

[I]n studies, PBs [puberty blockers] are followed by cross-sex hormones (CSH) over 90% of the time; this de facto combination therapy introduces new and potentially serious risks (e.g., concerning fertility) and has never been subjected to any FDA-regulated clinical trial for any population. Further, research shows that when the evidence supporting a particular off-label use is of very low certainty—as is the case for PMT [pediatric medical transition]—the already elevated risk of adverse effects associated with off-label use is increased even further.

U.S. DEP'T OF HEALTH & HUM. SERVS., TREATMENT FOR PEDIATRIC GENDER

DYSPHORIA: REVIEW OF EVIDENCE AND BEST PRACTICES 102 (Nov. 19, 2025) (“HHS REVIEW”). Although off-label prescribing itself is a generally permitted practice under federal law, “[t]he unfavorable risk/benefit profile distinguishes [puberty blockers and cross-sex hormones for minors] from many other off-label uses of drugs and medical devices.” *Id.* at 231.

Moreover, the widespread off-label use of these powerful drugs also undermines the regulatory system that Congress established to ensure that drugs are used consistent with sound scientific data. *See Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 619 (1973) (noting that legislative history for portions of FDCA “show a marked concern that impressions or beliefs of physicians [regarding a drug’s efficacy], no matter how fervently held, are treacherous”). The FDCA rests on the premise that safety and efficacy must be demonstrated through rigorous, publicly accountable testing, rather than assumed based on clinical theory or intuition, or shaped by advocacy-driven ideology unrelated to scientific rigor. *Cf.* HHS REVIEW, at 210–217 (finding that appearance of broad medical consensus was largely manufactured through reliance on small committees aligned with advocacy-based organizations such as World Professional Association for Transgender Health (WPATH) and marked by suppression of dissenting views and discouragement of scientific debate).

The subpoena here seeks information relevant to an FDCA investigation in two respects. *First*, RIH may itself be engaged in conduct that implicates the FDCA, as the Hsiao Declaration attached to the Government’s initial Petition (Doc. 1-1) explains. There

is no basis to predetermine in a subpoena proceeding, as explained *supra*, without the benefit of any factual record, the potential scope of RIH's activities, and its relationship to the statute.

*Second*, RIH may also have relevant information about the conduct of manufacturers and distributors of drugs that may have violated the FDCA. In particular, misbranding, via false or misleading “written, printed, or graphic matter” on a drug, container, or wrapper or that supplements, explains, or is designed for use with a drug, is a classic FDCA violation. *See, e.g., United States v. Marschall*, 82 F.4th 774, 779 (9th Cir. 2023) (upholding misbranding conviction of the defendant who shipped drugs with false informational sheets). Drug manufacturers and distributors also can be convicted of FDCA violations, for example, for shipping drugs in interstate commerce intending that they be used off-label, with that intent frequently shown through evidence of promoting the drugs for such uses. *See* 21 C.F.R. § 201.128 (intent may “be shown by labeling claims, advertising matter,” “oral or written statements,” and “circumstances in which the [drug] is, with the knowledge of” certain persons, “offered or used for a purpose for which it is neither labeled nor advertised”); *see, e.g., United States v. Cephalon, Inc.*, No. 2:08-cr-598 (E.D. Pa. Oct. 10, 2008), Doc. 11 (conviction of manufacturer for promoting three drugs for off-label uses). Thus, in such prosecutions, the government may rely on evidence of communications between pharmaceutical sales representatives and prescribing physicians and recommendations to doctors of diagnostic codes to mask off-label prescriptions to ensure payment for unapproved uses. *See, e.g., Cephalon*, Doc. 1, ¶¶ 12–18 (criminal information); Press Release, U.S. Dep’t of Just., *Eli Lilly and*

*Company to Pay U.S. \$36 Million Relating to Off-Label Promotion* (Dec. 21, 2005), <https://perma.cc/2Y64-FUK5> (announcing guilty plea of drug manufacturer involving illegal off-label promotion, highlighting evidence that the defendant “[e]ncourag[ed] sales representatives ... to send unsolicited medical letters to promote the drug for an unapproved use to doctors”).

The subpoena here is plainly calculated to seek this same sort of evidence, including (for example) materials from and communications with manufacturers and sales representatives regarding the use of puberty blockers or hormones (Requests 7 through 9) and evidence of manufacturers’ financial incentives to prescribing physicians to prescribe puberty blockers or hormones (Request 10). Similarly, billing codes and communications with manufacturers or distributors about billing for off-label uses (Requests 3 through 6) may produce evidence of intentionally misleading coding that could, in turn, be traced to manufacturers or distributors attempting to conceal misbranding.

The initial Hsiao Declaration details precisely how and why each category of information the subpoena seeks is relevant and necessary to further the Government’s investigation, including how physician prescribing practices are relevant. *See* Doc. 1-1 at ¶¶ 43–44. The requested records bear directly on whether the practices surrounding distribution, promotion, and the sale of these drugs—unproven as safe and effective for treating gender dysphoria or any other mental disorder—may be violating federal law and endangering children. Such inquiries fall squarely within the Government’s statutory mandate to protect the public from misbranded, adulterated, and unapproved drugs. *See*

*United States v. Dotterweich*, 320 U.S. 277, 285 (1943) (FDCA protects the “innocent public who are wholly helpless” to protect themselves from such products).

## **II. RIH Will Not Suffer Irreparable Harm**

RIH’s motion also fails on the second requirement, that it prove it will be irreparably harmed absent a stay. “[A] showing of irreparable harm is a necessary prerequisite for a stay,” *KalshiEX LLC v. Commodity Futures Trading Comm’n*, 119 F.4th 58, 64 (D.C. Cir. 2024), and RIH has not made such a showing. “The irreparable-harm analysis focuses on the *moving party*, not the nonmoving party or some third party.” *Kansas v. United States*, 124 F.4th 529, 534 (8th Cir. 2024) (citing *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008)) (emphasis added).

RIH’s assertions about irreparable harm are that responding to the subpoena will moot the case, that it will cost money to collect documents to respond to the subpoena, and that its relationships with its patients will be harmed absent a stay. Doc. 7 at 12–14. Even crediting the untested, general affidavits RIH offers, none of these things qualifies as cognizable irreparable harm.

First, producing documents to the Government is not irreparable harm and will not moot the case. *Church of Scientology of Cal. v. United States*, 506 U.S. 9, 12–15 (1992) (holding that still-available remedies prevent subpoena challenges from becoming moot after disclosure of documents in compliance with subpoena). The subpoena requires production of nonprivileged, pre-existing business records of a large, closely regulated healthcare provider. Accepting RIH’s argument would mean that any time a court orders

compliance with a subpoena, the subpoenaed party would automatically be able to make a showing of irreparable harm. That is not and cannot be not the law.

Moreover, RIH has not explained how the Government seeing its nonprivileged business records as part of a lawful criminal investigation could possibly qualify as irreparable harm—the only consequence would be the Government investigating to see whether federal law was violated. In fact, even if there is “harm” from the Government seeing RIH’s documents, that harm is eminently reparable: The Court can order complete return of the documents on any potential remand if RIH is successful on appeal, and the Court can order that no information gleaned from those documents be used in the investigation. That is an adequate remedy to address the concern. *See United States ex rel. Barko v. Halliburton Co.*, 4 F. Supp. 3d 162, 169 (D.D.C. 2014); *Church of Scientology*, 506 U.S. at 15 (“[T]his case is not moot because if the summons were improperly issued or enforced a court could order that the IRS’ copies of the tapes be either returned or destroyed.”).

Second, spending money to comply with the subpoena is not an irreparable harm to RIH because, among many other things, “[t]he burden of complying with a subpoena does not constitute irreparable injury.” *Nikon Corp. v. GlobalFoundries U.S., Inc.*, No. 17-MC-80071, 2017 WL 4865549, at \*2 (N.D. Cal. Oct. 26, 2017). “In general, the cost to businesses of complying with governmental subpoenas are normal costs of doing business which should be borne by the company.” *Hurt v. Dime Sav. Bank*, 151 F.R.D. 30, 31 (E.D.N.Y. 1993). RIH is a large, highly-regulated healthcare provider, and its parent company owns multiple such hospitals; spending money to comply with Government

subpoenas is unremarkable and certainly not irreparable for such an institution. And that purported harm is even less understandable here: RIH sat on the subpoena for ten months and produced one document. Because RIH did not move to quash, it could or should have been collecting, reviewing, and readying documents for production. Its failure to move to quash or comply with the subpoena over the course of ten months cannot constitute irreparable harm now. “[S]elf-inflicted harm is not irreparable.” *Texas v. EPA*, 662 F. Supp. 3d 739 (S.D. Tex. 2023); *see Texas v. Biden*, 10 F.4th 538, 558 (5th Cir. 2021) (no irreparable harm where litigant “could have avoided this problem” by adopting a different litigation strategy).

Finally, the disclosure of patient records to the Government does not constitute irreparable harm to RIH’s relationships with its patients. The Government understands that patients would prefer to keep their medical records private—indeed, that was one of the animating purposes of HIPAA, of which the administrative subpoena provision of the statute is a key element. But it does not follow that patients’ preference for privacy would lead to irreparable harm to *RIH*, which is the only relevant inquiry. *Kansas*, 124 F.4th at 534.

First, this investigation is not—and has never been—an investigation of patients or parents seeking treatment for gender dysphoria, and the subpoena statute at issue generally forbids the Government from using patient medical records to investigate patients. 18 U.S.C. § 3486(e). But more importantly, the Hospital’s ubiquitous privacy practices disclosure for patient treatment—a familiar feature in all modern healthcare settings—discloses to all RIH patients that patient health information may be shared with



the Government in response to subpoenas for law-enforcement investigations, as well as numerous other types of disclosures. Lifespan Joint Privacy Notice at 7, available at [https://www.brownhealth.org/sites/default/files/2021-07/EN-Joint-Privacy-Notice-English\\_2021.pdf](https://www.brownhealth.org/sites/default/files/2021-07/EN-Joint-Privacy-Notice-English_2021.pdf). RIH does not mention this fact or even attempt to explain how it could be irreparably harmed by doing something that it disclosed to patients it could do and that it is legally obligated to do.

### **III. The Balance of Equities Does Not Favor RIH**

Because RIH does not make an adequate showing on the first two factors, balancing the other factors is unnecessary. But even if the Court were convinced RIH made some sort of showing on either factor, that showing is outweighed by the Government's interest in enforcing the law and in continuing a lawful investigation that is a priority of the Executive Branch—and this is also the public's interest. “[I]n the context of a stay, assessing the harm to the opposing party and weighing the public interest merge when the Government is the opposing party.” *Pursuing Am.’s Greatness v. FEC*, 831 F.3d 500, 511 (D.C. Cir. 2016). The Government has an “uncontested interest” in the “faithful execution of law.” *Newsom v. Trump*, 141 F.4th 1032, 1054 (9th Cir. 2025). Indeed, “[t]he government has a compelling interest in identifying illegal activity and in deterring future misconduct,” and that interest “outweighs the privacy rights of those whose [medical] records” are sought via a properly issued HIPAA subpoena, “particularly in light of the limitation placed on uses of subpoenaed information by § 3486.” *In re Subpoena Duces Tecum*, 228 F.3d 341, 351 (4th Cir. 2000); *see also Samia v. United States*, 599 U.S. 635, 655 (2023) (reiterating the government’s

“compelling interest in finding, convicting, and punishing those who violate the law”  
(citation omitted)).

In short, RIH producing nonprivileged business records to the Government as part of a lawful investigation into violations of federal law is not a harmful act at all, let alone one that would support the “extraordinary relief” of a stay pending appeal.

### **CONCLUSION**

This Court should deny the motion for a stay pending appeal.

Dated: this 8<sup>th</sup> day of May 2026.

Respectfully submitted,

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### **CERTIFICATE OF SERVICE**

I hereby certify that on May 8, 2026, I electronically filed this Opposition and it is available for viewing and downloading from the Court's CM/ECF System, and the participants in the case that are registered CM/ECF users will be served electronically by the CM/ECF system.

/s/ Patrick R. Runkle  
PATRICK R. RUNKLE  
Assistant Director

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF RHODE ISLAND**

In Re: Administrative Subpoena  
25-1431-032 to Rhode Island Hospital

Misc. Action No. \_\_\_\_\_

**EMERGENCY MOTION TO QUASH  
SUBPOENA DUCES TECUM**

**REQUEST FOR EXPEDITED RELIEF  
PURSUANT TO LR CV 9**

---

**DECLARATION OF GLENN R. FRIEDEMANN, ESQ.**

I, Glenn R. Friedemann, declare as follows:

1. I am the Associate General Counsel in the Office of the General Counsel for Brown University Health (“Brown Health”). I have been in this role for 20 years. In this role, I have supervised matters related to the Health Insurance Portability and Accountability Act Subpoena No. 25-1431-032 (“the Subpoena”) issued to Rhode Island Hospital (“RIH”).

2. Brown Health is a not-for-profit health system based in Providence, Rhode Island. Brown Health is organized as a Rhode Island nonprofit corporation (IRS 501(c)(3)) and has been domiciled in the state of Rhode Island since its formation. Brown Health is the parent organization of RIH.

3. Brown Health’s corporate offices are located at 15 Lasalle Sq., Providence, Rhode Island, 02903.

4. RIH’s principal place of business is 593 Eddy Street, Providence, RI 02903. The vast majority of RIH’s hospitals, clinics, and patient care sites are located in Rhode Island. RIH has two community hospital affiliates that operate in Fall River, Massachusetts, and Taunton, Massachusetts.

5. All of Brown Health's and RIH's corporate functions—such as legal, communications, human resources, and finance operations—are carried out from Providence, Rhode Island.

6. RIH provides gender-affirming care through the Gender and Sexuality Program at Hasbro Children's Hospital, which is the pediatric division of RIH. Hasbro Children's Hospital primary place of business is 593 Eddy St, Providence, RI 02903.

7. On July 9, 2025, RIH was served with the Subpoena by the Department of Justice. The Subpoena included request for production with a return date of August 7, 2025, at the Department of Justice's office in Washington, D.C.

8. On July 9, 2025, counsel for the Government contacted me by phone about the Subpoena. On that call, counsel for the Government informed me that it did not believe that RIH had engaged in any criminal wrongdoing.

9. RIH produced a responsive, six-page document by the Subpoena's August 7 return date. As part of this production, RIH noted that its agreement to produce information and records responsive to the subpoena did not constitute a waiver of any objection that RIH may have to the subpoena or to any of its requests. Specifically, RIH expressly reserved, and did not waive, (1) its right to object to certain of the government's requests as unduly burdensome, irrelevant, or otherwise requiring the production of material or information protected from disclosure under federal or state law or (2) its right to seek a protective order or any other judicial relief in any litigation arising in connection with the subpoena. The Government did not object to RIH's reservation of rights.

10. The Court's April 30, 2026, Order requires compliance with the Subpoena within a 14-day period, by May 14, 2026.

11. Full compliance with the Subpoena by May 14 is not possible. The data is not hosted in a manner that can be easily collected or reviewed. The data must be collected from disparate platforms (including legacy platforms) and hard copy sources, processed, de-duplicated, and reviewed for privilege and confidentiality. This process alone will take several months.

12. Moreover, many of the custodians whose documents are required are actively practicing medical providers who care for patients daily. Every hour they spend identifying documents, reviewing materials, meeting with counsel, and engaging in other activities necessary to comply with the Subpoena detracts from their ability to administer patient care.

13. Finally, to protect its patients' privacy, RIH is exploring ways in which it can anonymize its patient records before any production. The Department of Justice has agreed to accept anonymized patient records in other litigation involving similar subpoenas. However, the process of anonymization is burdensome and will take several months to complete.

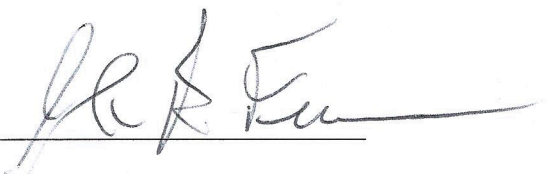
14. Accordingly, full compliance with the Subpoena will carry an irreparable monetary harm of millions of dollars that RIH will be unable to recover if the Subpoena is found invalid.

15. RIH will retain and protect all responsive materials pending a determination in this matter.

16. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: 5/9/26

/s/

  
Glenn R. Friedemann, Esq.



**UNITED STATES DISTRICT COURT  
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---

**DECLARATION OF DR. PHYLLIS DENNERY, M.D.**

I, Dr. Phyllis Dennery, declare as follows:

1. I am the chief of pediatrics for Brown University Health (“Brown Health”) and pediatrician-in-chief for Rhode Island Hospital. I have served in this role for 11 years.

2. RIH provides comprehensive, multi-disciplinary gender-affirming care in Rhode Island, including through the Gender and Sexuality Program at Hasbro Children’s Hospital, which is the pediatric division of RIH. Hasbro Children’s Hospital’s primary place of business is 593 Eddy St, Providence, RI 02903.

3. I understand that the Department of Justice (the “Government”) issued a subpoena (the “Subpoena”) to RIH in July 2025, and that the Subpoena requests production of medical records and confidential personal information concerning minor patients who received gender-affirming care at RIH.

4. The Government’s request for patient information will have detrimental effects that will impact the entire RIH patient population, their families, and the broader community.

5. The patient-physician relationship is essential in helping people to live healthy, productive lives. The cornerstone of that relationship is confidentiality. Patients seek medical care

from RIH with the understanding that RIH will maintain the confidentiality of their highly sensitive and private medical records and personal information.

6. Trust is critical to the patient-physician relationship, especially for minor patients seeking gender-affirming care, who may experience harassment, bullying, and other traumatic events if private information about their care were to be disclosed outside the patient-physician relationship. Trust between a physician, patient, and the patient's family members allows for open, honest, and thorough discussion of a patient's medical conditions, questions, concerns, and potential treatment plans.

7. Production of a patient's medical records, name, Social Security number, and/or home address in response to the Subpoena will result in identification of the patient and disclosure of the patient's most intimate and personal details to the Government. Such disclosure could cause severe emotional distress for the patient and their family and could expose the patient and their family to the possibility of harassment, discrimination, and violence, especially if that information was leaked to the public.

8. Disclosure of minor patients' highly sensitive and private medical could have a chilling effect on these patients, decreasing the likelihood that an already vulnerable class of patients will continue to seek medical care. Moreover, any patients who do continue to seek medical care are likely to be reluctant to disclose sensitive information out of fear of similar government requests.

9. The disclosure of patient records to the Government, accordingly, would undermine the trust that patients have in their doctors, eroding the patient-physician relationship and making it more difficult for medical providers to accurately diagnose and provide effective medical care to patients.



10. The patient's privacy would not be protected by simply redacting the patient's name or address from records, as patients typically disclose other personally identifiable information to their providers—such as their relationships in school, parents' occupations, and extra-curricular activities—during their care.

11. For all the reasons above, I believe that disclosure of the patients' medical records pursuant to the Subpoena would cause irreparable harm to the patients. I also believe that disclosure of patients' medical records pursuant to the Subpoena will irreparably harm the relationship between patients and medical care providers at RIH, which is based on trust and confidentiality.

12. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: 05/07/2026

/s/ 

Dr. Phyllis Dennerly, M.D.

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF RHODE ISLAND**

In Re: Administrative Subpoena  
25-1431-032 to Rhode Island Hospital

Misc. Action No. \_\_\_\_\_

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**REQUEST FOR EXPEDITED RELIEF  
PURSUANT TO LR CV 9**

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**DECLARATION OF DR. ABIGAIL DONALDSON, M.D.**

I, Dr. Abigail Donaldson, declare as follows:

1. I am the division director of the Adolescent Medicine Division of Hasbro Children's at Rhode Island Hospital (RIH). I have served in this role for 5 years.
2. RIH provides comprehensive, multi-disciplinary gender-affirming care in Rhode Island, including through the Gender and Sexuality Program at Hasbro Children's Hospital, which is in the pediatric division of RIH. Hasbro Children's Hospital's primary place of business is 593 Eddy St, Providence, RI 02903.
3. As part of its gender-affirming care services for minors, RIH uses a patient-centered, consent-based process to better understand its patients' gender and sexual health care needs and goals. The range of services it provides includes thorough medical and psychosocial evaluations, initiation and continuation of gender care and hormone therapy, and referrals to other providers and community resources.
4. I understand that the Department of Justice (the "Government") issued a subpoena (the "Subpoena") to RIH in July 2025, and that the Subpoena requests production of medical

records and confidential personal information concerning minor patients who received gender-affirming care at RIH.

5. A minor patient who receives gender-affirming care at RIH, along with that patient's parents or guardian, typically meet with one or more RIH providers and collaborating medical professionals over the course of multiple visits. No minor is seen at RIH for gender-affirming care without the knowledge and consent of their parent or legal guardian.

6. Throughout those visits and in related communications, the patient discloses private information about their mental health, sexual health, and fertility; information about relationships in school, parents' occupations, and neighborhood; names of families and friends, family medical history, any involvement with Rhode Island Department of Children, Youth, and Families or other state agencies; and more. All such disclosures are made to RIH for purposes of diagnosing and treating the patient.

7. During the course of the patient's care, the patient, along with the patient's parents, typically discuss a recommended treatment plan and any concerns about the treatment plan privately with the patient's provider. Each patient has a uniquely tailored care plan based on their mental health and medical assessments.

8. If medical treatment is being considered, and especially gender affirming hormone treatment, the assessment process includes a thorough medical and psychosocial evaluation of the patient, which includes (but is not limited to) evaluating the patient's physical function, cognitive abilities, communication skills, emotional functioning, and capacity for decision-making.

9. No medical treatments will begin until after informed consent is obtained from the parent(s)/legal guardian(s) with medical decision-making authority over the minor patient, and the minor patient provides their consent.

10. Part of a patient's medical treatment plan may include taking hormonal medications. A provider, in consultation with the patients and their families, will determine which medications best serve the medical needs of the patient.

11. The patient-physician relationship is sacred and fundamental. Confidentiality is central to that relationship. Patients seek medical care from RIH with the understanding that RIH will keep their highly sensitive and private medical records and personal information confidential.

12. Production of a patient's medical records, name, Social Security number, and/or home address in response to the Subpoena will result in identification of the patient and disclosure of the patient's most intimate and personal details to the Government. Any such disclosure could cause severe emotional distress for the patient and family members and expose the patient and family members to the possibility of bullying, harassment, discrimination, and violence. Moreover, disclosure of this information will curtail the likelihood that an already vulnerable population of individuals will receive the care they need. The chilling effect caused by disclosure of patient records could also extend beyond gender-affirming care treatment to other aspects of medical care, such as mental health treatment, preventative care, emergency care, and other subspecialty care.

13. The patient's privacy would not be protected by simply redacting the patient's name or address from records, as patients typically disclose other personally identifiable information to their providers—such as their relationships in school, parents' occupations, and extra-curricular activities—during their care.

14. For all the reasons above, I believe that disclosure of the patients' medical records would cause irreparable harm to the patients. I also believe that disclosure of patients' medical records will irreparably harm the relationship between patients and medical care providers at RIH, which is based on trust and confidentiality.

15. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated:

5/7/26

/s/ 

Dr. Abigail Donaldson, M.D.

**From:** [Gunn, David L \(CRM\)](#)  
**To:** [Narver, Clint](#)  
**Cc:** [Olshan, Eric G.](#); [Shahane, Rhea T.](#); [Dahlquist, Scott B \(CIV\)](#); [Campbell, Jordan C \(CIV\)](#); [Goldstein, Ross \(CRM\)](#); [Runkle, Patrick](#); [Scott, Steven R \(CRM\)](#)  
**Subject:** RE: Rhode Island Hospital / Production of Search Terms  
**Date:** Thursday, April 30, 2026 6:10:21 PM  
**Attachments:** [2026.04.30 - Rhode Island - USA Petition for Enforcement \(FILED\).pdf](#)  
[2026.04.30 - Rhode Island - Ex. A.pdf](#)  
[2026.04.30 - Rhode Island - Ex. B.pdf](#)  
[2026.04.30 - Rhode Island - Ex. C.pdf](#)  
[2026.04.30 - Rhode Island - Proposed Order.pdf](#)

**\*\*EXTERNAL EMAIL; use caution with links and attachments\*\***

Clint,

No immediate need to connect now. I had hoped to talk before we filed the attached. I'm sure we will discuss soon.

Best,  
David

---

**From:** Narver, Clint <[cnarver@mcguirewoods.com](mailto:cnarver@mcguirewoods.com)>  
**Sent:** Wednesday, April 29, 2026 5:11 PM  
**To:** Gunn, David L (CRM) <[David.L.Gunn@usdoj.gov](mailto:David.L.Gunn@usdoj.gov)>; Dahlquist, Scott (CIV) <[Scott.Dahlquist2@usdoj.gov](mailto:Scott.Dahlquist2@usdoj.gov)>  
**Cc:** Olshan, Eric G. <[eolshan@mcguirewoods.com](mailto:eolshan@mcguirewoods.com)>; Shahane, Rhea T. <[rshahane@mcguirewoods.com](mailto:rshahane@mcguirewoods.com)>  
**Subject:** [EXTERNAL] RE: Rhode Island Hospital / Production of Search Terms

David,

We are happy to connect. Would Monday of next week work?

Thanks.

Clint

## Clint Narver

Partner

McGuireWoods LLP

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[cnarver@mcguirewoods.com](mailto:cnarver@mcguirewoods.com)

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**From:** Gunn, David L (CRM) <[David.L.Gunn@usdoj.gov](mailto:David.L.Gunn@usdoj.gov)>  
**Sent:** Tuesday, April 28, 2026 10:36 AM

**To:** Narver, Clint <[cnarver@mcguirewoods.com](mailto:cnarver@mcguirewoods.com)>; Dahlquist, Scott B (CIV) <[Scott.Dahlquist@usdoj.gov](mailto:Scott.Dahlquist@usdoj.gov)>  
**Cc:** Olshan, Eric G. <[eolshan@mcguirewoods.com](mailto:eolshan@mcguirewoods.com)>; Shahane, Rhea T. <[rshahane@mcguirewoods.com](mailto:rshahane@mcguirewoods.com)>  
**Subject:** RE: Rhode Island Hospital / Production of Search Terms

**\*\*EXTERNAL EMAIL; use caution with links and attachments\*\***

Good morning Clint and Eric,

I've been out a few weeks and hope all is well. In reviewing our production charts, it does not appear we have received any productions from your client in light of your search terms below. (In fact, it appears the one and only production was in August 2025). Can we conference this week regarding status?

---

**From:** Narver, Clint <[cnarver@mcguirewoods.com](mailto:cnarver@mcguirewoods.com)>  
**Sent:** Wednesday, February 4, 2026 10:52 AM  
**To:** Gunn, David L (CRM) <[David.L.Gunn@usdoj.gov](mailto:David.L.Gunn@usdoj.gov)>; Dahlquist, Scott B (CRM) <[Scott.B.Dahlquist@usdoj.gov](mailto:Scott.B.Dahlquist@usdoj.gov)>  
**Cc:** Olshan, Eric G. <[eolshan@mcguirewoods.com](mailto:eolshan@mcguirewoods.com)>; Shahane, Rhea T. <[rshahane@mcguirewoods.com](mailto:rshahane@mcguirewoods.com)>  
**Subject:** [EXTERNAL] Rhode Island Hospital / Production of Search Terms

David and Scott,

Following up on our recent call, please see the attached correspondence.

Best,

Clint

**Clint Narver**

Partner

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**UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

**IN RE: ADMINISTRATIVE  
SUBPOENA NO. 25-1431-014**

**MISCELLANEOUS ACTION  
NO. 25-MC-0039-MAK**

**GOVERNMENT’S MEMORANDUM IN OPPOSITION  
TO CHILDREN’S HOSPITAL OF PHILADELPHIA’S MOTION TO MODIFY**

While the Government recognizes this investigation concerns potential misconduct undertaken in the context of a politically sensitive subject matter, that fact does not in any way make the subpoena’s request for patient records—to which the Children’s Hospital of Philadelphia (“CHOP”) specifically objects—invalid or unenforceable. Because the statute that authorizes the administrative subpoenas in this case already strikes an appropriate privacy balance, CHOP’s objections to producing patient records are meritless.

**BACKGROUND**

The Government is conducting an investigation into, among other things, whether off-label promotion and/or unlawful dispensing of puberty blockers and cross-sex hormones for use by minors violated federal law, including the Food, Drug, and Cosmetic Act (“FDCA”). Because public or private insurance plans were presented with claims related to off-label use of these medications, such a violation of the FDCA could constitute a “federal health care offense” as defined by 18 U.S.C. § 24.

CHOP acknowledges that it provides gender-related medical care to minors, including the use of puberty blockers and cross-sex hormones that are one of the foci of the investigation. CHOP Memorandum (“Memo.”) at 5-6. Puberty blockers are administered off-label for treating



gender dysphoria, and they are not authorized by FDA for that use. *United States v. Skrametti*, 605 U.S. \_\_\_, 145 S. Ct. 1816, 1841 (June 18, 2025) (Thomas, J., concurring).

The instant subpoena to CHOP was duly issued on June 13, 2025, and was served on counsel for CHOP. The return date specified in the subpoena was set as July 9, 2025. CHOP has stated that it will comply with the other requests in the subpoena, but has refused to comply with the requests for patient information.

## **ARGUMENT**

Respectfully, the Court should deny CHOP's request to avoid compliance with the Government's subpoena. HIPAA authorized the Government to send HIPAA subpoenas in exactly this type of investigation and to obtain exactly the type of information this subpoena requests. CHOP's arguments to the contrary are either based on inapplicable law or reflect a fundamental misunderstanding of the interests at stake.

### **I. THE WESTINGHOUSE TEST DOES NOT APPLY TO THIS SUBPOENA.**

CHOP's entire privacy argument rests exclusively on a novel application of *United States v. Westinghouse Elec. Corp.*, 638 F.2d 570, a 1980 Third Circuit decision. In that matter, the National Institute for Occupational Safety and Health ("NIOSH") issued a subpoena under its statute for medical records of Westinghouse employees whom NIOSH believed had been exposed to a dangerous substance. Westinghouse resisted the subpoena, and the Third Circuit conditionally ordered the records produced, fashioning a non-statutory seven-factor test not found in any Supreme Court precedent or prior decision. *Id.* at 579. The Court also fashioned a complex, non-statutory notice-and-response remedy as to medical records of individual employees not involved in the litigation. *Id.* at 581–82.

But the *Westinghouse* test does not apply to HIPAA subpoenas. Indeed, CHOP does not cite a single case applying the *Westinghouse* factors to a HIPAA subpoena, because it cannot, as

there is no case in this circuit or elsewhere applying *Westinghouse* to a HIPAA subpoena.<sup>1</sup>

*Westinghouse* is simply inapposite, for two independent reasons: First, the HIPAA statute—and the HIPAA subpoenas it created—superseded the *Westinghouse* test by addressing the concerns about medical privacy that animated the *Westinghouse* decision; and second, *Westinghouse* was wrongly decided.

#### **A. The *Westinghouse* Test Does Not Apply to Medical Records Sought Via HIPAA Subpoena.**

The Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) “is the primary federal law which was passed to ensure an individual's right to privacy over medical records.” *United States v. Elliott*, 676 F. Supp. 2d. 431, 436 (D. Md. 2009). Congress created the type of administrative subpoena at issue here as part of HIPAA. Because HIPAA and HIPAA subpoenas did not exist in 1980, the issue of whether a HIPAA subpoena is subject to the *Westinghouse* test could not have been, and was not, decided by *Westinghouse*.

HIPAA sets forth a small number of basic procedural requirements for a HIPAA subpoena to be valid, and CHOP apparently believes those requirements are met here because it has agreed to produce non-patient-specific documents. 18 U.S.C. § 3486(a). Conspicuously absent from the statutory requirements for a HIPAA subpoena, however, is the seven-factor balancing test from *Westinghouse*. “If the text [of a statute] is clear and unambiguous, this Court must simply apply it.” *In re KB Toys Inc.*, 736 F.3d 247, 251 (3d Cir. 2013). This Court should therefore hold that HIPAA subpoenas are not subject to the *Westinghouse* test.

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<sup>1</sup> In fact, the only case the Government is aware of in this circuit discussing a HIPAA subpoena makes no mention at all of *Westinghouse*, instead citing and quoting from the Sixth Circuit’s decision in *Doe v. United States*, 253 F.3d 256 (6th Cir. 2001)—in which the Sixth Circuit affirmed the denial of a motion to quash a HIPAA subpoena—to explain that “it appears clear, both from the language of the statute and from Congress’s intent in enacting HIPAA, that the DOJ’s subpoena power in investigating federal health care offenses is meant to be broad” and that Section 3486’s language “illustrat[es] the substantial scope of the subpoena power Congress intended to give the Attorney General.” *United States v. Hertel & Brown Physical & Aquatic Therapy*, No. 1:21-CR-39, 2025 WL 83789, at \*7 (W.D. Pa. Jan. 13, 2025).

By passing HIPAA in 1996, Congress directly addressed the privacy concerns that animated *Westinghouse* by generally prohibiting the disclosure of protected health information by covered entities. “Through HIPAA, Congress has spoken about the protection that must be extended to patients regarding their health related information.” *Wade v. Vabnick-Wener*, 922 F. Supp. 2d 679, 685 (W.D. Tenn. 2010). And in that same law, Congress in essence abrogated the *Westinghouse* test for HIPAA subpoenas by giving the Department of Justice a specific, Constitutionally-compliant subpoena power to obtain the very medical records that are protected by the HIPAA statute. Congress had medical privacy at the forefront of its mind, but it obviously did not believe that the *Westinghouse* factors—or anything like them—were warranted for HIPAA subpoenas or necessary to protect patient privacy. Put differently, a HIPAA subpoena that meets the statutory requirements for enforcement satisfy the *Westinghouse* test (and the Constitution’s privacy guarantees) as a matter of law; no further balancing is required.

The only circuit courts to have considered HIPAA subpoenas have upheld them over Constitutional challenges that attempt to place privacy-based, *Westinghouse*-like additional restrictions on their use. *In re Subpoena Duces Tecum*, 228 F.3d 341, 350 (4th Cir. 2000) (“[W]e reject [the subpoena recipient’s] implied argument that the subpoena power as defined by 18 U.S.C. § 3486 is constitutionally unreasonable.”); *Doe v. United States*, 253 F.3d 256, 264–65 (6th Cir. 2001) (“We agree with the Fourth Circuit that the reasonable relevance test should apply to [HIPAA] subpoenas.”); *United States v. Whispering Oaks Residential Care Facility, LLC*, 673 F.3d 813, 817 (8th Cir. 2012).

This is because, among other reasons, the Government’s “compelling interest in identifying illegal activity and in deterring future misconduct” using a § 3486 subpoena outweighs Constitutional privacy concerns as a matter of law; the disclosure to the government of patient records is not “meaningfully distinguishable from a host of other unpleasant invasions of

privacy that are associated with many facets of health care.” *In re Subpoena Duces Tecum*, 228 F.3d at 351. Furthermore, as these courts have also determined, HIPAA already provides Constitutionally reasonable privacy protection for patient information obtained via HIPAA subpoenas. *Id.* (“[The government’s] interest outweighs the privacy rights of those whose records were turned over to the government, particularly in light of the limitation placed on uses of subpoenaed information by § 3486.”).

Because the *Westinghouse* test does not apply, and because CHOP does not identify another source of law to resist complying with the Government’s subpoena, this Court should deny CHOP’s motion and order it to produce the requested documents.

#### **B. *Westinghouse* Was Wrongly Decided.**

The Government recognizes that *Westinghouse* is a precedential decision of the Third Circuit, but wishes to preserve the argument that the case was wrongly decided should this Court decide that *Westinghouse* does apply in this context. Among other things, as described above, *Westinghouse* identified no actual basis in the statute or Supreme Court case law for the rule it articulated, erecting extra-statutory barriers to the enforcement of valid administrative subpoenas—as CHOP casually admits in its filing. *See* CHOP Memo. at 9 (“Even where a subpoena satisfies the criteria for judicial enforcement, a court must consider seven factors in determining whether an intrusion into an individual’s privacy is justified.”).

To the extent that *Westinghouse* purported to base its holding on an amorphous Constitutional right to the privacy of medical records, even the *Westinghouse* court recognized that the contours of such a right were unclear. 638 F.2d at 577. The Government is highly skeptical that an affirmative, free-floating right to control the disclosure of medical records in whatever context they may be found exists under current Constitutional jurisprudence, given the lack of historical grounding for such a right. *See Washington v. Glucksberg*, 521 U.S. 702, 722

(1997). The Government is also highly skeptical that CHOP has standing to raise a Fourth Amendment challenge to this subpoena on behalf of all its patients—perhaps this is why CHOP does not directly raise such a challenge, but only raises it indirectly through *Westinghouse*. *United States v. Miller*, 425 U.S. 435, 443 (1976) (“[T]he Fourth Amendment does not prohibit the obtaining of information revealed to a third party and conveyed by him to Government authorities, even if the information is revealed on the assumption that it will be used only for a limited purpose and the confidence placed in the third party will not be betrayed.”).

For these reasons, among others, the other circuits that have considered privacy-based challenges to administrative subpoenas have rejected such additional requirements. *In re Subpoena Duces Tecum*, 228 F.3d at 350; *Doe*, 253 F.3d at 264–65; *Whispering Oaks Residential Care Facility*, 673 F.3d at 817.

## II. IN THE ALTERNATIVE, THE GOVERNMENT MEETS THE *WESTINGHOUSE* TEST.

The Court should also overrule CHOP’s objections even if the *Westinghouse* test applies. The seven *Westinghouse* factors are: (1) the type of record requested; (2) the information it does or might contain; (3) the potential for harm in any subsequent nonconsensual disclosure; (4) the injury from disclosure to the relationship in which the record was generated; (5) the adequacy of safeguards to prevent unauthorized disclosure; (6) the degree of need for access; and (7) whether there is an express statutory mandate, articulated public policy, or other recognizable public interest favoring access. *Doe v. SEPTA*, 72 F.3d 1133, 1140 (3d Cir. 1995).

### A. “[T]he degree of need for access” (factor 6) and “whether there is an express statutory mandate” (factor 7) are essentially dispositive and strongly favor the Government.

Although CHOP acknowledges that factors 6 and 7 favor the Government, Memo. at 20–21 (putting these factors “on the other side of the ledger”), it gives short shrift to the proper interpretation and weight of these factors compared to the others. First, as to the government’s

need for this information, the acts being investigated here are, at base, statutory violations commonly investigated by the Government in many contexts over many decades—such as violations of the Federal Food, Drug, and Cosmetic Act affecting the safety of the Nation’s pharmaceutical supply, *see United States v. Dotterweich*, 320 U.S. 277, 280 (1943), and fraudulent practices in the healthcare system, *see Harkonen v. Sebelius*, No. C 13-0071 PJH, 2013 WL 5734918, at \*16 (N.D. Cal. Oct. 22, 2013) (noting “the [G]overnment’s interests in deterring fraud in the delivery of health care and health care items and services, and in protecting federal health care programs and their beneficiaries from individuals who have behaved in an untrustworthy manner”). The document requests here are common in such investigations, and CHOP does not really argue otherwise.

Next, as to CHOP’s suggestion that the Government should settle for what CHOP is willing to provide, Memo. at 20, subpoena recipients do not typically get to choose what types of evidence the Government gets in its investigations. *In re Grand Jury*, 103 F.3d 1140, 1149 (3d Cir. 1997) (“the public has a right to every man’s evidence”). CHOP does not offer the Court a compelling reason for the Court to authorize such an endeavor here. And the amount of secrecy in this area makes it difficult or impossible for the Government to investigate the on-the-ground provision of these services without obtaining the requested records.<sup>2</sup>

Finally, the Government’s need under factor 6 is extremely heightened in this area, because—as discussed *supra* at 7–8—the investigation relates to potential misconduct committed against vulnerable children, leaving lifelong mental and physical side effects and consequences.

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<sup>2</sup> For example, in denying an effort by WPATH, whose guidelines CHOP uses, to keep records of its guidelines’ development from being publicly released, the Middle District of Alabama observed that WPATH “touts its guidelines and standards of care for treating transgender children as the product of rigorous science and broad consensus. Given this wide acceptance of what WPATH claims to be reliable evidence, one would think it would be willing and eager to demonstrate as much. It is not.” *Boe v. Marshall*, 22-cv-184 (M.D. Ala.), (ECF No. 754, *Memorandum Opinion and Order Granting Time Sensitive Motion for Relief*, June 9, 2025.).

See *New York v. Ferber*, 458 U.S. 747, 756 (1982) (“It is evident beyond the need for elaboration that a State’s interest in safeguarding the physical and psychological well-being of a minor is compelling.”); *In re Subpoena Duces Tecum*, 228 F.3d at 351 (“The government has a compelling interest in identifying illegal activity and in deterring future misconduct.”).

In these circumstances, therefore, factor 6 is essentially dispositive. The Government’s compelling interest in investigating health care offenses involving minors outweighs, as a matter of law, an individual’s privacy interest in medical records. The Constitution cannot reasonably be interpreted to divest the Government of its ability to protect children and combat offenses committed against them.

Finally, even CHOP admits that factor 7 significantly favors the Government, because the statute “affords DOJ latitude,” Memo. at 20, to undertake this investigation.<sup>3</sup> And that is an understatement. Congress enacted an express statutory mandate in HIPPA for DOJ to investigate the sort of offenses under investigation here—a mandate that “ranks with the other public interests which have been found to justify intrusion into records and information normally considered private.” *Westinghouse*, 638 F.2d at 579.

**B. “[T]he adequacy of safeguards to prevent unauthorized disclosure” also favors the Government.**

As to factor 5, the circuit courts to have considered the privacy protections in the HIPAA subpoena statute have found them adequate to protect patient privacy. *In re Subpoena Duces Tecum*, 228 F.3d at 350; *Doe*, 253 F.3d at 264–65; *Whispering Oaks Residential Care Facility*, 673 F.3d at 817. Specifically, the statute requires the government to return records if the investigation does not ripen into an enforcement action. 18 U.S.C. § 3486(a)(8). More relevant to

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<sup>3</sup> CHOP mentions a vacated HHS regulation about reproductive healthcare in its footnote 15. It is unclear how a vacated regulation on what on its face appears to be a different subject matter assists CHOP in its motion.

CHOP's objections, the statute broadly prohibits the government from using or disclosing "health information about an individual" that is obtained via this subpoena, and it further generally prohibits the government from using protected health information about a patient against that patient. 18 U.S.C. § 3486(e).

CHOP misunderstands this factor by citing theoretical ways in which records obtained via HIPAA subpoena could be shared with, for example, state law-enforcement agencies under existing law. Memo. at 18. Factor 5, however, is focused only on "unauthorized disclosure," and disclosures permitted under the laws at issue would not be unauthorized. CHOP also cites statements of Executive Branch officials about disclosures of unrelated documents in other, unrelated investigations and subject matters to suggest that somehow patient records, in violation of the statute, will be leaked by unknown Government actors. *Id.* at 18–19. None of the statements CHOP cites even remotely indicate that the Government will not follow the HIPAA statute in this matter. *See United States v. Martinez*, 103 F. Supp. 3d 675, 678 (E.D. Pa. 2015) (collecting cases on judicial presumption that Executive Branch officials have "properly discharged their official duties").

Furthermore, CHOP does not consider other obvious ways that the records could be further protected, such as a protective order, a letter agreement with the Government, or an order placing the records under seal. In sum, this factor weighs in favor of production.

**C. "The type of record requested," "the information it does or might contain," and the "potential for harm in any subsequent nonconsensual disclosure" are outweighed by the need for the information.**

The Government is skeptical that factors 1, 2, and 3 should be weighed as three separate factors. In this matter, as will almost always be the case, the three factors are essentially identical: the HIPAA subpoena requests sensitive health information about children, gender, and



sexuality (factor 1), the records do in fact likely contain sensitive information (factor 2), and—because the information is sensitive—disclosures could cause embarrassment or harm (factor 3).

The Government does not quibble with the sensitivity of the patient information involved in this subpoena. The disagreement is rather with CHOP’s characterization and balancing of these three factors, which CHOP seems to believe are all but dispositive because of the controversies surrounding gender-related care for minors. But CHOP’s lengthy and repeated invocations about the sensitivity of this information prove too much.

CHOP chooses to bankroll and run a specialty clinic that provides controversial pharmaceutical and surgical care for minors, and it is unclear how CHOP believes the Government can investigate violations of federal law in the context of “sensitive” areas of medicine—which are plentiful—without having the *Westinghouse* factors weighing strongly against it at the outset. The Government cannot investigate, for example, the provision of pharmaceuticals to minors without obtaining records of pharmaceuticals provided to minors.

Indeed, CHOP seems to believe that if a provider operates in a “sensitive” area of medicine, that medical provider should also operate in a zone of impunity where the Government is unable to subpoena the actual records of treatment of patients. That is plainly not the law: Plaintiffs can cite no constitutional provision, statute, or even case categorically exempting sensitive medical practices broadly from investigation. Indeed, those are precisely the sort of practices that are most likely to merit investigation.

Contrary to CHOP’s suggestions, in this investigation, the sensitivity of the records actually militates in favor of disclosure, not against it—because the consequences to children of unlawful practices in gender-related care practices are potentially so severe. Justice Thomas’ recent concurrence in *Skrametti* lays out numerous concerning pieces of evidence suggesting that gender-related care for minors in the United States is rife with potential consumer-protection

violations: false statements made to induce patient and parental consent to off-label drug use and other life-altering procedures; powerful pharmaceuticals casually being given off-label to very young minors, causing lifelong side effects; purported treatment guidelines based on false or insufficient evidence; and other alarming trends that the Executive Branch could reasonably believe deserve exploration. *Skrmetti*, 145 S. Ct. at 1845-49.

Although CHOP tells the Court in a declaration that everything is fine at its clinic, the entire point of conducting an investigation is that the Government need not take CHOP's word that it is not violating federal law, and may use the subpoena power that Congress gave the Attorney General to determine the veracity of CHOP's representations. *United States v. Oncology Servs. Corp.*, 60 F.3d 1015, 1019 (3d Cir. 1995) (citing *United States v. Morton Salt Co.*, 338 U.S. 632, 643 (1950)) ("When investigative duties are delegated by statute to an agency, it may take steps to inform itself as to whether there is a probable violation of the law."). In sum, CHOP's showing on the first three *Westinghouse* factors is entirely outweighed by the need for the records and the Government's interest in preventing potential lifelong consequences to children. Furthermore, the Government is willing to work with CHOP to minimize the impact on vulnerable patients, such as by accepting anonymized records as a first pass with the potential for obtaining more information on specific records should the need arise.

**D. "[T]he injury from disclosure to the relationship in which the record was generated" is at least neutral.**

The fourth factor looks at the relationship between the patient and the entity that created the medical record. This factor is similar to the first three in that it will almost always militate against disclosure of patient records to the Government by providers—because a medical provider will always be able to say that its relationship with its patients will be affected by it

having to produce patient files to the Government.<sup>4</sup> Similar to the lack of insight given by the first three factors, this means that in any case involving a sensitive area of medicine, the Government has four out of seven *Westinghouse* factors weighing against it before subpoena enforcement even begins. This would create an “exception” to HIPAA subpoena enforcement that would essentially swallow the rule. *EEOC v. Am. Exp. Centurion Bank*, 758 F. Supp. 217, 221 (D. Del. 1991) (“[T]he federal courts are and should be most cautious about interfering with the investigative power delegated by Congress to agencies[.]”).

Although the Government does not doubt that the relationship between CHOP and its patients might be somehow affected by CHOP being investigated and thus having to provide its patients’ medical records to the Government, there is no meaningful way to test this speculation. This assertion would also be true in nearly every health care investigation of any medical provider. The fourth factor should be weighed as neutral here, as it should in any Government investigation of a medical provider.

In sum, CHOP’s potential showing on the first four factors—which are really just one factor—is clearly outweighed by the Government’s need for patient records in order to investigate—pursuant to a statutory mandate—expressly prohibited potential misconduct in the healthcare field, in this case involving lifelong consequences to vulnerable minors. And if this issue still hangs in the balance—it should not—the statutory privacy protections resolve any doubt in the Government’s favor. A conclusion to the contrary would hamstring the Government’s ability to carry out its statutorily authorized mandate to investigate misconduct relating to healthcare.

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<sup>4</sup> The only realistic scenario in which factor four would not weigh against the Government is something like *Westinghouse* itself, where the record was created or held by an employer or some other non-medical entity.

## CONCLUSION

For the reasons explained above, the United States respectfully requests that the Court deny CHOP's motion in its entirety. The government stands ready and willing to meet and confer with the hospital about practical ways to mitigate its concerns about patient privacy.

Dated this 4<sup>th</sup> day of August, 2025.

Respectfully submitted,

**FOR THE UNITED STATES OF AMERICA**

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Assistant Attorney General

JORDAN C. CAMPBELL  
Deputy Assistant Attorney General

SARMAD KHOJASTEH  
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### **CERTIFICATE OF SERVICE**

I hereby certify that I caused this document to be filed electronically with the Court's CM/ECF system and is available for viewing and downloading from the CM/ECF system; the CM/ECF system will serve it on all counsel of record by operation of the CM/ECF system this 4<sup>th</sup> day of August, 2025.

/s/ Ross S. Goldstein  
ROSS S. GOLDSTEIN

**UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF PENNSYLVANIA**

**IN RE: 2025 UPMC SUBPOENA**

MISCELLANEOUS ACTION

Case No. 2:25-mc-1069-CB

**GOVERNMENT’S SUPPLEMENTAL BRIEF**

The United States submits this supplemental brief pursuant to the Court’s order of December 24, 2025. ECF 52. Respectfully, the plaintiffs now lack Article III standing, which means the Court now lacks jurisdiction. Accordingly, the Court should dismiss this action, thereby allowing UPMC to produce to the Government de-identified information that does not impinge in any way on plaintiffs’ privacy interests. Even if the action is not fully moot, the application of the *Westinghouse* factors as to de-identified records now weighs strongly in favor of the Government. Hence, the Court should make clear in its order dismissing this action that UPMC is permitted to comply with all specifications of the subpoena in full as long as all patient information provided is de-identified pursuant to HIPAA’s de-identification procedures.

**BACKGROUND**

UPMC has not filed a motion to quash the instant subpoena, and the anonymous plaintiffs in this matter sought relief only as to patient identities, health information, and records. Prior to plaintiffs filing suit, the Government conferred with UPMC counsel and agreed that the Government would accept de-identified patient records in a first wave of productions, with the parties delaying until after such data was produced the question of whether any unredacted data would be produced. UPMC had not yet produced any identified or de-identified patient records

or information prior to plaintiffs filing suit and have not produced any such material since due to the pendency of this action. ECF 40-1.

On December 15, 2025, the Government revised its agreement with UPMC counsel so that the subpoena would be fully satisfied by production of only de-identified records, so that no individual patient could be identified to the Government. ECF 47. The Government made this concession in part to address the privacy concerns that animated plaintiffs' lawsuit. *Id.*; *see* ECF 2 at 8 (citing the government's "intrusion into [patients'] privacy"). The Government has also promised to inform the plaintiffs if the Government issues another HIPAA subpoena seeking patient records to UPMC, which the Government has no current plans to do. ECF 47. The Government informed the Court on December 16 of its withdrawal of the requests for identified patient information. *Id.*

On December 24, 2025, the Court issued an order quashing requests 11-13 as to unredacted records and finding standing on a "zone of interests" theory. ECF 52. The Court also granted the Government's Motion to Allow Supplemental Briefing and invited the parties to provide additional briefing on the question of de-identified patient records, "as envisioned in the government's Motion (Doc. 47) to supplement." *Id.* In a conference after the Court's December 24 order, UPMC counsel and the Government discussed the de-identification of material that could be produced pursuant to the outstanding requests in the subpoena. UPMC promised to de-identify any material provided to the Government, and that it would follow the specific HIPAA regulations that govern how a medical provider should de-identify patient records so that dissemination of such records would not implicate HIPAA privacy provisions.

## ARGUMENT

### 1. The Plaintiffs Lack Standing and the Suit Is Moot

The agreement between UPMC and the Government concerning the production of de-identified patient records deprives plaintiffs of any Article III standing they may have had, and this lawsuit should be dismissed as moot.

“It is axiomatic that standing to sue is a prerequisite to Article III jurisdiction.” *Kerchner v. Obama*, 612 F.3d 204, 207 (3d Cir. 2010). The constitutional requirement of standing requires that a plaintiff have: “(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision.” *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016). The plaintiff “bears the burden of establishing these elements.” *Id.* “An injury in fact is an invasion of a legally protected interest which is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical.” *Berg v. Obama*, 586 F.3d 234, 239 (3d Cir. 2009).

Article III “requires that a plaintiff’s claim be live not just when he first brings the suit but throughout the entire litigation.” *Lusardi v. Xerox Corp.*, 975 F.2d 964, 974 (3d Cir. 1992); *see Spencer v. Kemna*, 523 U.S. 1, 7 (1998) (“[T]hroughout the litigation, the plaintiff must have suffered, or be threatened with, an actual injury traceable to the defendant and likely to be redressed by a favorable judicial decision.” (quotation omitted)). A case is moot when “there is no longer a live controversy.” *Hartnett v. Pa. State Educ. Ass’n*, 963 F.3d 301, 306 (3d Cir. 2020). “For a case to be moot in the Article III sense, all plaintiffs who once had Article III standing must have lost it, and none of the recognized exceptions to mootness”—as relevant here, voluntary cessation and conduct capable of repetition yet evading review—“can apply.” *Gulden v. Exxon Mobil Corp.*, 119 F.4th 299, 305 (3d Cir. 2024). Plaintiffs no longer have



standing and neither exception to mootness applies, meaning that this case is no longer justiciable.

#### **A. Plaintiffs Lack Standing**

The Government's agreement with UPMC deprives plaintiffs of standing. The de-identification of medical records has legal significance; the vast weight of authority recognizes that patients do not have legally cognizable privacy interests in de-identified medical records. *In re NHL Players' Concussion Injury Litig.*, 120 F. Supp. 3d 942, 955 (D. Minn. 2015) ("Once the identifying information is removed from the record, the patient's privacy interest is essentially eliminated.") (collecting cases); *United States ex rel. Roberts v. QHG of Ind., Inc.*, 1998 U.S. Dist. LEXIS 23512, at \*29-30 (N.D. Ind. Oct. 8, 1998) ("[T]he privacy interests of a patient in his or her medical records is tied to identity information contained in the records").

HIPAA regulations and HHS guidance describe in extreme detail what information must be redacted before a medical record can be shared without violating HIPAA. *See* 45 C.F.R. § 164.502(d); HHS OCR, "Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with [HIPAA]" (Nov. 26, 2012) (attached as Ex. A). Veteran counsel for UPMC—who has extensive experience in healthcare investigations—has represented that UPMC will diligently perform this de-identification.<sup>1</sup>

The plaintiffs' privacy interest in a *de-identified* medical record is—by definition—not "concrete and particularized." *See Berg v. Obama*, 586 F.3d 234, 239 (3d Cir. 2009). Because the record is de-identified under the relevant HIPAA regulation and could legally—after de-

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<sup>1</sup> The States' assertions in their amicus brief (filed today) that patient records cannot actually be de-identified is belied by federal law, 45 C.F.R. § 164.502(d), and by the rigorous methods discussed in Exhibit A. The States also base this argument on facially incorrect and fact-free assertions that the Government is asking for a simple redaction of "name, address, [and] Social Security number." ECF 55-1 at 13.

identification—be shared with *anyone*, there is no cognizable injury. *See* Ex. A at 29 (“The Privacy Rule does not limit how a covered entity may disclose information that has been de-identified.”). There is also no way for any third party to reliably identify whether a concrete or particularized injury has even occurred, and the plaintiffs’ claims therefore become a “generalized grievance” about the fact that a de-identified record somewhere, possibly related to them, has been disclosed to someone who is unable to determine to whom the record relates. *See Carney v. Adams*, 592 U.S. 53, 60 (2020) (recognizing that a “generalized grievance” is insufficient for purposes of Article III standing). This is simply insufficient as a matter of law to support standing because it is not recognized by the law as a cognizable privacy interest.<sup>2</sup> *C.N. v. Ridgewood Bd. of Educ.*, 430 F.3d 159, 180 (3d Cir. 2005) (“The cases in which a disclosure-based privacy violation has been found involve situations where there was either actual identification or the disclosure of identifying information such as would allow the individual to be identified and ultimately connected to his or her private information.”); *Dinerstein v. Google, LLC*, 73 F.4th 502, 513 (7th Cir. 2023) (discussing modern Article III jurisprudence and stating that “the dissemination of anonymized [medical] information” likely did not “give rise to any injury at all—let alone one concrete enough to support Article III standing”).

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<sup>2</sup> *Northwestern Memorial Hospital v. Ashcroft*, 362 F.3d 923 (7th Cir. 2004), is not to the contrary. First, that case does not present the standing question here because the subpoena recipient hospital there challenged the trial subpoena at issue and clearly had standing to do so. Second, Judge Posner apparently mistook what de-identifying a medical record entails, because the example he gave—of a photograph of a naked patient—would not pass the HIPAA de-identification test. Ex. A at 8 (requiring removal of “full-face photographs and any comparable images”). Finally, the irony of plaintiffs citing *Northwestern Memorial Hospital* would be that Judge Posner stated in dicta that HIPAA subpoenas appear to “override the HIPAA regulations,” meaning that Judge Posner believed the Government would have been able to obtain the challenged records in that case via the exact type of subpoena at issue here. 362 F.3d at 925.

Furthermore, the harm from the disclosure of a de-identified record is entirely conjectural and hypothetical, because a de-identified record does not invade any specific patient’s zone of privacy, and a generalized preference that a de-identified record not be produced is simply not enough to support standing. If anyone who prefers that a document that is meaningful to them in the hands of a third party not be produced to the Government has standing to sue the Government to prevent disclosure, virtually any law enforcement subpoena could be easily overcome. That is simply not what black-letter law says about administrative subpoenas, which are supposed to allow broad disclosure akin to a grand jury subpoena. *In re Grand Jury Proceedings*, 486 F.2d 85, 90 (3d Cir. 1973) (“[A]n administrative subpoena and a grand jury subpoena perform[] essentially the same function[.]”). And as the Fourth Circuit has noted in a case involving a HIPAA subpoena like the one at issue here, the disclosure of some amount of patient information is simply part of our modern system of medicine for multiple reasons, including the fact that (as here) patients apparently agreed to have their medical records released to insurance companies and others.<sup>3</sup> *United States v. Bailey (In re Subpoena Duces Tecum)*, 228 F.3d 341, 351 (4th Cir. 2000); Ex. B.

Just as plaintiffs have proceeded anonymously in this Court to protect their privacy, their privacy interests are similarly safeguarded by the Government's concession that it will not obtain any identifying health information of any patients at UPMC pursuant to this subpoena, let alone any PHI of the four anonymous plaintiffs. Because nothing produced under the subpoena will implicate any patients' specific privacy interest, the anonymous plaintiffs lack an injury-in-fact

<sup>3</sup> UPMC documents suggest that UPMC patients—which would include plaintiffs—understand and consent in some form to their *identified* medical records being shared with, among others, the Government via a subpoena—as well as with a list of about a dozen other types of entities. *See* Notice of Privacy Practices (Ex. B); Patient Agreement (Ex. C).

sufficient to support standing to file a suit against the United States and to challenge a duly authorized subpoena that the subpoena recipient itself has not challenged. Lastly, to the extent that plaintiffs claim that even de-identified patient records could somehow nevertheless betray their identity due to the nature of the treatment provided, such “argument rests on [] highly speculative fear” that “does not satisfy the requirement that threatened injury must be certainly impending.” *See Clapper v. Amnesty Int’l USA*, 568 U.S. 398, 410 (2013).

### **B. The Case Is Moot**

“In light of [plaintiffs’] current lack of Article III standing, this case is moot [because] no exception to a dismissal on mootness grounds applies.” *Gulden*, 119 F.4th at 308. There are two possible exceptions to dismissal: voluntary-cessation and capable-of-repetition-yet-evading-review. The voluntary-cessation exception ensures that a defendant is unable to “suspend its challenged conduct after being sued, win dismissal, and later pick up where it left off.” *Fed. Bureau of Investigation v. Fikre*, 601 U.S. 234, 241 (2024). The exception does not apply here because, under the agreement with UPMC, the Government does not “remain[] ‘free to return to [its] old ways.’” *Id.* (quoting *United States v. W.T. Grant Co.*, 345 U.S. 629, 632 (1953)). In other words, because UPMC will provide only de-identified documents, the Government’s “challenged conduct” will not, and cannot, resume “as soon as the case is dismissed.” *Knox v. Serv. Emps. Int’l Union, Loc. 1000*, 567 U.S. 298, 307 (2012). The Government has no “plan[s] to reinstate” its request for identified patient records in the future and cannot “reasonably be expected to engage in the challenged behavior again.” *Hartnett*, 963 F.3d at 306; *see Fikre*, 601 U.S. at 241 (“[O]ur precedents hold [that] a defendant’s voluntary cessation of a challenged practice will moot a case only if the defendant can show that the practice cannot reasonably be

expected to recur.” (quotation omitted)). Therefore, the voluntary-cessation exception does not apply.

The “capable-of-repetition-yet-evading-review exception does not apply here either.” *Gulden*, 119 F.4th at 309. This is because there is no “reasonable expectation” or “demonstrated probability” that the “*same* controversy will recur involving the *same* complaining party.” *FEC v. Wis. Right to Life, Inc.*, 551 U.S. 449, 463 (2007); see *City of Los Angeles v. Lyons*, 461 U.S. 95, 109 (1983) (“[T]he capable-of-repetition doctrine applies only in exceptional situations, and generally only where the named plaintiff can make a reasonable showing that he will again be subjected to the alleged illegality.”). Because of the Government’s agreement with UPMC, among other things, the four anonymous plaintiffs cannot demonstrate that the Government will again seek their identifying information via a HIPAA subpoena. This is not an “exceptional” situation; the exception does not apply.

Because of the agreement to accept de-identified records and information deprived plaintiffs of any Article III standing they may have had, this case was moot before the Court entered its prior order. The Court should therefore vacate its prior order and dismiss the case for lack of jurisdiction.

**2. These Plaintiffs Do Not Have Standing to Assert the Rights of Other Patients or Seek Full Quashal**

To the extent the Court finds that this case is not moot or performs a *Westinghouse* balancing test in any forthcoming order, the Court should limit such relief to the four plaintiffs in this action. Although this issue was in the Government’s opening brief, the Court did not address it in the December 24 order. However, the agreement with UPMC further cements what was already clear: these four anonymous plaintiffs—to the extent they have standing to do anything at all—do not have standing to prevent UPMC from disclosing *other patients’* de-identified

records. *California v. Texas*, 593 U.S. 659, 672 (2021) (stating that remedies “operate with respect to specific parties”); *Curry v. United States*, 192 F.2d 571, 572 (5th Cir. 1951) (“[A plaintiff] can not vicariously assert the constitutional rights of others who do not complain.”). Even accepting the incorrect notion that these four patients could somehow assert the legal rights of hundreds or thousands of other patients as to unredacted records, that right becomes nonsensical when applied to de-identified records of other patients that could legally be shared with anyone.

Also, even if the Court concludes the case remains justiciable, it should, at the least, limit the scope of its order to identified patient records. This is only relief necessary to redress the stated privacy injury, and federal courts are powerless to provide anything more. *See Lewis v. Casey*, 518 U.S. 343, 357 (1996) (“The remedy must of course be limited to the inadequacy that produced the injury in fact that the plaintiff has established.”). To the extent that the plaintiffs contend UPMC could make redaction mistakes while de-identifying their records, the Government’s proposed order allows UPMC to share the de-identified records of the four plaintiffs privately with those patients in a reasonable, time-limited procedure where they can identify any redaction concerns prior to the records being turned over to the Government.

### **3. Even if Plaintiffs Have Marginal Standing, the *Westinghouse* Test Now Strongly Favors the Government**

Should the Court still determine that these four plaintiffs do have standing as to their own de-identified medical records, their *Westinghouse*-based arguments now fall flat, and the Court should require the production of de-identified records and information. First, even accepting the incorrect idea that *Westinghouse* applies to the Government’s original HIPAA subpoena issued pursuant to 18 U.S.C. § 3486—a statute that Congress passed 16 years after *Westinghouse* to allow the Government to obtain medical records in order to investigate federal healthcare

offenses, as it is attempting to do here—*Westinghouse* should not apply at all to a request for de-identified patient records, because a de-identified record does not raise any of the privacy concerns that animated *Westinghouse* in the first place.

Moreover, this Court is not writing on a blank slate here, because the Third Circuit, in a published opinion, has already rejected a *Westinghouse*-based privacy challenge to the disclosure of very sensitive but anonymized information related to minors. In *C.N. v. Ridgewood Board. of Education*, a school district asked high-school students to take an anonymous survey on sensitive topics such as drug use and sexual activity, and then released the results of the survey to the public. 430 F.3d at 161-64. Parents sued under a number of constitutional and federal statutory privacy theories. *Id.* Applying *Westinghouse* balancing, the Third Circuit rejected the challenges to the release of the information and found that the effective anonymization of the survey responses lessened the plaintiff’s showing on “the privacy side of the balance”—which the court described as “the first five factors” of the *Westinghouse* test—to the extent that the disclosure was permissible under *Westinghouse*. *Id.* at 180-82. So too here.

The seven *Westinghouse* factors are: (1) the type of record requested; (2) the information it does or might contain; (3) the potential for harm in any subsequent nonconsensual disclosure; (4) the injury from disclosure to the relationship in which the record was generated; (5) the adequacy of safeguards to prevent unauthorized disclosure; (6) the degree of need for access; and (7) whether there is an express statutory mandate, articulated public policy, or other recognizable public interest favoring access. *Doe v. SEPTA*, 72 F.3d 1133, 1140 (3d Cir. 1995).

Under the first three *Westinghouse* factors, and as described in an analogous situation in the district court opinion that the Third Circuit affirmed in *C.N.*, the nature of a de-identified medical record is simply not the same as an unredacted record and does not raise the same

privacy concerns. *C.N. v. Ridgewood Bd. of Educ.*, 319 F. Supp. 2d 483, 495 (D.N.J. 2004) (“[A]s already discussed there was no actual disclosure, at least in such a form that could produce harm in an individual.”). The overwhelming weight of authority recognizes that patients’ privacy interests are tied to personally identifiable information contained in medical records—which renders factors one, two, and three strongly to favor the Government.

Specifically on factor one, the “type of record” now requested is a fully de-identified record over which numerous courts have recognized there are no patient privacy interests at all and that can be shared with anyone. On factor two, the information the record might contain is de-identified medical procedure documentation that cannot be traced to an individual patient. As to factor three, the HIPAA regulations themselves—through requiring providers to redact the exact same personal information that will be redacted here—reflect that the disclosure of de-identified medical records do not cause the type of privacy harm that *Westinghouse* recognized.

On factor four, which is the harm to the relationship between the patients and UPMC, there are three facts that favor the Government despite the patients’ anticipated concerns about disclosure. First, UPMC has ceased providing puberty-blocker medications, cross-sex hormones, and surgeries for minors with gender dysphoria, meaning that there will be no harm to any ongoing relationship between the patients and UPMC related to the care at issue. Second, UPMC patients apparently agreed that UPMC could share medical records in response to subpoenas, as noted above and in the attached Exhibits. And third, due to the fact that de-identified medical records have no HIPAA protection and there is no legal impediment to sharing them, also as described above, the patients’ subjective concerns about their relationship with UPMC providers are not objectively reasonable—because de-identified medical records are



shared by healthcare providers on a regular basis for a variety of purposes. *Bailey*, 228 F.3d 341 at 351.

Factor five, which is the risk of “inadvertent disclosure,” also strongly weighs in favor of the government here, because after a HIPAA-compliant redaction to a patient record, UPMC would be legally permitted to disclose the de-identified record without any HIPAA constraints. It is hard to understand how the Government—which is under a legal obligation to maintain the privacy of the patient information it obtains via these subpoenas, 18 U.S.C. § 3486(e)—could be faulted for the theoretical possibility of a leak when the record could be publicly disclosed without running afoul of the law.

On factor six, which considers “the need for access,” this subpoena was issued as part of an investigation into *health care providers* and *pharmaceutical companies* promoting and getting paid for controversial, potentially life-altering *drugs* and *surgeries*—care that has been banned or curtailed in multiple Western European countries as ineffective and potentially harmful. The Government simply cannot investigate whether an expensive, name-brand, FDA-regulated pharmaceutical was misbranded when delivered to a patient—which can happen, among other things, when the drug is promoted by a pharmaceutical company for an off-label use—without looking at the circumstances under which the expensive, name-brand, FDA-regulated pharmaceutical was delivered to the patient. The idea that the federal government is not permitted to investigate what happened to (anonymous) patients who received adulterated or misbranded FDA-regulated pharmaceuticals—simply because there is sustained political opposition to this investigation—is incorrect. The Government has a need for these materials to continue a lawful investigation that has been ordered by the Attorney General of the United States. And finally, on factor seven, the subpoena was issued pursuant to an express statutory



### **CERTIFICATE OF SERVICE**

I hereby certify that on January 16, 2026, I served the foregoing Supplemental Brief via ECF to counsel of record.

Dated this 16th day of January 2026.

/s/ Patrick Runkle  
PATRICK RUNKLE

**UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF PENNSYLVANIA**

**IN RE: 2025 UPMC SUBPOENA**

MISCELLANEOUS ACTION

Case No. 2:25-mc-1069-CB

**PROPOSED ORDER**

Whereas the Government has agreed with UPMC counsel that the subpoena will be fully satisfied by production of only de-identified records, so that no individual patient will be identified to the Government;

Whereas the Government has committed to inform the plaintiffs if it seeks to obtain their unredacted medical records via another HIPAA subpoena;

Whereas the Court recognizes that UPMC will allow the plaintiffs, if they so choose, to see the de-identified versions of their own medical records (and any other documents that have been de-identified that mention the plaintiffs) at least 14 days prior to UPMC turning those documents over to the Government, and will reasonably address any concerns about the de-identification of the plaintiffs' records.

Based on these recitations, the Court finds that this action is now moot and DISMISSES it without prejudice for lack of jurisdiction. The Court therefore VACATES its prior order entered on December 24, 2025. UPMC is permitted to comply with all specifications of the subpoena in full, and the subpoena is MODIFIED based on the Government's agreement with UPMC so that all patient-related information provided pursuant to this subpoena is fully de-identified pursuant to the relevant HIPAA de-identification procedures.

JA269

## ***In Re 2025 Children's Hospital of Los Angeles Subpoena***

### **SETTLEMENT AGREEMENT**

This Settlement Agreement is entered into between Moving Parties Parents AA, BB1, BB2, CC, DD, and EE and Legal Guardian FF (collectively, "Moving Parties") and Respondent United States of America ("United States" or the "Government"), parties to *In Re 2025 Children's Hospital of Los Angeles Subpoena*, No. 2:25-cv-11183-MWC-JDE (C.D. Cal.) ("the Action").

### **RECITALS**

1. On or around June 11, 2025, the Government issued a Subpoena to Children's Hospital of Los Angeles demanding the production of documents related to the provision of gender-related care for patients under the age of 18. A true and correct copy of the Subpoena is attached as Exhibit A.

2. Among the items sought by the Government in the subpoena were the following:

**Request 11:** "Documents sufficient to identify each patient (by name, date of birth, social security number, address, and parent/guardian information) who was prescribed puberty blockers or hormone therapy."

**Request 12:** "For each such patient identified in Subpoena [Request 11], documents relating to the clinical indications, diagnoses, or assessments that formed the basis for prescribing puberty blockers or hormone therapy."

**Request 13:** "All documents relating to informed consent, patient intake, and parent or guardian authorization for minor patients identified in [Request 11], including any disclosures about off-label use (i.e., uses not approved by the United States Food and Drug Administration) and potential risks."

3. The Subpoena also contained requests for items that could contain patient-identifying information, including the following:

**Request 2:** "All documents, including billing records, insurance claims, internal protocols, or guidance, concerning the use of ICD (i.e., International Classification of Diseases) diagnosis codes in connection with the treatment of minor patients receiving gender-related care."

**Request 4:** “All documents reflecting communications among Company employees (including physicians, billing staff, and administrators), or between the Company and any third party, relating to whether or how to code or bill for treatment of gender dysphoria by using alternative diagnoses or alternative ICD Codes.”

**Request 15:** “All documents relating to any adverse event, side effect, or medically unfavorable consequence or outcome in a minor patient with regard to gender-related care.”

4. The Government has represented that the purpose of the Subpoena is to investigate potential incidents of violations of the Food, Drug, and Cosmetic Act (FDCA) and related offenses. DOJ is not currently aware of information that would support the federal prosecution of parents or guardians who have sought and consented to receiving gender-related care for their children at Children’s Hospital of Los Angeles.

5. On November 21, 2025, Moving Parties, as parents and legal guardians of former patients at Children’s Hospital Los Angeles’s Center for Transyouth Health and Development, filed a Motion to Quash Administrative Subpoena, Motion to Proceed Under Pseudonym, and Motion for Class Certification and Appointment of Class Counsel.

6. On December 8, 2025, the Government instructed Children’s Hospital of Los Angeles—and Children’s Hospital of Los Angeles agreed—to redact any patient identifying information in records that are produced in response to the Subpoena, and withdrew Subpoena Requests 11, 12, and 13 in their entirety. A true and correct copy of the withdrawal is attached as Exhibit B.

7. As of the date of this Agreement, the Government has not received any document from Children’s Hospital Los Angeles in response to Requests 11, 12, and 13, and further, the Government has not received any document from Children’s Hospital Los Angeles in response to the Subpoena that contains patient identifying information.

8. As of the date of this Agreement, the Government has not issued another subpoena to Children’s Hospital Los Angeles or its related entities for records involving patient identifying information such as those described in Requests 11, 12, and 13 and does not currently plan to do so.

9. The Parties now desire to settle Moving Parties' Motion to Quash Administrative Subpoena, Motion to Proceed Under Pseudonym, and Motion for Class Certification and Appointment of Class Counsel.

## AGREEMENT

In consideration of the Recitals above, the Parties agree as follows:

A. **Patient identifying information** means all individually identifiable health information as defined in the HIPAA Privacy Rule, 45 C.F.R. § 160.103:

Information that is a subset of health information, including demographic information collected from an individual and:

(1) Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and

(2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and

(i) That identifies the individual; or

(ii) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.

B. **Redaction** means removing patient identifying information or replacing patient identifying information with a unique code.

C. At a minimum, the Government shall require Children's Hospital of Los Angeles to redact the following patient identifying information from records produced in response to the Subpoena, following the HIPAA Privacy Rule, 45 C.F.R. § 164.514(b)(2)(i):

1. The following identifiers of the individual or of relatives, employers, or household members of the individual:
  - (A) Names;



- (B) All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:
  - (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and
  - (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000;
- (C) All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
- (D) Telephone numbers;
- (E) Fax numbers;
- (F) Electronic mail addresses;
- (G) Social security numbers;
- (H) Medical record numbers;
- (I) Health plan beneficiary numbers;
- (J) Account numbers;
- (K) Certificate/license numbers;
- (L) Vehicle identifiers and serial numbers, including license plate numbers;
- (M) Device identifiers and serial numbers;
- (N) Web Universal Resource Locators (URLs);
- (O) Internet Protocol (IP) address numbers;
- (P) Biometric identifiers, including finger and voice prints;
- (Q) Full face photographic images and any comparable images; and
- (R) Any other unique identifying number, characteristic, or code, except when the hospital assigns a code or other means of record identification to allow information de-identified to be re-identified by the hospital, provided that this process follows de-identification requirements under 45 C.F.R. § 164.514(c)

D. If the Government receives a document in response to the Subpoena that contains patient identifying information, the Government shall make

all reasonable efforts to ensure it does not have access to the document thereafter, including by returning the document to Children's Hospital of Los Angeles or destroying the document in a secure manner. The Government will not use this patient identifying information to support any investigation or prosecution.

E. If the Government receives patient identifying information from Children's Hospital of Los Angeles in response to the Subpoena, the Government shall, within three (3) calendar days of learning of the receipt of this information, inform Moving Parties' counsel by email at [htran@wclp.org](mailto:htran@wclp.org), [amy@lawyersforgoodgovernment.org](mailto:amy@lawyersforgoodgovernment.org), and [lrifkin@impactfund.org](mailto:lrifkin@impactfund.org), or to other attorneys designated by these organizations.

F. If, at any time before February 1, 2029, the Government plans (1) to issue to Children's Hospital of Los Angeles a new subpoena with the above-mentioned Requests 11, 12, and 13; (2) to rescind its instructions to Children's Hospital of Los Angeles to redact any patient identifying information in records that are produced in response to the Subpoena as described in the above-mentioned Paragraph 6; and/or (3) to issue a new subpoena to any entity or person that requests documents or items related to the provision of gender related care by Children's Hospital Los Angeles that contains patient-identifying information, the Government shall, to the extent such advance notice is legally permitted, provide advance email notice to Moving Parties' counsel at least 28 calendar days prior to taking the foregoing actions. The Government will email Moving Parties' counsel at [htran@wclp.org](mailto:htran@wclp.org), [amy@lawyersforgoodgovernment.org](mailto:amy@lawyersforgoodgovernment.org), and [lrifkin@impactfund.org](mailto:lrifkin@impactfund.org), or to other attorneys designated as their replacements by the Moving Parties. The parties acknowledge that, this provision of the Agreement notwithstanding, Rule 6(e) of the Federal Rules of Criminal Procedure prohibits the Government from "disclos[ing] a matter occurring before the grand jury" to Moving Parties or their counsel. The parties mutually understand that HIPAA does not prohibit the advance notice contemplated in this Paragraph.

G. Within 14 days of the date that the Agreement is fully executed, Moving Parties shall file the Notice of Dismissal attached as Exhibit C, dismissing the Action without prejudice, and attaching this executed Agreement.

H. The Parties shall bear their own fees and costs.

I. The Agreement, including exhibits, constitutes a single, integrated written contract and describes the entire agreement of the Parties resolving this matter.

J. The Agreement may be executed in counterparts, including documents exchanged by electronic mail, all of which together shall constitute a single, unified document.

K. In any claim to construe the terms of the Agreement, this Agreement shall be considered the product of negotiation by and among the parties hereto. No clause or provision shall be interpreted more strongly in favor or against one party of the other, based upon the source of the draftsmanship, but shall be interpreted in a neutral manner.

L. Each signatory to this Agreement represents and warrants that they are fully authorized to enter into this Agreement on behalf of the persons or entities indicated below, and has done so freely and voluntarily, without any degree of duress or compulsion. This Agreement is effective when executed by all of the undersigned.

## **AGREED AND ACCEPTED**

**FOR MOVING PARTIES Parent AA, Parents BB1 & BB2, Parent CC,  
Parent DD, Parent EE, and Legal Guardian FF:**



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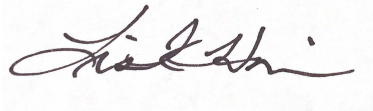
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**FOR RESPONDENT UNITED STATES OF AMERICA:**

Department of Justice  
Enforcement and Affirmative Litigation Branch



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UNITED STATES OF AMERICA  
DEPARTMENT OF JUSTICE

SUBPOENA DUCES TECUM

No. 25-1431-013

To: Children's Hospital Los Angeles  
4650 Sunset Boulevard  
Los Angeles, California 90027

*YOU ARE HEREBY COMMANDED TO APPEAR BEFORE Patrick Runkle, Ross Goldstein, and/or Francisco Unger, officials of the United States Department of Justice, and you are hereby required to bring with you and produce the following:*

Please see Attachment A

*which are necessary in the performance of the responsibility of the United States Department of Justice to investigate Federal health care offenses as defined in 18 U.S.C. § 24(a).*

*Please contact Assistant Director Patrick Runkle, Assistant Director Ross Goldstein, or Trial Attorney Francisco Unger at 202-616-0295 if you have any questions regarding this Subpoena Duces Tecum.*

PLACE AND TIME FOR APPEARANCE:

United States Attorney's Office, 312 North Spring Street, Los Angeles, California  
on Wednesday, the 9<sup>th</sup> day of July, 2025, at ten o'clock a.m.

---

Failure to comply with the requirements of this subpoena will render you liable to proceedings in the district court of the United States to enforce obedience to the requirements of this subpoena, and to punish default or disobedience.

---

Issued under authority of Section 248 of the Health Insurance Portability & Accountability Act of 1996,  
Public Law No. 104-91 (18 U.S.C. § 3486)



IN TESTIMONY WHEREOF

Brett A. Shumate, Assistant Attorney General, the undersigned official of the United States Department of Justice, has set his hand this 11<sup>th</sup> day June, 2025.

**BRETT  
SHUMATE**

(signature)

Digitally signed by BRETT  
SHUMATE  
Date: 2025.06.11  
12:04:40 -04'00'

## RETURN OF SERVICE

*I, being a person over 18 years of age, hereby certify that a copy of this subpoena was duly served on the person named herein by means of:*

*1. Personal delivery to an individual, to wit:*

(name)

(title)

(address)

**2. *Personal delivery to an address, to wit:***

*(description of premises)*

$$(address)$$

3. *Registered or certified mailing to:*

(name)

$$(address)$$

At \_\_\_\_\_ a.m. | p.m. on \_\_\_\_\_

(date)

(signature)

(title)

UNITED STATES OF AMERICA  
DEPARTMENT OF JUSTICE

JA278

# SUBPOENA DUCES TECUM

*Upon contumacy or refusal to obey, this subpoena shall be enforced by order of the appropriate United States District Court.*

## **ATTACHMENT A TO SUBPOENA TO:**

CHILDREN'S HOSPITAL LOS ANGELES  
4650 SUNSET BOULEVARD  
LOS ANGELES, CALIFORNIA 90027

### **I. DEFINITIONS**

1. "You," "Your Company," "the Company," and "CHLA" means:
  - a. Children's Hospital Los Angeles, a California nonprofit public benefit corporation, whose principal place of business is located at 4650 Sunset Boulevard, Los Angeles, California, without regard to any name under which it has done business;
  - b. All of its predecessors, subsidiaries, affiliates, branches, divisions, groups, business units, business segments, operations, units, parent organizations, successors, assigns, plants, and any joint ventures of which they were or are a part, including without limitation the Center for Transyouth Health and Development; and
  - c. Each of its present or former officers, directors, employees, attorneys, representatives, and agents acting or purporting to act or appearing to act on behalf of the Company, whether or not acting within the proper scope of his or her actual authority.
2. "Employee" means any person including, but not limited to, any independent contractor or agent, all past and present directors, officers, agents, representatives, attorneys, accountants, advisors, and consultants who acted or purported to act on behalf of the Company or who have performed any service for the Company or under its name, whether on a full-time, part-time, piece-work, commission, volunteer, or other basis, and whether paid or unpaid.
3. "Document" should be afforded the broadest possible meaning and includes every writing or record of whatever type or description, including but not limited to any electronically stored data or paper document, in the possession, custody, or control of the Company. This includes, but is not limited to:
  - a. All material that is handwritten, typed, printed, recorded, transcribed, taped, filmed, in graphic form, or in aural form;

- b. Drawings, designs, manuals, memoranda, emails, reports, financial reports, notes, diaries, notations of any sort of conversations, working papers, letters, envelopes, telegrams, messages, studies, analyses, books, articles, notebooks, booklets, circulars, bulletins, notices, instructions, pamphlets, pictures, films, videos, voice recordings, maps, work papers, arithmetical computations, calendars (including electronic calendars), date books, task lists, minutes, all communications of any type (e.g., e-mail, voice mail, text messaging, WhatsApp and similar applications), social media content (including posts, messages, comments, and metadata), audio and video files,
  - c. Electronically stored data on magnetic or optical storage media as an “active” file or files (readily readable by one or more computer applications or forensics software), including metadata;
  - d. Any electronic files saved as a backup, including metadata;
  - e. Any deleted but recoverable electronic files, including metadata;
  - f. Any electronic file fragments (files that have been deleted and partially overwritten with new data), including metadata;
  - g. Every copy of every document where such copy is not identical to the original because of any addition, deletion, alteration, or notation; and
  - h. All attachments, enclosures, or other matter affixed to, transmitted with, or incorporated by reference within documents responsive to this Subpoena including, but not limited to, any pages showing who reviewed, approved, or rejected a particular document.
4. “Relevant Time Period” means January 1, 2020, through the present date. All responsive documents that were prepared, dated, sent, received, altered, in effect, or which came into existence during this period are to be produced pursuant to this Subpoena.
5. “Or” as well as “and” shall be construed interchangeably in a manner that gives this Subpoena the broadest possible meaning.
6. “Any” shall be construed to include the word “all” and the term “all” shall be construed to include the word “any.”
7. “Relate to” means to make a statement about, refer to, discuss, describe, reflect, identify, deal with, consist of, or in any way pertain, in whole or in part to the subject.



8. “Communication” means any transmission or exchange of information, statements, ideas, inquiries, or data between two or more persons orally, in writing, digitally, visually, or electronically regardless of the medium or platform used, including social media interactions, voicemails, and virtual meetings (e.g., Zoom, WebEx, Microsoft Teams). The term includes all drafts, versions, replies, responses, forwards, and attachments associated with or forming part of the communication, as well as any records or logs reflecting the time, date, participants, and content of such communications.
9. “Gender-related care” means any medical, surgical, psychological, or social treatment provided to individuals to alter their physical appearance or social presentation to resemble characteristics typically associated with the opposite biological sex.
10. “Puberty blockers” means any gonadotropin-releasing hormone (“GnRH”) agonists or related drugs (e.g., leuprolide, triptorelin) used to delay the onset of puberty.
11. “Hormones” includes testosterone, estrogen, and any other hormonal drugs used in hormonal treatments sometimes known as “gender affirming hormone therapy” (“GAHT”) or transgender hormone therapy used to induce cross-sex characteristics.
12. “Minor” means any patient under the age of 18 at the time of consultation, treatment, or prescription.

## II. GENERAL INSTRUCTIONS

1. You are required to produce the **originals** of each document and other item that is responsive, in whole or in part, to any request set forth in this Subpoena, together with all copies of any such document that exist.
  - a. If a copy is identical to the original, you are not required to produce it, but if you choose not to, your records custodian (the “Custodian,” as described below) must maintain a written log identifying the location(s) where each identical copy of the original document was located, including all locations, if more than one. This includes, in the case of information stored in electronic form, a description, including drives, directories, and computers of where the document is located.
  - b. If a copy differs from the original by virtue of any addition, deletion, alteration, notation, or inscription on any part of the front or back of the document, the original and copy must each be produced.

2. **No document called for by this subpoena shall be destroyed, modified, redacted, removed, or otherwise made inaccessible.** Documents called for by this Subpoena for which a claim of privilege is made, in compliance with the instruction below, shall be retained and protected.
3. Your Company is to designate someone as the person responsible to produce documents on the Subpoena return date (the “Custodian”).
  - a. Such Custodian shall have personal, direct, and thorough knowledge of, and responsibility for, the search conducted by the Company for documents responsive to this Subpoena.
  - b. The Custodian shall be prepared on the return date to submit to examination concerning the method and completeness of the Company’s response, the exact location(s) within the Company’s premises at which documents produced in response to the Subpoena were found, and other matters pertaining to the search.
  - c. The Custodian shall further be prepared to provide a written log identifying the location(s) in which each produced document was located, indicating all locations, if more than one. This includes, in the case of information stored in electronic form, a description, including drives, directories, and computers, of where the document is located.
4. The Company shall identify the paragraph and subparagraph of Section III of this Attachment to the Subpoena (“Documents to Be Produced”) to which each document produced pursuant to this Subpoena is responsive.
5. If the Company has knowledge of any document that would be responsive to this Subpoena, but has been lost, destroyed, or discarded, it shall identify the document to the extent possible, and provide an explanation of the loss, destruction or discarding, including identification of each person authorizing or having knowledge of the loss, destruction, or discarding.
6. The singular form of a word shall be construed to include within its meaning the plural form of the word, and *vice versa*, and the use of any tense of any verb shall be considered to include all other tenses in a manner that gives this Subpoena the broadest reading.
7. All electronically stored information must be collected using a forensically sound process. When the image file is produced, the Company must preserve the integrity of the electronic document’s contents, including the original formatting of the document, its metadata and, where applicable, its revision history.

8. If the Company withholds any document on the ground of any claimed privilege, it shall provide a statement with respect to each document setting forth
  - a. The name and title of the author (and if different, the preparer and signatory);
  - b. The name(s) and title(s) of the individual(s) to whom the document was addressed;
  - c. The name(s) and title(s) of the individuals to whom the document or a copy of the document was sent or to whom the document or a copy, or any part thereof, was shown;
  - d. The date of the document;
  - e. The number of pages;
  - f. A brief description of the subject matter;
  - g. A statement of the specific basis on which privilege is claimed; and
  - h. The paragraph or subparagraph in Section III of this Attachment (“Documents to Be Produced”) to which it is responsive.

### **III. DOCUMENTS TO BE PRODUCED**

1. Complete personnel files for each employee, contractor, or affiliate of the Company in the following categories: (a) executives, management employees, or board members with authority to direct any aspect of the Company’s affairs; (b) employees, contractors, or affiliates who have authority to prescribe medications or perform medical evaluations; and (c) employees, contractors, or affiliates who are engaged in billing activities.
2. All documents, including billing records, insurance claims, internal protocols, or guidance, concerning the use of ICD (*i.e.*, International Classification of Diseases) diagnosis codes in connection with the treatment of minor patients receiving gender-related care.
3. All documents that show or relate to any use of diagnosis codes for minors other than those specifically identifying transsexualism, gender dysphoria, gender incongruence, or gender identity disorder (*e.g.*, codes for endocrine disorder, unspecified hormonal disorders, medication management, etc.).

4. All documents reflecting communications among Company employees (including physicians, billing staff, and administrators), or between the Company and any third party, relating to whether or how to code or bill for treatment of gender dysphoria by using alternative diagnoses or alternative ICD codes.
5. All communications with public or private health care benefit programs or plans regarding the use of ICD codes for gender-related care, including any inquiries, denials, or appeals related to claims for such care.
6. Any training materials, coding manuals, presentations, or communications relating to billing or coding practices for gender-related care, puberty blockers, or hormone therapy.
7. All documents relating to communications between You and any pharmaceutical manufacturer of puberty blockers or hormones, or any compounding pharmacy providing puberty blockers or hormones, relating to the use of such drugs in gender-related care for minors.
8. All documents relating to communications with pharmaceutical sales representatives, marketing departments, or medical science liaisons regarding the use of puberty blockers or hormones for gender-related care or the treatment of gender dysphoria, including with regard to the safety and efficacy of such drugs for those uses.
9. All documents, including presentations and promotional materials, received from pharmaceutical manufacturers or compounding pharmacies concerning uses of their products in minors for gender-related care or for the treatment of gender dysphoria, including so-called “scientific exchange” materials.
10. All documents relating to contracts, sponsorships, speaking engagements, consulting agreements, grants, or financial or promotional arrangements between You and any manufacturer or compounder of puberty blockers or hormones.
11. Documents sufficient to identify each patient (by name, date of birth, social security number, address, and parent/guardian information) who was prescribed puberty blockers or hormone therapy.
12. For each such patient identified in Subpoena specification 11, *supra*, documents relating to the clinical indications, diagnoses, or assessments that formed the basis for prescribing puberty blockers or hormone therapy.
13. All documents relating to informed consent, patient intake, and parent or guardian authorization for minor patients identified in Subpoena specification 11, *supra*, including any disclosures about off-label use (*i.e.*, uses not

approved by the United States Food and Drug Administration) and potential risks.

14. All documents reflecting communications with pharmaceutical manufacturers, compounding pharmacies, or government agencies relating to the safety of puberty blockers or hormones used in the treatment of minor patients.
15. All documents relating to any adverse event, side effect, or medically unfavorable consequence or outcome in a minor patient with regard to gender-related care.

#### **IV. FORM OF PRODUCTION**

Documents responsive to this Subpoena should be produced in the format specified in the "Production Specifications," attached as ATTACHMENT B to this Subpoena.

## SUBPOENA ATTACHMENT B

### Specifications for Production of ESI and Digitized (“Scanned”) Images (“Production Specifications”)

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#### Collection of Electronically Stored Information (ESI)

Careful consideration should be given to the methodology, implementation and documentation of ESI collection to ensure that all responsive data and metadata are preserved in the collection process. Consideration should also be given as to whether production media should be encrypted when producing to the government when required by law (i.e. Health Insurance Portability and Accountability Act (HIPAA), Family Educational Rights and Privacy Act (FERPA), etc. *See* Section 24 below.

#### 1. Specification Modifications

Any modifications or deviations from the Production Specifications may be done only with the express permission of the government and these modifications or deviations should be communicated to the government and approved by the government in written form. Any responsive data or documents that exist in locations or native forms not discussed in these Production Specifications remain responsive and, therefore, arrangements should be made with the government to facilitate their production.

#### 2. Production Format of ESI and Imaged Hard Copy Documents

Responsive ESI shall be produced in its unprocessed form (i.e., in its native format), without altering native electronic file formats and maintains the integrity of all source, custodian, application, embedded and metadata related thereto. The native electronic file formats provided shall be of a type and nature which is functionally useable by all parties. No alteration shall be made to file names or extensions for responsive native electronic files. If a producing party is converting native files to image files for its own purposes, the Government requests a copy of that image file along with production of the native file.

For ESI, a producing party may provide an image file without a native file only if the affected document requires a privilege redaction or other permitted redaction.. Except as outlined below in sections 5 – 21, the redacted document shall be rendered to TIFF image format, and accompanied by an Opticon/Concordance® Image Cross Reference file. Paper documents shall also be imaged pursuant to the requirements below.

All applicable metadata/database (see section 3 below) shall be extracted and provided in Concordance® load file format.

- a. **Image File Format:** All imaged documents shall be produced in black and white TIFF format unless the image requires color. An image requires color when color in the document adds emphasis to information in the document or is itself information that would not be readily apparent on the face of a black and white image.
- b. When producing black and white paper documents scanned to images, or rendered ESI, they shall be produced as 300 dpi, 1 bit, single-page TIFF files, CCITT

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Group IV (2D Compression). When producing in *color*, paper documents scanned to images, or rendered ESI, they shall be produced as 300 dpi single-page JPG. Images should be uniquely and sequentially Bates numbered and unless otherwise specified, Bates numbers should be an endorsement on each image.

- i. All TIFF file names shall include the unique Bates number burned into the image. (See section 22, below, regarding Bates number instructions.)
  - ii. All TIFF image files shall be stored with the “.tif” extension.
  - iii. Images without corresponding extracted text shall be OCR’d using standard COTS products.
    1. An exception report shall be provided when limitations of paper digitization software/hardware or attribute conversion do not allow for OCR text conversion of certain images. The report shall include the DOCID or Bates number(s) corresponding to each such image.
  - iv. All pages of a document or all pages of a collection of documents that comprise a folder or other logical grouping, including a box, shall be delivered on a single piece of media.
  - v. No image folder shall contain more than 2,000 images.
- c. **Opticon/Concordance® Image Cross Reference file:** Images should be accompanied by an Opticon load file that associates each Bates number with its corresponding single-page TIFF image file. The Cross Reference file should also contain the relative image file path for each Bates numbered page. The Opticon/Concordance® Image Cross Reference file is a page level load file, with each line representing one image.

Below is a sample:

```
REL000000001,,.\IMAGES\001\REL000000001.TIF,Y,,,  
REL000000002,,.\IMAGES\001\REL000000002.TIF,,,,  
REL000000003,,.\IMAGES\001\REL000000003.TIF,,,,  
REL000000004,,.\IMAGES\001\REL000000004.TIF,Y,,,  
REL000000005,,.\IMAGES\001\REL000000005.TIF,,,,
```

The fields are, from left to right:

- Field One – (REL000000001) – the Bates Number. This value must be unique for each row in the OPT file. The first page of each document must match the DOCID or BEGDOC# value of the respective document.
- Field Two – (blank) – the volume identifier. This field is not required.
- Field Three – (.IMAGES\001\REL000000001.TIF) – The relative file path to the image to be loaded.
- Field Four – (Y) – the document marker. A “Y” indicates the start of a unique document.
- Field Five – (blank) – The folder indicator. This field is not required, and typically is not used.

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- Field Six – (blank) – The box indicator. This field is not required, and typically is not used.
- Field Seven – (blank) – The page count. This field is not required.

d. **Concordance® Load File:** Images should also be accompanied by a flat, document-level load file to provide the metadata and native files containing delimited text that will populate fields in a searchable, flat database environment. The file encoding must be one of four types: Western European (Windows), Unicode (UTF16), Big-Endian Unicode or UTF8. The file should contain the required fields listed below in section 3.

1. Text delimited load files are defined using the standard Concordance delimiters. For example:

|                        |               |
|------------------------|---------------|
| <i>Field Separator</i> | ¶ or Code 020 |
| <i>Text Qualifier</i>  | þ or Code 254 |
| <i>Newline</i>         | ® or Code 174 |
| <i>Multi-value</i>     | ; or Code 059 |
| <i>Nested values</i>   | \ or Code 092 |

2. This load file should contain the relative file path to the individual multi-page, document level text files.
3. This load file should also contain the relative file path to all provided native files, such as Microsoft Excel or PowerPoint files.
4. There should be one line for every record in a collection.
5. The load file must contain a header listing the metadata/database fields contained within. For example, if the data file consists of a First Page of a Record (BegDoc#), Last Page of a Record (ending Bates / ENDDOC#), DOCID, DOCDate, File Name, and a Title, then the structure may appear as follows:

```
þBEGDOCþ¶þENDDOCþ¶þDOCIDþ¶þDOCDATEþ¶þFILENAM
Eþ¶þTITLEþ
```

- d. **The extracted/OCR text** should be provided for each document as a separate single text file. The file name should match the BEGDOC# or DOCID for that specific record and be accompanied by the .txt extension.
- e. **Directory and folder structure:** The directory structure for productions should be:

```
\CaseName\LoadFiles
\CaseName\Images < For supporting images (can include subfolders as
needed, should not include more than 2,000 files per folder)
\CaseName\Natives <Native Files location (can include subfolders as
needed, should not include more than 2,000 files per folder)
\CaseName\Text <Extracted Text files location (can include subfolders as
needed, should not include more than 2,000 files per folder)
```



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\CaseName\Translated Images < For supporting images of translated documents (as needed for rendered translated documents; can include subfolders as needed, should not include more than 2,000 files per folder)  
 \CaseName\Translated Text <Translated Text files location (as needed for translated text; can include subfolders as needed, should not include more than 2,000 files per folder).

### 3. Required Metadata/Database Fields

A “✓” denotes that the indicated field should be present in the load file produced. “Other ESI” includes data discussed in sections 5 – 21 below, but does not include email, email repositories (section 11), “stand alone” items (section 12), imaged hard copy material (section 9) and production from ESI collected from Smart Phones, Mobile Devices and Other Technology (section 13). Email, email repositories, and “stand alone” materials (section 12) should comply with “Email” column below. Imaged hard copy materials should comply with the “Hard Copy” column. Production from ESI collected from Smart Phones, Mobile Devices and Other Technology should comply with the requirements of section 13. The parties will meet and confer about any field which cannot be populated automatically (i.e. would require manual population of information).

| Field name              | Field Description                                                                                              | Field Type                 | Field Value | Hard Copy | E-mail | Other ESI |
|-------------------------|----------------------------------------------------------------------------------------------------------------|----------------------------|-------------|-----------|--------|-----------|
| COLLECTION SOURCE       | Name of the Company/Organization data was collected from                                                       | Text                       | 160         | ✓         | ✓      | ✓         |
| SOURCE ID (BOX #)       | Submission/volume/box number                                                                                   | Text                       | 10          | ✓         | ✓      | ✓         |
| CUSTODIAN               | Custodian/Source - format: Last, First or ABC Dept.                                                            | Text                       | 160         | ✓         | ✓      | ✓         |
| DUPECUSTODIAN           | Custodian/Source – all custodians who had the document before de-duplication; format: Last, First or ABC Dept. | Text – semicolon delimited | Unlimited   |           | ✓      | ✓         |
| DUPECUSTODIAN FILE PATH | Listing of all the file locations of the document before de-duplication                                        | Text – semicolon delimited | Unlimited   |           | ✓      | ✓         |
| AUTHOR                  | Creator of the document                                                                                        | Text                       | 500         |           |        | ✓         |
| BEGDOC#                 | Start Bates (including prefix) - No spaces                                                                     | Text                       | 60          | ✓         | ✓      | ✓         |
| ENDDOC#                 | End Bates (including prefix) - No spaces                                                                       | Text                       | 60          | ✓         | ✓      | ✓         |
| DOCID                   | Unique document Bates # or populate with the same value as Start Bates (DOCID = BEGDOC#)                       | Text                       | 60          | ✓         | ✓      | ✓         |

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| Field name  | Field Description                                                                                                                                   | Field Type                 | Field Value | Hard Copy | E-mail | Other ESI |
|-------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|-------------|-----------|--------|-----------|
| PGCOUNT     | Page Count                                                                                                                                          | Number                     | 10          | ✓         | ✓      | ✓         |
| GROUPID     | Contains the Group Identifier for the family, in order to group files with their attachments                                                        | Text                       | 60          |           | ✓      | ✓         |
| PARENTID    | Contains the Document Identifier of an attachment's parent                                                                                          | Text                       | 60          |           | ✓      | ✓         |
| ATTACHIDS   | Child document list; Child DOCID or Child Start Bates                                                                                               | Text – semicolon delimited | Unlimited   | ✓         | ✓      | ✓         |
| ATTACHLIST  | List of Attachment filenames                                                                                                                        | Text – semicolon delimited | Unlimited   |           | ✓      | ✓         |
| BEGATTACH   | Start Bates number of parent                                                                                                                        | Text                       | 60          | ✓         | ✓      | ✓         |
| ENDATTACH   | End Bates number of last attachment                                                                                                                 | Text                       | 60          | ✓         | ✓      | ✓         |
| RECORD TYPE | Use the following choices: Image, Loose E-mail, E-mail, E-Doc, Attachment, Hard Copy or Other. If using Other, please specify what type after Other | Text                       | 60          | ✓         | ✓      | ✓         |
| FROM        | Sender (i.e.: e-mail address, Last name, First name)                                                                                                | Text                       | 160         |           | ✓      | ✓         |
| TO          | Recipient (i.e.: e-mail address, Last name, First name)                                                                                             | Text – semicolon delimited | Unlimited   |           | ✓      | ✓         |
| CC          | Carbon Copy Recipients (i.e.: e-mail address, Last name, First name)                                                                                | Text – semicolon delimited | Unlimited   |           | ✓      | ✓         |
| BCC         | Blind Carbon Copy Recipients (i.e.: e-mail address, Last name, First name)                                                                          | Text – semicolon delimited | Unlimited   |           | ✓      | ✓         |
| SUBJECT     | Subject line of email                                                                                                                               | Text                       | Unlimited   |           | ✓      |           |
| TITLE       | Document Title                                                                                                                                      | Text                       | Unlimited   |           |        | ✓         |
| CONVINDEX   | E-mail system ID used to track replies, forwards, etc.                                                                                              | Text                       | Unlimited   |           | ✓      |           |

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| Field name     | Field Description                                                                                                                                 | Field Type    | Field Value                | Hard Copy | E-mail | Other ESI |
|----------------|---------------------------------------------------------------------------------------------------------------------------------------------------|---------------|----------------------------|-----------|--------|-----------|
| DOCDATE        | Last Modified Date for files and Sent date for e-mail, this field inherits the date for attachments from their parent. Do not provide 00/00/0000. | Date          | MM/DD/YY<br>YY             |           | ✓      | ✓         |
| TEXT FILEPATH  | Relative file path of the text file associated with either the extracted text or the OCR                                                          | Text          | Unlimited                  | ✓         | ✓      | ✓         |
| DATE TIME SENT | Date and time Sent (USE TIME ZONE OF COLLECTION LOCALITY) Numbers must be populated. If date is unknown, leave blank. Do not provide 00/00/0000   | Date and Time | MM/DD/YY<br>YY<br>HH:MM:SS |           | ✓      |           |
| DATE TIME CRTD | Date Created (USE TIME ZONE OF COLLECTION LOCALITY) Numbers must be populated. If date is unknown, leave blank. Do not provide 00/00/0000         | Date and Time | MM/DD/YY<br>YY<br>HH:MM:SS |           | ✓      | ✓         |
| DATE TIME SVD  | Date Saved (USE TIME ZONE OF COLLECTION LOCALITY) Numbers must be populated. If date is unknown, leave blank. Do not provide 00/00/0000           | Date and Time | MM/DD/YY<br>YY<br>HH:MM:SS |           | ✓      | ✓         |
| DATE TIME MOD  | Date Last Modified (USE TIME ZONE OF COLLECTION LOCALITY) Numbers must be populated. If date is unknown, leave blank. Do not provide 00/00/0000   | Date and Time | MM/DD/YY<br>YY<br>HH:MM:SS |           | ✓      | ✓         |
| DATE TIME RCVD | Date Received (USE TIME ZONE OF COLLECTION LOCALITY) Numbers must be populated. If date is unknown, leave blank. Do not provide 00/00/0000        | Date and Time | MM/DD/YY<br>YY<br>HH:MM:SS |           | ✓      |           |

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| Field name       | Field Description                                                                                                                                                                                                           | Field Type    | Field Value                | Hard Copy | E-mail | Other ESI |
|------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|----------------------------|-----------|--------|-----------|
| DATE TIME ACCD   | Date Accessed (USE TIME ZONE OF COLLECTION LOCALITY)<br>Numbers must be populated. If date is unknown, leave blank. Do not provide 00/00/0000                                                                               | Date and Time | MM/DD/YY<br>YY<br>HH:MM:SS |           | ✓      | ✓         |
| TIME ZONE OFFSET | Time zone of collection locality, relative to Coordinated Universal Time (UTC). E.g., for US Central Standard Time (CST), the value for this field should be -6.0                                                           | Decimal       | 10                         |           | ✓      |           |
| FILE SIZE        | Native File Size in KBs                                                                                                                                                                                                     | Decimal       | 10                         |           |        | ✓         |
| FILE NAME        | File name - name of file as it appeared in its original location                                                                                                                                                            | Text          | Unlimited                  |           |        | ✓         |
| APPLICATION      | Application used to create native file (e.g. Excel, Outlook, Word)                                                                                                                                                          | Text          | 160                        |           | ✓      | ✓         |
| FILE EXTENSION   | Extension for the file (e.g. .doc, .pdf, .wpd)                                                                                                                                                                              | Text          | 10                         |           | ✓      | ✓         |
| FILEPATH         | Data's original source full folder path                                                                                                                                                                                     | Text          | Unlimited                  |           | ✓      | ✓         |
| NATIVE LINK      | Relative file path location to the native file                                                                                                                                                                              | Text          | Unlimited                  |           | ✓      | ✓         |
| FOLDER ID        | Complete E-mail folder path (e.g. Inbox\Active) or Hard Copy container information (e.g. folder or binder name)                                                                                                             | Text          | Unlimited                  | ✓         | ✓      |           |
| HASH VALUE       | Identifying value of an electronic record that is used for deduplication during processing. MD5 or SHA1 hash algorithms may be used, but must be kept consistent throughout all productions and communicated to Government. | Text          | Unlimited                  |           | ✓      | ✓         |
| MESSAGEHEADER    | E-mail header.                                                                                                                                                                                                              | Text          | Unlimited                  |           | ✓      |           |
| ATTACHMOUNT      | Number of attachments (any level child document) associated with a ParentID                                                                                                                                                 | Text          | 10                         |           | ✓      |           |

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| Field name          | Field Description                                                                                                                                                                    | Field Type | Field Value | Hard Copy | E-mail | Other ESI |
|---------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|-------------|-----------|--------|-----------|
| FILE TYPE           | Description that represents the file type to the Windows Operating System. E.g., Adobe Portable Document Format, Microsoft Word 97 – 2003, or Microsoft Office Word Open XML Format. | Text       | 160         |           | ✓      | ✓         |
| HAS HIDDEN CONTENT  | Identifies whether the document has comments, track changes or other hidden content or data associated with it                                                                       | Text       | Yes/No      |           | ✓      | ✓         |
| MESSAGE TYPE        | Exchange Message class or equivalent                                                                                                                                                 | Text       | 60          |           | ✓      |           |
| EXTENDED PROPERTIES |                                                                                                                                                                                      | Text       | Unlimited   |           | ✓      | ✓         |
| HAS REDACTIONS      | Identifies whether a record has been produced with redactions; should be populated with Y for records with redactions and N for records without redactions.                          | Text       | Yes/No      | ✓         | ✓      | ✓         |
| HAS TRANSLATIONS    | Identifies whether a document has been produced with translated text or audio contains a transcript                                                                                  | Text       | Yes/No      | ✓         | ✓      | ✓         |

#### 4. Search, De-Duplication, Near-Duplicate Identification, Technology Assisted Review, E-mail Conversation Threading and Other Culling Procedures

- De-duplication of exact hash copies shall only be permitted if the producing party can meet all the provisions of this section. If a producing party cannot comply with any requirement of this section, it shall not conduct de-duplication of exact hash copies.
- De-duplication of exact hash copies shall be performed globally – across all custodians. The custodian of each record shall be populated in the DupeCustodian field.
- All files found on the National Institute of Standards and Technology (NIST) list, commonly referred to as deNISTing, should be excluded from delivery to the Government. All available metadata from files withheld from delivery due to the deNISTing process will be available upon request.
- All files should be globally de-duplicated with the following conditions:

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- i. The “DupeCustodian” metadata field (listing of all custodians who had the document before de-duplication) must be provided with the document production.
  - ii. The “DupeCustodian File Path” metadata field (listing all the file locations of the document before de-duplication) must be provided with the document production.
  - iii. All files and metadata for the duplicate documents removed during de-duplication must be preserved and available for production upon request.
  - iv. No customization of hashing may occur without prior express approval by the Government.
  - v. De-duplication must be done by document family, not by individual document.
  - vi. A detailed description of the steps taken to de-duplicate (including the process of obtaining hash values) must be provided to the Government. For every production after the first, a separate Unified Custodian overlay shall be provided. If no overlay is necessary due to the fact that no documents de-duped out in connection with previously produced documents, this shall be expressly stated in the cover letter accompanying the subsequent production(s).
- e. The Producing Party shall not use any other procedure to cull, filter, group, separate or de-duplicate, or near-deduplicate, etc. (i.e., reduce the volume of) responsive material before discussing with and obtaining the written approval of the government. All objective coding (e.g., near duplicate ID or e-mail thread ID) shall be discussed and produced to the government as additional metadata fields. The Producing Party will not employ analytic software or technology to search, identify, or review potentially responsive material, including but not limited to, technology assisted review or predictive coding, without first discussing with the government.

## **5. Hidden Text**

All hidden text (e.g. track changes, hidden columns, mark-ups, notes) shall be expanded and rendered in the image file. Except for Adobe PDF files, for any files that cannot be expanded, the native files shall be produced with the image file. If an Adobe PDF’s hidden text cannot be expanded and rendered in an image file, it need only be produced in native form if individually requested by a specific document identifier or bates number.

## **6. Embedded Files and File Links**

All non-graphic embedded objects (Word documents, Excel spreadsheets, .wav files, etc.) that are found within a file shall be extracted and produced. For purposes of production, the embedded files shall be treated as attachments to the original file, with the parent/child relationship preserved.

The parties shall meet and confer regarding how to treat file links, including links within e-mails to centralized document repositories (e.g. MS OneDrive and Google Drive).

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## **7. Image-Only Files**

All image-only files (non-searchable .pdfs, multi-page TIFFs, Snipping Tool and other screenshots, etc., as well as all other images that contain text) shall be produced with OCR text and metadata/database fields identified in section 3 for “Other ESI.”

## **8. Encrypted Files**

Any data (whether individual files or digital containers) that is protected by a password, encryption key, digital rights management, or other encryption scheme, shall be decrypted prior to processing for production.

- a. The unencrypted text shall be extracted and provided per section 2.d. The unencrypted files shall be used to render images and provided per sections 2.a and 2.b. The unencrypted native file shall be produced pursuant to sections 10-21.
- b. If such protected data is encountered but unable to be processed, each file or container shall be reported as an exception in the accompanying Exception Report (pursuant to section 27) and shall include all available metadata associated with the data, including custodian information.

## **9. Production of Imaged Hard Copy Records**

All imaged hard copy material shall reflect accurate document unitization including all attachments and container information (to be reflected in the PARENTID, ATTACHID, BEGATTACH, ENDATTACH and FOLDERID).

- a. Unitization in this context refers to identifying and marking the boundaries of documents within the collection, where a document is defined as the smallest physical fastened unit within a bundle. (e.g., staples, paperclips, rubber bands, folders, or tabs in a binder).
- b. The first document in the collection represents the parent document and all other documents will represent the children.
- c. All imaged hard copy documents shall be produced as 300 dpi single-page TIFF files, CCITT Group IV (2D Compression). All documents shall be produced in black and white TIFF format unless the image requires color. An image requires color when color in the document adds emphasis to information in the document or is itself information that would not be readily apparent on the face of a black and white image. Images identified as requiring color shall be produced as color 300 dpi single-page JPEG files.
- d. All objective coding (e.g., document date or document author) should be discussed and could be produced to the government as additional metadata/database fields should they be deemed as necessary.

## **10. Production of Spreadsheets and Presentation Files**

All spreadsheet and presentation files (e.g. Excel, PowerPoint) shall be produced in the unprocessed “as kept in the ordinary course of business” state (i.e., in native format), with an associated placeholder image and endorsed with a unique Bates number. *See* section 22 below.

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The file produced should maintain the integrity of all source, custodian, application, embedded and related file system metadata.

#### **11. Production of E-mail Repositories**

E-mail repositories, also known as e-mail databases (e.g., Outlook PST, Lotus NSF), can contain a variety of items, including: messages, calendars, contacts, tasks, etc. E-mail database systems should not be produced without consultation with and written consent of the government about the format for the production of such databases.

#### **12. Production of Items Originally Generated in E-mail Repositories but Found and Collected Outside of E-mail Repositories, i.e., “Stand-alone” Items**

Any parent e-mail or other parent items (e.g., calendar, contacts, tasks, notes, etc.) found and collected outside of e-mail repositories (e.g., items having extensions .msg, .htm, .mht, etc.), shall be produced with the “Loose E-mail” metadata fields outlined in section 3, including but not limited to any attachments, maintaining the family (parent/child) relationship.

#### **13. Production of ESI Collected from Mobile Devices, Messaging Platforms, Workplace Collaboration Tools and Other Technologies**

The responding party shall identify, collect, and produce any and all data which is responsive to the requests, collected from mobile devices, messaging platforms, workspace collaboration tools and other technologies. These technologies include, but are not limited to smart phones, cell phones, tablets, PDAs, Blackberry, smart phone data, tablet data, voicemail messaging data, instant messaging, chat messaging, text messaging, Slack, conference call data, video/audio conferencing, workspace collaboration tools (e.g., GoTo Meeting, WebEx, MS Teams, Zoom), and related/similar technologies. However, such data, logs, metadata or other files related thereto, as well as other less common but similar data types, shall be produced after consultation with and written consent of the government about the format for the production of such data.

The expectation of the government is that all familial relationships for all data will be maintained. Similar to email conversations and families, the expectation is that all messages/texts in a conversation will be provided the same conversation index and groupid data (maintaining the familial relationship) allowing the government to read the entire conversation in context. Messages should be produced to align with the formats listed in section 2 and as individual Unicode text files, and attachments should be produced as native files with images and OCR text.

While the parties shall meet and confer on precise metadata formats, as an example, metadata collected from mobile devices shall be provided in formats such as the following:



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| Field Name           | Field Description                                                      | Mobile | Mobile Cellerbrite Categories |        |         |       |                 |           |                |                |                  |
|----------------------|------------------------------------------------------------------------|--------|-------------------------------|--------|---------|-------|-----------------|-----------|----------------|----------------|------------------|
|                      |                                                                        |        | Chats                         | MMS    | SMS     | Email | Instant Message | Voicemail | Recordings     | Notes          | Calendar         |
| TXT-ROWNUMBER        | Row number.                                                            | ✓      | #                             | #      | #       | #     | #               | #         | #              | #              | #                |
| TXT-CHATNUMBER       | Chat number, identifies chat groups.                                   | ✓      | Chat #                        |        |         |       |                 |           |                |                |                  |
| TXT-STARTTIME        | Start date-time for conversation, calendar item.                       | ✓      | Start Time: Date              |        |         |       |                 |           |                |                | Start Date: Date |
| TXT-ENDTIME          | End date-time for calendar item.                                       | ✓      |                               |        |         |       |                 |           |                |                | End Date: Date   |
| TXT-LASTACTIVITYTIME | End date-time for conversation.                                        | ✓      | Last Activity: Date           |        |         |       |                 |           |                |                |                  |
| TXT-PARTICIPANTS     | Who was involved in the conversation, meeting.                         | ✓      | Participants                  |        | Party   |       |                 |           |                |                | Attendees        |
| TXT-MSGAGNUMBER      | Individual identifier for message.                                     | ✓      | Instant Message #             |        |         |       |                 |           |                |                |                  |
| TXT-BODY             | Body of the chat, message, item.                                       | ✓      | Body                          | Body   | Message |       |                 |           |                | Body           |                  |
| TXT-STATUS           | Whether the text was Sent or Read on the device.                       | ✓      | Status                        | Status | Status  |       |                 |           |                |                | Status           |
| TXT-LOCATION         | GPS Information.                                                       | ✓      | Location                      |        |         |       |                 | Location  |                |                | Location         |
| TXT-TIMESTAMP        | Timestamp of item. Equivalent to DateReceived for incoming items or to | ✓      | Timestamp: Date               | Date   | Date    | Date  |                 |           | Timestamp-Date | Timestamp-Date |                  |

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| Field Name       | Field Description                                                                                                                                                                                                                                                      | Mobile | Mobile Cellebrite Categories |         |           |       |                 |                 |            |         |          |
|------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|------------------------------|---------|-----------|-------|-----------------|-----------------|------------|---------|----------|
|                  |                                                                                                                                                                                                                                                                        |        | Chats                        | MMS     | SMS       | Email | Instant Message | Voicemail       | Recordings | Notes   | Calendar |
|                  | DateSent for outgoing items.                                                                                                                                                                                                                                           |        |                              |         |           |       |                 |                 |            |         |          |
| TXT-READDATE     | Date read                                                                                                                                                                                                                                                              | ✓      | Read: Date                   |         | Read-Date |       |                 | Read-Date       |            |         |          |
| TXT-DELETED      | Indicates whether a message was deleted and recovered by Cellebrite.                                                                                                                                                                                                   | ✓      | Deleted - Chat               | Deleted |           |       | Deleted         | Deleted         | Deleted    | Deleted | Deleted  |
| TXT-STARMESSAGE  | Notes whether the message was flagged.                                                                                                                                                                                                                                 | ✓      | Starred message              |         |           |       |                 | Starred message |            |         |          |
| TXT-THREAD-GROUP | Populate with the DOCID of the first text in the chat conversation to allow the entire chat conversation to be grouped as a family. (Sort each device by Chat Number and then by Row Number to assign TXT-THREAD-GROUP identifier). This is NOT the BEGATTACH field or | ✓      | Chat #                       |         |           |       |                 |                 |            |         |          |

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| Field Name | Field Description                                                                            | Mobile | Mobile Cellebrite Categories |           |           |           |                 |           |            |          |          |
|------------|----------------------------------------------------------------------------------------------|--------|------------------------------|-----------|-----------|-----------|-----------------|-----------|------------|----------|----------|
|            |                                                                                              |        | Chats                        | MMS       | SMS       | Email     | Instant Message | Voicemail | Recordings | Notes    | Calendar |
|            | Relativity Group Identifier.                                                                 |        |                              |           |           |           |                 |           |            |          |          |
| TXT-SMSC   | Short Message Service Center (handles SMS text messages on behalf of phone service provider) | ✓      |                              |           | SMSC      |           |                 |           |            |          |          |
| DIRECTION  | Direction of communication ; Outgoing or Incoming.                                           | ✓      |                              | Direction | Direction | Direction |                 | Direction |            |          |          |
| IMPORTANCE |                                                                                              | ✓      |                              | Priority  |           |           | Priority        |           |            |          | Priority |
| ACCOUNT    | Account identifier for device user: email address, phone number, account number.             | ✓      |                              | Name      |           |           | Account         |           | Name       |          |          |
| DURATION   | Duration time of call, voice message, audio, video in HH:MM:SS format, e.g. 00:00:32         | ✓      |                              |           |           |           |                 |           | Duration   | Duration |          |

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#### **14. Production of Social Media**

Prior to any production of responsive data from social media (e.g., Twitter, Facebook, LinkedIn, etc.), the producing party shall first discuss with the government the potential export formats before collecting the information, to ensure it is collected and produced in a way that preserves the original metadata, has a clear chain of custody, and provides as much information as possible regarding the source and history of each individual communication.

Social media platforms offer different functions, forms of content, and capability for downloading accounts. Because of these differences, prior to collection of social media data, the producing party must discuss with the government the available export and production methods and formats that the producing party is considering. Unless the government agrees to an alternative in writing, regardless of the social media platform, productions of social media content must meet the following general requirements: (1) separate (2) searchable (3) static images of (4) each responsive posting on the social media platform, (5) all related content (e.g., comments, likes, share or re-transmittal information, images, videos, linked documents and content), and (6) associated metadata (e.g., user name(s), date, and time of all posts, comments, likes, share or re-transmittals).

These general requirements are in addition to any more specific requirements in a particular request (e.g., geolocation data), and the producing party must ask the government about any perceived conflict between these requirements and another source of specifications or requirements. If available from the social media platform or through social media data processing software, files that facilitate interactive review of the data (i.e., html files) as well as load files in .csv format must be produced with the associated content.

#### **15. Production of Structured Data**

Prior to any production of responsive data from a structured database (e.g., Oracle, SAP, SQL, MySQL, QuickBooks, proprietary timekeeping, accounting, sales rep call notes, CRMs, SharePoint, etc.), the producing party shall first identify the database type and version number, discuss providing the database dictionary (in whole or part) and any user manuals, or any other documentation describing the structure and/or content of the database and a list of all reports that can be generated from the database. Upon consultation with and written consent of the government, if a report is provided, the standard format of that report provided should be in comma separated values (.csv) format. The information contained in any such report must be thoroughly explained to the government before production.

#### **16. Production of Photographs with Native File or Digitized ESI**

Photographs shall be produced as single-page JPEG files with a resolution equivalent to the original image as they were captured/created. All JPEG files shall have extracted metadata/database fields provided in a Concordance® load file format as outlined in section 3 for “Other ESI.”

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**17. Production of Images from which Text Cannot be OCR Converted**

An exception report shall be provided when limitations of paper digitization software/hardware or attribute conversion do not allow for OCR text conversion of certain images. The report shall include the DOCID or Bates number(s) corresponding to each such image.

**18. Production of Translated Text with Non-English Language ESI or Documents**

To the extent translated text is available to the producing party through machine language translation, such translations shall be provided to the government with the production. The producing party shall provide the original extracted text as well as the translated extracted text in load ready format. The translated text and images of translated documents shall be provided as a separate folder volume to the main production. The parties shall meet and confer regarding any required translated text redactions.

**19. Production of Audio File Transcripts**

To the extent audio files are produced and transcripts are available to the producing party through machine transcription, such transcripts shall be provided to the government with the production. The producing party shall provide the audio file transcript as a text file in load ready format like any other text file named by the BEGDOC#. The parties shall meet and confer regarding any required audio file redactions.

**20. Production of ESI from Non-PC or Non-Windows-based Systems**

If responsive ESI is in non-PC or non-Windows-based Systems (e.g., Apple, IBM mainframes, and UNIX machines, Android device, etc.), the ESI shall be produced after discussion with and written consent of the government about the format for the production of such data.

**21. Production of Native Files (When Applicable Pursuant to These Specifications)**

Production of native files, as called for in these specifications, shall have extracted metadata/database fields provided in a Concordance® load file format as defined in the field specifications for “Other ESI” as outlined in section 3 as well as a placeholder image which indicates a native file is being produced.

ESI shall be produced in a manner which is functionally usable by the government. The following are examples:

- a. AutoCAD data, e.g., DWG and DXF files, shall be processed/converted and produced as single-page JPG image files and accompanied by a Concordance® Image formatted load file as described above. The native files shall be placed in a separate folder on the production media and linked by a hyperlink within the text load file.
- b. GIS data shall be produced in its native format and be accompanied by a viewer such that the mapping or other data can be reviewed in a manner that does not detract from its ability to be reasonably understood.

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- c. Audio and video recordings shall be produced in native format and be accompanied by a viewer if such recordings do not play in a generic application (e.g., Windows Media Player).

## 22. Bates Number Convention

All images should be assigned Bates numbers before production to the government. Each Bates number shall be a standard length, include leading zeros in the number, and be unique for each produced page. The numbers should be endorsed on the actual images at a location that does not obliterate, conceal, or interfere with any information from the source document. Native files should be assigned a single Bates number for the entire file which will represent the native document in the Opticon/ Concordance® Image Cross Reference file. The load file will include a reference to the native file path and utilize the NATIVELINK metadata field). The Bates number shall not exceed 30 characters in length and shall include leading zeros in the numeric portion. The Bates number shall be a unique number given sequentially (i.e. page one of document is PREFIX0000000001, page two of the same document is PREFIX0000000002) to each page (when assigned to an image) or to each document (when assigned to a native file). If the parties agree to a rolling production, the numbering convention shall remain consistent throughout the entire production. There shall be no spaces between the prefix and numeric value. If suffixes are required, please use “dot notation.” Below is a sample of dot notation:

|         | <u>Document #1</u>   | <u>Document #2</u>   |
|---------|----------------------|----------------------|
| Page #1 | PREFIX0000000001     | PREFIX0000000002     |
| Page #2 | PREFIX0000000001.002 | PREFIX0000000002.002 |
| Page #3 | PREFIX0000000001.003 | PREFIX0000000002.003 |

## 23. Media Formats for Storage and Delivery of Production Data

Electronic documents and data shall be delivered on any of the following media:

- a. CD-ROMs and/or DVD-R (+/-) formatted to ISO/IEC 13346 and Universal Disk Format 1.02 specifications; Blu-ray.
- b. External hard drives (USB 3.0 or higher, formatted to NTFS format specifications) or flash drives
- c. Government approved File Transfer Protocol (FTP) technologies.
- d. Storage media used to deliver ESI shall be appropriate to the size of the data in the production.
- e. Media should be labeled with the case name, production date, Bates range, and producing party.

## 24. Virus Protection and Security for Delivery of Production Data

Production data shall be free of computer viruses. Any files found to include a virus shall be quarantined by the producing party and noted in a log to be provided to the government. Password protected or encrypted files or media shall be provided with corresponding passwords and specific decryption instructions. All encryption software shall be used with approval by and with the written consent of the government.

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**25. Privilege Logs**

- a. The name and title of the author (and if different, the preparer and signatory);
- b. The name(s) and title(s) of the individual(s) to whom the document was addressed;
- c. The name(s) and title(s) of the individuals to whom the document or a copy of the document was sent or to whom the document or a copy, or any part thereof, was shown;
- d. The date of the document;
- e. The number of pages;
- f. A brief description of the subject matter;
- g. A statement of the specific basis on which privilege is claimed; and
- h. The paragraph or subparagraph of the Subpoena to which it is responsive.

**26. Compliance and Adherence to Generally Accepted Technical Standards**

Production shall be in conformance with standards and practices established by the National Institute of Standards and Technology (“NIST” at [www.nist.gov](http://www.nist.gov)), U.S. National Archives & Records Administration (“NARA” at [www.archives.gov](http://www.archives.gov)), American Records Management Association (“ARMA International” at [www.arma.org](http://www.arma.org)), American National Standards Institute (“ANSI” at [www.ansi.org](http://www.ansi.org)), International Organization for Standardization (“ISO” at [www.iso.org](http://www.iso.org)), and/or other U.S. Government or professional organizations.

**27. Read Me Text File**

All deliverables shall include a “read me” text file at the root directory containing: total number of records, total number of images/pages or files, mapping of fields to plainly identify field names, types, lengths, and formats. The file shall also indicate the field name to which images will be linked for viewing, date and time format, and confirmation that the number of files in load files matches the number of files produced.

**28. Exception Report**

An exception report, in .csv format, shall be included, documenting any production anomalies during the collection, processing, and production phases. The report shall provide all available BEGDOC# or DOCID values and metadata listed in section 3, including but not limited to file names and file paths for all affected files.

**29. Transmittal Letter to Accompany Deliverables**

All deliverables should be accompanied by a transmittal letter including the production date, case name and number, producing party name, and Bates range produced. Technical instructions on how to decrypt media should be included in the transmittal letter but the password should be transmitted separately.

-XXX-

## Subject: [EXTERNAL] RE: CHLA



**Diskant, Ted** <Ediskant@mwe.com>

Mon, Dec 8, 2025,

to Goldstein, Ross (CRM), Runkle, Patrick, Dahlquist, Scott B (CRM)

Thanks, Ross. Received and all noted.

### Edward B. Diskant

Partner

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Will & Schulte

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**From:** Goldstein, Ross (CRM) <[Ross.Goldstein@usdoj.gov](mailto:Ross.Goldstein@usdoj.gov)>

**Sent:** Monday, December 8, 2025 2:11 PM

**To:** Diskant, Ted <[Ediskant@mwe.com](mailto:Ediskant@mwe.com)>

**Cc:** Runkle, Patrick <[Patrick.R.Runkle@usdoj.gov](mailto:Patrick.R.Runkle@usdoj.gov)>; Dahlquist, Scott B (CRM)

<[Scott.B.Dahlquist@usdoj.gov](mailto:Scott.B.Dahlquist@usdoj.gov)>

**Subject:** CHLA

### [ External Email ]

Ted,

As I mentioned on Friday during our call, I am writing regarding the HIPAA subpoena issued to CHLA on June 11, (Subpoena No. 25-1431-013).

First, based on your representations that CHLA is not the appropriate party to produce the information, the government withdrawing requests Nos. 11, 12, and 13 (relating to patient records) in their entirety. CHLA need not produce documents or information responsive to those requests.

Second, as to all remaining requests in the subpoena—to the extent that there even is any patient identifying information—the government will accept production with the patient's personally identifying information anonymized, with the exception that patient age or patient birth month and year should be included if present in the document. All other identifiers may be removed or replaced with a unique code, provided the underlying medical and other responsive information remains intact.

Please let me know if you have any questions or if you anticipate any issues implementing these modifications.

Regards,

Ross



---

**Ross S. Goldstein | Assistant Director**

United States Department of Justice



**WESTERN CENTER ON LAW & POVERTY**

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(Additional counsel on following page)

**UNITED STATES DISTRICT COURT  
CENTRAL DISTRICT OF CALIFORNIA**

In Re 2025 Children's Hospital of  
Los Angeles Subpoena

Case No: 2:25-cv-11183

**NOTICE OF DISMISSAL**

**LAWYERS FOR GOOD GOVERNMENT**

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*Attorneys for Moving Parties*

*\*Pro hac vice*

1 **NOTICE OF DISMISSAL**

2 Moving Parties respectfully notify the Court that the parties have reached a  
3 settlement of this matter. *See* Exhibit 1, attached. Pursuant to Federal Rule of Civil  
4 Procedure 41(a)(1)(A)(i), Moving Parties hereby dismiss this action without  
5 prejudice.

6  
7 Dated: January 16, 2026

Respectfully submitted,

8  
9 WESTERN CENTER ON LAW & POVERTY  
10 LAWYERS FOR GOOD GOVERNMENT  
11 IMPACT FUND

12 /s/ Amy Powell

13 \_\_\_\_\_  
14 AMY POWELL

15 /s/ Joy Dockter

16 \_\_\_\_\_  
17 JOY DOCKTER

18  
19 *Attorneys for Moving Parties*  
20  
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IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF TEXAS  
FORT WORTH DIVISION

IN THE MATTER OF  
ADMINISTRATIVE SUBPOENA 25-  
1431-032

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Civil Action No. 4:26-MC-00006-O

**OPINION & ORDER**

Before the Court are Rhode Island Hospital’s Emergency Motion for Stay Pending Appeal (ECF No. 7); and the Government’s Response (ECF No. 11). Having considered the Motion, briefing, and applicable law, the Court finds that Rhode Island Hospital’s Motion should be, and hereby is, **DENIED**.

**I. BACKGROUND**

The Court’s recitation of the facts is taken from the parties’ briefing. On July 9, 2025, the Department of Justice served an administrative subpoena on Rhode Island Hospital (“RIH”) at its principal place of business in Providence, Rhode Island. The Government set a return date of August 7 and requested production at the office of the DOJ’s Consumer Protection Branch (now the Enforcement and Affirmative Litigation Branch), which is located in Washington, D.C. The Government issued the subpoena pursuant to the Health Insurance Portability and Accountability Act (“HIPAA”), 18 U.S.C. § 3486, to “investigate Federal health care offenses.”<sup>1</sup>

Over the ensuing roughly nine months, RIH produced one six-page document. RIH did not otherwise move to quash the subpoena or make any other attempt to explain non-compliance. It did seek the Government’s views on proposed search terms and received no response. On April

<sup>1</sup> Pet. Ex. B at 2, ECF No. 1-2.

30, 2026, the Government moved to enforce the subpoena in this Court. After reviewing the petition, the Court concluded that the subpoena had a legitimate inquiry, the records sought were relevant, and therefore entered an order enforcing the subpoena. RIH filed a notice of appeal and moved this Court to stay its order pending appeal.

## II. LEGAL STANDARD

A stay pending appeal is “extraordinary relief” for which the movant bears a “heavy burden.” *Plaquemines Par. v. Chevron USA, Inc.*, 84 F.4th 362, 373 (5th Cir. 2023). In determining whether RIH has met its burden, the Court considers “four factors”: “(1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure other parties interested in the proceeding; and (4) where the public interest lies.” *United States v. Texas*, 97 F.4th 268, 274 (5th Cir. 2024) (quoting *Nken v. Holder*, 556 U.S. 418, 426 (2009)). “The first two factors of the traditional standard are the most critical.” *Id.* (quoting *Nken*, 556 U.S. at 434). But “[a] stay pending appeal ‘is not a matter of right, even if irreparable injury might otherwise result.’” *Id.* (quoting *Nken*, 556 U.S. at 427).

The party requesting a stay bears the burden of showing that the circumstances justify an exercise of [the court’s] discretion.” *Nken*, 556 U.S. at 433–34. Importantly, “[a] stay is not a matter of right, even if irreparable injury might otherwise result,” but “[i]t is instead an exercise of judicial discretion, and [t]he propriety of its issue is dependent upon the circumstances of the particular case.” *Plaquemines Parish*, 84 F.4th at 373 (quoting *Nken*, 556 U.S. at 433). A court must thoughtfully consider the factors because “‘a stay is an intrusion into the ordinary processes of administration and judicial review.’” *Campaign for S. Equality v. Bryant*, 773 F.3d 55, 57 (5th Cir. 2014) (quoting *Nken*, 556 U.S. at 427).



recognized the summary nature of administrative subpoena enforcement proceedings.” *Burlington N. R.R. v. Office of Inspector Gen.*, 983 F.2d 631, 637 (5th Cir.1993); *see also EEOC v. Bay Shipbuilding Corp.*, 668 F.2d 304, 310 (7th Cir. 1981) (“The great discretion afforded by motion rules is appropriate when regulating the form of opposition to subpoena enforcement because . . . subpoena enforcement is meant to be a summary proceeding.”).

Generally, a “district court does not abuse its discretion or violate a non-movant’s due process rights by deciding a motion to dismiss before the non-movant has responded if ‘the response would [not] have affected the outcome of the decision.’” *Vodicka v. Ermatinger*, No. 3:19-CV-0056-B, 2022 WL 992600, at \*10 (N.D. Tex. Apr. 1, 2022) (alteration adopted) (quoting *United States v. Rand*, 924 F.3d 140, 144–45 (5th Cir. 2019)). So too here.

The Court need not wait for a response if it reasonably believes that the response will not change the outcome. *See Vodicka*, 2022 WL 992600 at \*10. In such a circumstance, the “central question” is “whether the response would have affected the outcome of the district court’s decision.” *Rand*, 924 F.3d at 145. In enforcing the instant subpoena, the Court considered RIH’s long-term non-compliance with the subpoena and the arguments in opposition that have been made to other district courts.<sup>4</sup> In the face of those considerations, it is plain that the Government’s inquiry is legitimate, the records sought are relevant, and save for one document, RIH has not complied. *Sandsend*, 878 F.2d at 879. Over the previous ten months, RIH has proffered no reason for its non-compliance with the subpoena, nor had it previously asserted any legal justification for the non-compliance. Indeed, the Government’s evidence indicates that RIH’s counsel represented several times that it would produce responsive documents.<sup>5</sup> But to date, RIH has produced only one six-

<sup>4</sup> Pet. 12, n.4, ECF No. 1.

<sup>5</sup> Pet. Ex. A at 19, ECF No. 1-1.

page document over the course of nearly a year.<sup>6</sup> It defies belief that one six-page document is the only non-objectionable responsive document. Such flagrant non-compliance and lack of legal challenge to the subpoena prior to the Government's enforcement petition left the Court to conclude that if RIH had a basis for non-compliance, then it would have asserted it. Even now, RIH has not sought reconsideration of the enforcement order to explain why it refused to comply beyond the one six-page document, nor has it indicated that it will end its seemingly intentional non-compliance and produce responsive non-objectionable documents.

Moreover, the process due in ex parte subpoena proceedings is instructive here. Courts have indicated that the proper due process protection to test the validity of a subpoena is a motion to quash or modify. *See In re Application of Eurasian Bank Joint Stock Co. for Expedited Judicial Assistance Pursuant to 28 U.S.C. § 1782*, No. 3:15-mc-106-L-BN, 2015 WL 6438256, at \*1 (N.D. Tex. Oct. 21, 2015) ( Noting that “once the subpoenas are served, [the respondent] will have the opportunity to move to quash or modify the subpoenas under Federal Rule of Civil Procedure 45,” so that “[t]he respondent's due process rights are not violated because he can later challenge any discovery request by moving to quash pursuant to Federal Rule of Civil Procedure 45(c)(3).” (cleaned up)). But even if a party were denied the opportunity to litigate the validity of a subpoena, a motion for reconsideration would be the proper mechanism to challenge an ex parte order. *In re Application of Eurasian Bank Joint Stock Co. for Expedited Judicial Assistance Pursuant to 28 U.S.C. § 1782 to Obtain Discovery for Use in Foreign Proc.*, No. CV 4:23-MC-96, 2025 WL 714374, at \*3 (E.D. Tex. Mar. 5, 2025) (noting that “a motion for reconsideration may seem like a strange motion at this juncture because this is Respondents’ first pleading on this issue. However, because the Court issued its Order on an ex parte basis, a motion

<sup>6</sup> *Id.*



for reconsideration is the proper procedural mechanism at this stage”). Again, RIH has neither moved to quash, to reconsider, nor produced responsive non-objectionable documents.

After ten months, RIH has made no showing as to why it is legally justified in withholding compliance, particularly given the “minimal” requirements for enforcement of a subpoena. *Burlington N R. Co.*, 983 F.2d at 637–38. Instead, all of the evidence indicates that RIH intends to delay and frustrate compliance, which demonstrates how RIH’s opposition would not have changed the outcome of the Court’s ruling. Accordingly, the Court finds that RIH fails to demonstrate a likelihood of success on its claim that it lacked the necessary due process.

Second, RIH argues that this Court is not the proper venue to adjudicate the Government’s petition.<sup>7</sup> Title 18 U.S.C. § 3486(c) permits enforcement of an administrative subpoena in “any court of the United States within the jurisdiction of which the investigation is carried on or of which the subpoenaed person is an inhabitant, or in which he carries on business or may be found.” According to the Declaration from the Acting Director of the Enforcement and Affirmative Litigation Branch there is substantial operational and decision-making control of the investigation being exercised at the U.S. Attorney’s Office in the Northern District of Texas, along with several subjects and potential targets of the investigation located therein.<sup>8</sup> The record therefore reflects that the investigation is being carried on in the Northern District of Texas and the Government’s enforcement petition was properly brought in this Court. Accordingly, RIH has failed to show a likelihood of success on the merits as to its venue challenge.

<sup>7</sup> Mot. Stay 6, ECF No. 7.

<sup>8</sup> See generally Hsiao Declaration (Sealed) Ex. 1, ECF No. 10-1. The Government has presented the Court with ex parte information that supports its choice to enforce the subpoena in this Court and due to the sensitive nature of that information, it was provided ex parte. See *In re Grand Jury Subpoena*, 419 F.3d 329 (5th Cir. 2005) (finding no abuse of discretion where the district court relied on the government’s ex parte submission in reaching its decision).

Finally, RIH argues that the subpoena is “unlawful” because it claims that the Government is proceeding on a theory that “‘off label use of puberty blockers and cross sex hormones’ is ‘a violation of the FDCA.’”<sup>9</sup> But the Government’s Petition does not advance this argument.<sup>10</sup> Regardless, a subpoena recipient “may not avoid an administrative subpoena on the ground that it has a valid defense to a potential subsequent lawsuit” and cannot raise “factual challenges based on a lack of statutory ‘coverage’” of a recipient’s activities, as RIH attempts to do here. *EEOC v. Karuk Tribe Hous. Auth.*, 260 F.3d 1071, 1076–77 (9th Cir. 2001); *Donovan v. Shaw*, 668 F.2d 985, 989 (8th Cir. 1982) (“[A] subpoena enforcement proceeding is not the proper forum in which to litigate the question of coverage under a particular federal statute.”); *United States v. Sturm, Ruger & Co.*, 84 F.3d 1, 5 (1st Cir. 1996) (“[Q]uestions concerning the scope of an agency’s substantive authority to regulate are not to be resolved in subpoena enforcement proceedings.”).

RIH also argues that the subpoena is overly broad and burdensome.<sup>11</sup> The Government responds that the subpoena seeks information relevant to an FDCA investigation as it relates to RIH itself and as it relates to the conduct of manufacturers and distributors of drugs that may have violated the FDCA.<sup>12</sup> As it relates to RIH, it presents no factual record in connection with its Motion to Stay as to the merits of the Government’s investigation such that the Court could determine in these proceedings the potential scope of RIH’s activities. Therefore, the Court has no basis to conclude RIH carried its burden to show it may succeed on the merits of this claim. As it relates to manufacturers and distributors, such entities also can be convicted of FDCA violations.

<sup>9</sup> Mot. Stay 8, ECF No. 7.

<sup>10</sup> Pet. 3–4, ECF No. 1 (explaining that when a drug is distributed for an intended use not approved by FDA—a potential FDCA violation—and an insurance plan pays for that drug, the FDCA violation becomes a “federal health care offense” under 18 U.S.C. § 24 and therefore may be investigated through a HIPAA subpoena).

<sup>11</sup> Mot. Stay 11, ECF No. 7.

<sup>12</sup> Resp. 11, ECF No. 11.

See e.g., 21 C.F.R. § 201.128 (intent may “be shown by labeling claims, advertising matter,” “oral or written statements,” and “circumstances in which the [drug] is, with the knowledge of” certain persons, “offered or used for a purpose for which it is neither labeled nor advertised”). RIH has not overcome the Government’s representation in the initial Hsiao Declaration that details precisely how and why each category of information the subpoena seeks is relevant and necessary to further the Government’s investigation. Nor has RIH sought reconsideration of the order to present that theory, nor has it included any evidence supporting it as a basis to stay enforcement.

Accordingly, the Court finds that RIH, who bears the burden, fails to demonstrate a likelihood of success on the merits, let alone the “strong” showing required for such “extraordinary relief” as a stay pending appeal. Therefore, this factor weighs heavily against granting a stay.

## **B. Irreparable Harm**

Turning to the second stay factor, the Court concludes that Defendants have not shown that they will suffer irreparable harm absent a stay pending appeal. RIH argues that it will suffer irreparable constitutional and monetary injuries without a stay.<sup>13</sup> The Court disagrees.

First, the subpoena requires production of nonprivileged, pre-existing business records of a large, closely regulated healthcare provider. The Court struggles to see how the Government seeing RIH’s nonprivileged business records as part of a lawful criminal investigation qualifies as irreparable harm. Moreover, the Court can order a complete return of the documents on any potential remand if RIH is successful on appeal, and the Court can order that no information gleaned from those documents be used in the investigation. Such a remedy is available and would not moot the case. *Church of Scientology of Cal. v. United States*, 506 U.S. 9, 12–15 (1992)

<sup>13</sup> Mot. Stay 12, ECF No. 7.

(“[T]his case is not moot because if the summons were improperly issued or enforced a court could order that the IRS’ copies of the tapes be either returned or destroyed.”).

Second, spending money to comply with the subpoena is not an irreparable harm to RIH because, among many other things, “[t]he burden of complying with a subpoena does not constitute irreparable injury.” *Nikon Corp. v. GlobalFoundries U.S., Inc.*, No. 17- MC-80071, 2017 WL 4865549, at \*2 (N.D. Cal. Oct. 26, 2017). “In general, the cost to businesses of complying with governmental subpoenas are normal costs of doing business which should be borne by the company.” *Hurt v. Dime Sav. Bank*, 151 F.R.D. 30, 31 (E.D.N.Y. 1993).

Finally, RIH argues that disclosure of patient records would irreparably harm its patients and its relationship with its patients.<sup>14</sup> But the “irreparable-harm analysis focuses on the moving party, not the nonmoving party or some third party.” *Kansas v. United States*, 124 F.4th 529, 534 (8th Cir. 2024) (citing *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008)). Thus, RIH has not shown how *it* would be harmed rather than its patients, who are third parties. In any event, RIH discloses to its patient that their health information may be shared with the Government in response to a subpoena.<sup>15</sup> Such a known, warned of, danger does not rise to the level of irreparable harm in this case. Accordingly, this factor does not weigh in favor of a stay.

### **C. Balance of Equities and the Public Interest**

The Court also finds that the remaining two factors—comparative balance of the equities and the public interest—likewise do not justify a stay pending appeal. *See Pursuing Am.’s Greatness v. FEC*, 831 F.3d 500, 511 (D.C. Cir. 2016) (“[I]n the context of a stay, assessing the harm to the opposing party and weighing the public interest merge when the Government is the opposing party.”). The Government has an “uncontested interest” in the “faithful execution of

<sup>14</sup> Mot. Stay 13, ECF No. 7.

<sup>15</sup> Resp. 15–16, ECF No. 11.

law.” *Newsom v. Trump*, 141 F.4th 1032, 1054 (9th Cir. 2025). Indeed, “[t]he government has a compelling interest in identifying illegal activity and in deterring future misconduct,” and that interest “outweighs the privacy rights of those whose [medical] records” are sought via subpoena, “particularly in light of the limitation placed on uses of subpoenaed information by § 3486.” *In re Subpoena Duces Tecum*, 228 F.3d 341, 351 (4th Cir. 2000). Thus, the Court finds that the public interest and balance of the equities weigh against a stay.

#### IV. CONCLUSION

For the foregoing reasons, the Court concludes that RIH has not met its burden of showing that the circumstances justify an exercise of the Court’s discretion to grant a stay pending appeal. Accordingly, the Court **DENIES** RIH’s Motion (ECF No. 7). The foregoing notwithstanding, the Court **STAYS** enforcement of the subpoena, except as to responsive non-privileged documents without a valid legal objection, pending RIH’s request for a stay before the Fifth Circuit Court of Appeals.<sup>16</sup>

**SO ORDERED** on this **10th day of May, 2026**.

  
Reed O'Connor

CHIEF UNITED STATES DISTRICT JUDGE

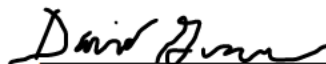
<sup>16</sup> The Court’s carve out is consistent with the standards for discovery and attorney conduct laid out in *Dondi*. See generally *Dondi Properties Corp. v. Commerce Sav. & Loan Ass’n*, 121 F.R.D. 284 (N.D. Tex. 1988). It is unclear whether RIH seeks to appeal enforcement of the subpoena as to non-privileged responsive documents with no valid legal objections. Regardless, there is no good reason to delay production of those documents.

## DECLARATION OF DAVID GUNN

Pursuant to 28 U.S.C. § 1746, I, David Gunn, hereby declare as follows:

1. I am a Trial Attorney in the Civil Division, Enforcement and Affirmative Litigation Branch, within the United States Department of Justice.
2. In late July 2025, the Department of Justice held an initial conference call with counsel for Rhode Island Hospital to discuss the administrative subpoena at issue. While I have no independent recollection of this video call, as I participated in numerous such calls during that time, it became the Department's practice to instruct those hospital subpoena recipients who inquired about potential anonymization of patient data in response to requests 11, 12, and 13 that the Government was open to accepting anonymized patient information under certain limited circumstances. In particular, the Department was open to the idea if (a) there was some method in place to identify anonymized patients across hospital records (so that we could identify and trace the continuum of care for particular patients); and (b) the hospital was willing to later unmask particular patients upon the good faith request of the Department. It is probable that the Department provided this information to Rhode Island Hospital, just as the Department provided it to others; however, I do not specifically recall. In subsequent conversations, to the best of my recollection, Rhode Island Hospital did not provide any plan to produce patient records whether anonymized or not.

I declare under penalty of perjury that the foregoing is true and correct. Executed on this 13<sup>th</sup> day of May, 2026.

  
\_\_\_\_\_  
DAVID GUNN

Trial Attorney  
Civil Division  
United States Department of Justice

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF RHODE ISLAND

In Re: Administrative Subpoena  
25-1431-032 to Rhode Island Hospital

Misc. No. 1:26-mc-00007-MSM-AEM

**NOTICE OF APPEAL**

PLEASE TAKE NOTICE that Respondent hereby appeals to the United States Court of Appeals for the First Circuit from this Court's Order and Judgment entered at ECF Nos. 38 & 39.

Date: May 14, 2026

Respectfully submitted,

BRETT A. SHUMATE  
Assistant Attorney General

JORDAN C. CAMPBELL  
Deputy Assistant Attorney General

/s/ Brantley T. Mayers  
BRANTLEY T. MAYERS  
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UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF RHODE ISLAND

In Re: Administrative Subpoena  
25-1431-032 to Rhode Island Hospital

Misc. No. 1:26-mc-00007-MSM-AEM

**NOTICE OF APPEAL**

PLEASE TAKE NOTICE that Respondent hereby appeals to the United States Court of Appeals for the First Circuit from this Court's Order entered at ECF No. 44.

Date: May 14, 2026

Respectfully submitted,

BRETT A. SHUMATE  
Assistant Attorney General

JORDAN C. CAMPBELL  
Deputy Assistant Attorney General

/s/ Brantley T. Mayers  
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IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF RHODE ISLAND

\* \* \* \* \* 26-MC-07-MSM  
\*  
In Re: Administrative Subpoena \*  
25-1431-032 to Rhode Island \* MAY 12, 2026  
Hospital \*  
\*  
\* Courtroom 1  
\* PROVIDENCE, RI  
\*  
\* \* \* \* \*

BEFORE THE HONORABLE MARY S. McELROY  
DISTRICT JUDGE  
(Motion to Quash)

**APPEARANCES:**

|                          |                             |
|--------------------------|-----------------------------|
| FOR THE PETITIONERS:     |                             |
| Child Advocate for the   | KEVIN LOVE HUBBARD, ESQ.    |
| State of Rhode Island    | DeLuca, Weizenbaum, Barry & |
|                          | Revens                      |
|                          | 199 North Main Street       |
|                          | Providence, RI 02903        |
| Rhode Island Hospital    | ERIC G. OLSHAN, ESQ.        |
|                          | McGuireWoods LLP            |
|                          | 260 Forbes Ave. Ste 1800    |
|                          | Pittsburgh, PA 15222-3142   |
| FOR THE RESPONDENT:      | BRANTLEY T. MAYERS          |
| United States of America | JORDAN C. CAMPBELL          |
|                          | DOJ-Civ                     |
|                          | 950 Pennsylvania Avenue NW  |
|                          | Washington, D.C. 20503      |
| Court Reporter:          | Denise P. Veitch, RPR       |
|                          | One Exchange Terrace        |
|                          | Providence, RI 02903        |

1 12 MAY 2026 -- 2:00 P.M.

2 THE COURT: Good afternoon. Thank you for  
3 accommodating us with the change of court.

4 (Discussion off the record)

5 THE COURT: We are on the record in a  
6 miscellaneous petition and we've moved courtrooms  
7 because we seem to have a lot of *amici* and other  
8 interested parties. The case number for us is  
9 26-MC-007, and it's an In Re: Administrative Subpoena  
10 25-1431-032 to Rhode Island Hospital.

11 So will counsel identify themselves for the  
12 record.

13 MR. LOVE HUBBARD: Good afternoon, your Honor.  
14 Kevin Love Hubbard on behalf of the Child Advocate for  
15 the State of Rhode Island.

16 MS. ROMERO: Good afternoon. Amy Romero for the  
17 Office of the Child Advocate for the State of Rhode  
18 Island.

19 MS. LABINGER: Lynette Labinger for the Office  
20 of Child Advocate.

21 MS. NAKASIAN: Good afternoon, your Honor.  
22 Stacey Nakasian on behalf of Rhode Island Hospital.

23 MR. OLSHAN: Good afternoon, your Honor.  
24 Eric Olshan on behalf of Rhode Island Hospital.

25 THE COURT: Okay.

1 MR. MAYERS: Good afternoon, your Honor.  
2 Brantley Mayers as counsel to the Assistant  
3 Attorney General Subdivision.

4 THE COURT: Okay.

5 MR. CAMPBELL: Good afternoon, your Honor.  
6 Jordan Campbell on behalf of the Government.

7 THE COURT: Okay. Now, I spoke to -- let me  
8 back up. This was begun by the Child Advocate's motion  
9 to quash the administrative subpoena that the  
10 Department of Justice issued to Rhode Island Hospital.  
11 The Department of Justice responded, and Rhode Island  
12 Hospital moved to intervene here. So they filed their  
13 papers on the weekend, I think Saturday, the motion to  
14 intervene and the brief that went along with it.

15 So the options today are to argue both petitions  
16 or stay the compliance with the subpoena unless and  
17 until Rhode Island Hospital has an opportunity to --  
18 I'm sorry, the Department of Justice has an opportunity  
19 to respond to Rhode Island Hospital's motions and then  
20 have another hearing, or, decide it on the papers. So  
21 I think I'll go with the Government selection. We  
22 can't -- the compliance with the subpoena needs to be  
23 stayed in order to give you more time, if you seek the  
24 time. Are you seeking more time?

25 MR. MAYERS: No, your Honor. We're fine to

1       argue both today.

2               THE COURT:   Okay.   Great.   So I'll begin by  
3       hearing from the Office of Child Advocate.

4               MR. LOVE HUBBARD:   Good afternoon, your Honor.

5               THE COURT:   Good afternoon.

6               MR. LOVE HUBBARD:   I want to start by thanking  
7       the Court and everybody on your staff for responding so  
8       promptly to this emergency filing.   I know we burden  
9       you with a lot of emergency filings and though it's not  
10      of our own making, we still know that it's a lot and  
11      there's been a lot of paper filed.   So I'm going to  
12      endeavor to be brief and invite you to ask any  
13      questions so that we can address what's on your mind,  
14      but thank you again for setting this hearing in such a  
15      hurry.

16              Your Honor, in this case the Child Advocate for  
17      the State of Rhode Island asks the Court to enforce the  
18      limits that Congress and the constitution impose on the  
19      Government's ability to demand compliance with  
20      administrative subpoenas and to protect the  
21      constitutional rights of vulnerable children in the  
22      State's care.

23              The Government issued a HIPAA subpoena to Rhode  
24      Island Hospital demanding the identities and complete  
25      medical records of every child and some young adults

1 who received medical care for gender dysphoria at Rhode  
2 Island Hospital over the course of more than five  
3 years. That subpoena was issued as part of a  
4 publicly-declared campaign by the Trump Administration  
5 to end that very medical care; care that is lawful,  
6 protected by Rhode Island state law, recognized as  
7 medically necessary by every major medical association,  
8 and regarded as lifesaving by the patients and the  
9 their families in Rhode Island. The Child Advocate,  
10 Katelyn Medeiros, who is here today, moved to quash the  
11 subpoena because she has a duty to protect the children  
12 in State care and custody, children who will be  
13 irreparably harmed if their motion is not granted.

14 The core questions before the Court are  
15 straightforward: Was the subpoena issued for a  
16 legitimate purpose, and, if so, does it seek  
17 information relevant to that purpose. As the record in  
18 this case and in seven other decisions from federal  
19 courts evaluating identical subpoenas make clear, the  
20 answer to both questions is no.

21 THE COURT: But are we at that point or are we  
22 not at that point because Rhode Island Hospital never  
23 moved to quash the subpoena in the first place.

24 MR. LOVE HUBBARD: We are at that point of  
25 determining whether the subpoena had a proper purpose



1 and also I think because the Child Advocate moved to  
2 quash and has standing to move to quash on a number of  
3 bases, which we'll get to, and there's an immediate  
4 need for the Court's intervention for -- based on  
5 events that are outside of our control. We have to  
6 answer that question now, yes.

7 THE COURT: Okay. Go ahead.

8 MR. LOVE HUBBARD: Though the core questions are  
9 straightforward, unfortunately this case is no longer  
10 straightforward because the Government's forum-shopping  
11 tactics, but in the end the complications raised by  
12 those tactics are simply irrelevant.

13 This Court unquestionably has jurisdiction. The  
14 Government does not contest that. And we are not  
15 asking this Court to do anything other than evaluate  
16 the subpoena pursuant to the standards that the  
17 Constitution and the administrative subpoena statute  
18 require, and protect the independent constitutional  
19 rights of Rhode Island's children, which have never  
20 been considered by any other Court. You are the first  
21 to consider that interest. This Court can and should  
22 exercise its jurisdiction to protect those rights and  
23 redress the immediate harm by quashing the subpoenas in  
24 their entirety.

25 THE COURT: So can we -- we're talking about a

1 constitutional right to informational privacy. Is that  
2 essentially the constitutional rights that we're  
3 talking about?

4 MR. LOVE HUBBARD: In addition to their Fourth  
5 Amendment limits on subpoenas.

6 THE COURT: Right. And with respect to  
7 informational privacy, in reading *Dobbs*, Justice Alito,  
8 who wrote for the majority, made a very clear  
9 distinction between decisional and informational  
10 privacy and seemed to say that *Roe*, which they  
11 overturned as you know in *Dobbs*, was wrongly decided  
12 because it was premised on decisional privacy, and he's  
13 clear that there's a distinction, and I think that the  
14 *Dobbs* case does tie the Supreme Court into the  
15 *Whalen v. Doe* case line of informational privacy.

16 Can you address informational privacy at some  
17 point. If now is not appropriate, you can do it later.

18 MR. LOVE HUBBARD: Absolutely. I'd be happy to  
19 address that now. I think there, as you identified  
20 they are in the First Circuit and I think, you know,  
21 *Dobbs* as a complicating factor on informational privacy  
22 we can certainly talk about, but there is also --

23 THE COURT: But, I'm sorry, maybe I'm misreading  
24 *Dobbs*, but I see the First Circuit case law is that  
25 there is informational privacy --

1 MR. LOVE HUBBARD: Absolutely.

2 THE COURT: -- and I see *Dobbs* as affirming  
3 that.

4 MR. LOVE HUBBARD: Absolutely.

5 THE COURT: Okay.

6 MR. LOVE HUBBARD: And the First Circuit also  
7 has decisional privacy -- excuse me; that was my error.

8 THE COURT: Oh, I apologize.

9 MR. LOVE HUBBARD: No, no, my fault.

10 The First Circuit also recognizes that ensuring  
11 autonomy in personal decisions, and I don't think  
12 anything, you know, that hasn't been revisited in light  
13 of *Dobbs* in the First Circuit, but there's nothing  
14 about the autonomy and decisional privacy rights that  
15 are implicated in the subpoenas that has been  
16 overturned by *Dobbs*. I don't think that is a fair  
17 reading of that case as applied to this unique set of  
18 circumstance.

19 THE COURT: I agree. Okay. I didn't mean to  
20 complicate it; I just wanted to...

21 MR. LOVE HUBBARD: So I want to start with some  
22 updates on procedural posture to the extent that I know  
23 them, and Rhode Island Hospital and the Government are  
24 actually parties in the other proceeding, but I'm just  
25 going to tell you what I know as relevant to my

1 argument.

2 In the Northern District of Texas over the  
3 weekend, the court there denied Rhode Island Hospital's  
4 motion to stay enforcement of its order compelling  
5 compliance with the subpoena. That order appears to  
6 have denied the stay but also temporarily state  
7 enforcement as to some of the records at issue,  
8 although not all of them.

9 THE COURT: And that would be the  
10 personally-identifying information of the minor  
11 patients.

12 MR. LOVE HUBBARD: I believe so.

13 THE COURT: I think it's Requests 11 through the  
14 end. I don't know --

15 MR. LOVE HUBBARD: Right, 11 through 15.

16 THE COURT: Okay. 11 through 15.

17 MR. LOVE HUBBARD: That's my understanding of  
18 the court's order.

19 THE COURT: That's my reading of it as well.

20 MR. LOVE HUBBARD: And then in the Fifth Circuit  
21 proceeding, Rhode Island Hospital has appealed in the  
22 Fifth Circuit. The Government apparently filed its  
23 opposition at some point while we were in this  
24 courtroom and the Hospital I think intends to reply,  
25 but we're awaiting a ruling from the Fifth Circuit on

1 the stay motion.

2 THE COURT: On the stay.

3 MR. LOVE HUBBARD: There's another development  
4 late last night, that NYU Langone issued a public  
5 statement that they were one of several institutions  
6 that received a grand jury subpoena from the  
7 U.S. Attorney's Office in the Northern District of  
8 Texas. According to that public statement which they  
9 issued under their state shield law -- just like Rhode  
10 Island has a shield law -- New York has a shield law  
11 that requires them to provide notice if the patients'  
12 records in gender-affirming care cases are at issue.  
13 According to NYU, that subpoena directs NYU to provide  
14 information pertaining to patients under the age of 18  
15 who received gender-affirming care between 2020 and  
16 2026. That's relevant only because when I talk about  
17 venue and I talk about grand jury subpoenas, I want you  
18 to know that I learned about it from a public filing  
19 and nothing that we shouldn't have heard about.

20 THE COURT: And you're telling me that that's a  
21 grand jury subpoena in Texas?

22 MR. LOVE HUBBARD: Issued from Texas to  
23 NYU Langone, yes.

24 THE COURT: So if there's a grand jury convened,  
25 and that's obviously public since NYU Langone issued

1 that statement, and assuming it's true, why -- what's  
2 the difference between a grand jury subpoena and an  
3 administrative subpoena? My reading of it is that a  
4 grand jury subpoena has more force and also requires  
5 more confidentiality. Am I missing that?

6 MR. LOVE HUBBARD: I don't think so, your Honor,  
7 and the standards for grand jury subpoenas aren't at  
8 issue here. But what's important about it is that NYU,  
9 according to its statement, received the subpoena  
10 May 7th, 2026. And so the temporal order of things,  
11 the administrative HIPAA subpoena in this case issued  
12 in July 2025, served on Rhode Island Hospital July 9th,  
13 and the Government moved after months of silence about  
14 Rhode Island Hospital's attempts to meet and confer  
15 about that subpoena, moved to compel in the Northern  
16 District of Texas in late April this year.

17 THE COURT: So I want to talk about that  
18 April 30th date, and I intend to talk to the Government  
19 about it as well. So my reading of the record is that  
20 the same gentleman who filed the brief in Texas and I  
21 think signed on to the brief here is a man named Ross  
22 Goldstein, and I assume he's DOJ, I assume he's in  
23 northern Texas, but I think that probably is a bad  
24 assumption.

25 MR. LOVE HUBBARD: He is not in Texas.

1 THE COURT: He's in D.C.; correct?

2 MR. LOVE HUBBARD: Yes.

3 THE COURT: Okay. So that there's an e-mail  
4 from him -- is it from him or am I looking at the wrong  
5 e-mail. There's an e-mail where the attorney from  
6 Rhode Island Hospital says essentially, you know, we'd  
7 like to get together and talk about search terms and  
8 obviously they're talking about complying with the  
9 subpoena, and Rhode Island Hospital then says they hear  
10 nothing for several weeks and then on the 28th this  
11 gentleman I think is the one who --

12 MR. LOVE HUBBARD: A different person from D.C.

13 THE COURT: Oh, I apologize.

14 MR. LOVE HUBBARD: That's all right. Also is an  
15 attorney from D.C. It's very important.

16 THE COURT: And he says okay, you know, sorry I  
17 was out for a couple of weeks; even though it was maybe  
18 two-and-a-half months of no response from DOJ. And  
19 they say, here it is: So the DOJ says, he says I've  
20 been out for a few weeks, and he requests a conference  
21 and that's on the 28th of April. On the 29th Rhode  
22 Island Hospital agrees and sends an e-mail saying, hey,  
23 let's connect whatever date next week, Monday,  
24 whatever. And then there's no response until after the  
25 order in Texas is filed and granted. Is that -- and

1 the response is an e-mail to the attorney for Rhode  
2 Island Hospital that includes a copy of the motion and  
3 the order. Is that accurate? It looks like it's at  
4 6:10 p.m. I don't know if that's Texas time. I'm  
5 assuming it is, but...

6 MR. LOVE HUBBARD: That's a completely accurate  
7 summary of the record as I understand it.

8 THE COURT: Okay. Thank you.

9 MR. LOVE HUBBARD: There are a number of things  
10 that are important about that. First of all it  
11 reflects the Government's litigation conduct which is  
12 relevant to the Court's evaluation of the timeliness of  
13 any motion to quash. I don't think any of those rules  
14 apply to the Child Advocate, who not a party to the  
15 subpoena, who had no opportunity to be heard about it,  
16 had no -- hadn't seen it. I don't think those rules  
17 apply. But even if they did, we cited extensive cases  
18 to the Court where courts can excuse untimeliness where  
19 there is (1) no prejudice to the party asserting delay;  
20 and certainly the Government could not claim any  
21 prejudice when it was the one was silent for months at  
22 a time, asked for a meet and confer, ignored the  
23 Hospital's response and moved to quash in a distant  
24 forum. And again, Rhode Island Hospital will be better  
25 suited to speak to this, but it's my understanding that



1 that was the first that Texas had ever been mentioned  
2 to Rhode Island Hospital, after -- when the order was  
3 already granted. Before that they were only having  
4 interaction with DOJ in D.C. and now will be relevant  
5 to the collateral attack doctrine and venue in Rhode  
6 Island -- in Texas, excuse me.

7 I do want to get to all those things, your  
8 Honor, but I do think stepping back from the sort of  
9 legal abstractions and the procedural morass of this  
10 case which is the result of the Government's conduct;  
11 because we represent the Child Advocate, part of my job  
12 here today is to attempt to keep things focused on the  
13 interest of the children that she represents.

14 THE COURT: I apologize.

15 MR. LOVE HUBBARD: No, no, not at all.

16 But there are real children, your Honor, young  
17 adults and their families who are being deeply affected  
18 by the subpoena and by the Government's attempts to go  
19 to Texas to enforce it.

20 I've heard from multiple parents of children who  
21 have received care at Rhode Island Hospital over the  
22 last week since we filed this motion. They're  
23 terrified that the Hospital will be forced to turn over  
24 their children's identities and most intimate medical  
25 records to the Government that has repeatedly and

1 publicly demeaned them and declared its hostility  
2 towards them and their families.

3 I spoke with one person who told me that their  
4 child struggled with suicidal thoughts before receiving  
5 care and that the medical care to treated gender  
6 dysphoria that they received at Rhode Island Hospital  
7 saved their child's life. They told me the subpoena,  
8 quote, is designed to put the trans and  
9 trans-supporting community in fear, to force people  
10 back into closets and despair, and that they would do  
11 anything to prevent that from happening to their child.

12 I spoke to a second parent who told me that her  
13 family had recently moved to Rhode Island specifically  
14 because they believed the medical care for gender  
15 dysphoria that their child depended on would be  
16 protected here after they were forced to uproot their  
17 lives and move from a state that implemented a ban on  
18 that care. They moved to Rhode Island to ensure their  
19 child would be safe and to be in a place where they  
20 could have the care that their child needs to thrive.  
21 They are willing to move heaven and earth for their  
22 child. They should not have to worry about being  
23 targeted by the Federal Government.

24 THE COURT: Can I have one second. Carrie.

25 (Judge confers with Clerk)

1 THE COURT: Sorry.

2 MR. LOVE HUBBARD: Not at all. I know it's not  
3 your courtroom.

4 (Pause)

5 THE COURT: Thank you.

6 MR. LOVE HUBBARD: Thank you.

7 Those are the real world consequences of what  
8 the Government is asking this Court to permit. They're  
9 not abstract by these interests; they are children and  
10 families in Rhode Island right now living in fear of  
11 their own Government. That context matters when this  
12 Court balances the Government's asserted need for  
13 whatever information it's seeking against the injury,  
14 the disclosure of that the information would cause  
15 constitutional injury to those children's rights.

16 So that injury segues naturally into the  
17 question of standing. The Child Advocate is asserting  
18 the privacy and welfare interests of children in DCYF  
19 custody, care or treatment of children Rhode Island law  
20 specifically charges her to protect. This Court has  
21 already recognized in its order denying the motion to  
22 transfer that the Child Advocate was not a party to the  
23 Northern District of Texas proceeding and had no notice  
24 or opportunity to be heard there. And the district  
25 court in Texas was explicit in its order denying the

1 stay over the weekend, that it did not consider  
2 patients' privacy rights in granting the Government's  
3 motion to compel.

4 THE COURT: Is there any indication that they  
5 considered Rhode Island law at all?

6 MR. LOVE HUBBARD: None.

7 THE COURT: Okay. And I ask because, you know,  
8 this sort of, I get the preemption issue and the  
9 argument, but seems to be an analysis that says that  
10 the federal HIPAA sets the floor and states can set  
11 higher standards. I wrong on that? It's also on HSS's  
12 website, too.

13 MR. LOVE HUBBARD: I think that is true, your  
14 Honor. I think, you know, unfortunately -- I take the  
15 Government's ability to conduct legitimate healthcare  
16 fraud investigation seriously, as you know, --

17 THE COURT: Yes.

18 MR. LOVE HUBBARD: -- and a HIPAA subpoena in  
19 general does preempt contrary to state law; I will  
20 acknowledge that. But the question of state law that  
21 is undoubtedly important here that the Texas court  
22 didn't consider is that this care is lawful, protected,  
23 and eligible for Medicaid reimbursement in the State of  
24 Rhode Island, and that the Federal Government does not  
25 get to make a contrary choice. The Supremacy Clause

1 does not entitle the Federal Government to decide to  
2 ban care that the State has chosen to both authorize  
3 and protect.

4 THE COURT: But the hospital -- the Government  
5 is saying, hey, we're not trying to ban anything, we're  
6 just trying to get information to see if people are  
7 mislabeling the drugs, and we'll get into that with the  
8 Government about who can be responsible for a crime of  
9 misbranding or mislabeling because I don't think  
10 hospitals can be, but...

11 MR. LOVE HUBBARD: I think that's absolutely  
12 right. But I want to in terms of the order of the  
13 Court's operation of decision we have to decided the  
14 purpose first; right? So there's the question of  
15 whether the subpoena meets the standards for the  
16 issuance of an administrative subpoena and the  
17 enforcement thereof, and that would be does it have a  
18 lawful purpose, is it relevant, and then is it  
19 reasonable to the lawful purpose. So the purpose  
20 analysis comes first, and that's critical here because  
21 it's the heart of this case.

22 The Government's purpose in issuing the subpoena  
23 is explicit. We're not asking the Court to  
24 second-guess is this prosecutorial discretion or  
25 resolve a debatable legal question. The Government's

1 own statements establish repeatedly and unambiguously  
2 that the purpose of these subpoenas is to end lawful  
3 medical care, not to investigate any federal crime.

4 Seven decisions of federal courts have so found,  
5 and what's important about those seven decisions isn't  
6 just that they were unanimous until the chosen forum  
7 gave a contrary order; it's that over the course of  
8 those seven decisions what you see is DOJ offering  
9 shifting and inconsistent explanations fishing about  
10 for a legitimate purpose. As the court in the Eastern  
11 District of Pennsylvania found, quote, the Department  
12 of Justice has shifted its explanations for the  
13 investigation before us our colleagues across the  
14 nation have identified problems with the Department's  
15 numerous subpoenas.

16 And that's true here now. We get a slightly  
17 different gloss on their attempts to find a legitimate  
18 FDCA purpose in this court than they offered in the  
19 other courts.

20 And in its opposition to our motion here the  
21 Government quibbles with a few of the interpretations  
22 of a couple of statements that we offer. But what they  
23 don't address is that when asked for comment after a  
24 court quashed an identical subpoena because the court  
25 found it had an improper purpose, the Department of

1 Justice responded: This Department of Justice will use  
2 every legal and law enforcement tool available to  
3 protect innocent children from being mutilated under  
4 the guise of care. As the *QueerDoc* Court found, no  
5 clearer evidence of improper purpose could exist than  
6 the Government's own repeated declarations.

7 There's an eighth case, your Honor, that's  
8 relevant. It's not about the exact same subpoenas  
9 here. But about three days ago, maybe four days ago in  
10 the District of Columbia, Judge Boasberg issued an  
11 opinion quashing a subpoena from the Federal Trade  
12 Commission. The case is *Endocrine Society vs. Federal*  
13 *Trade Commission*, the cite is 26-CV-0512-JEB. It's not  
14 a HIPAA subpoena case, but it is relevant because  
15 Judge Boasberg described the DOJ subpoenas and the FTC  
16 demands as part of the same "multi-agency campaign."  
17 He rejected the Government's argument -- which it makes  
18 here too -- that there is no cause of action allowing  
19 the recipient of a CID to challenge the violation of  
20 its constitutional rights. That's wrong for all the  
21 reasons we'll talk about when it comes to standing.

22 He reaffirmed the unremarkable principle that a  
23 plaintiff subject to unconstitutional action by  
24 executive officers can sue those officers, to enjoin  
25 those actions. And he also talked at length about a

1 workshop offered by the FTC called The Dangers of  
2 "Gender-Affirming Care" for Minors. Now, we cited  
3 statements from Deputy Assistant Attorney General  
4 Campbell of the Enforcement and Affirmative Litigation  
5 Branch of the Civil Division of the Department of  
6 Justice in our motion to quash. The Government's  
7 opposition claimed that we mischaracterized the  
8 statement.

9 As I think the discussion from Judge Boasberg at  
10 that workshop will make clear, as will the transcript  
11 itself, we did not mischaracterize the statement. And  
12 the relevance of that statement to the Government's  
13 improper purpose has only increased since then since  
14 Deputy Attorney Assistant General Campbell has now  
15 appeared in this case.

16 There's a difference between the Administration  
17 prioritizing enforcement of existing law in an area of  
18 policy concern and one that issues subpoenas to end the  
19 lawful practice through intimidation and law fear  
20 (phonetic). The former is enforcement discretion; the  
21 latter is an abuse of process. The Government has told  
22 us which one this is.

23 And I think, your Honor, improper purpose cases  
24 are often difficult, right, we're asking you to look  
25 behind the subpoena and determine what the Government



1 was thinking when it issued. This is not a difficult  
2 case. The purpose is in black and white. They've made  
3 it clear over and over and over again.

4 The Government's only response with respect to  
5 purpose is to say that you'd have to find that it was  
6 the sole purpose of the improper purpose to quash the  
7 subpoena and that even if it was partly motivated by  
8 this improper purpose, that shouldn't matter because  
9 they may have had another legitimate purpose. But the  
10 question isn't whether the Government can generate an  
11 imaginary legitimate purpose; it's whether the  
12 Government's actual purpose is legitimate on the record  
13 before the Court. A legally foreclosed theory doesn't  
14 become a legitimate purpose just because the Government  
15 labels it one. On the record here, including the  
16 Government's own admission that Rhode Island Hospital  
17 was not suspected of any criminal wrongdoing, shows  
18 that its FDCA theories were developed after the  
19 subpoena issued --

20 THE COURT: And they also say nor were the  
21 children or the caregivers for the children; is that  
22 correct?

23 MR. LOVE HUBBARD: Correct, your Honor.

24 THE COURT: Go ahead. I'm sorry.

25 MR. LOVE HUBBARD: The explanations for their

1 FDCA theory has shifted again in this court, but the  
2 subpoena hasn't shifted and the improper purpose that  
3 motivates them not changed.

4 This is not a legitimate criminal investigation.  
5 It's a campaign of intimidation and harassment designed  
6 to achieve a policy goal, the end of medical care for  
7 gender dysphoria that the Executive Branch otherwise  
8 lacks the authority to pursue, and it's  
9 unfortunately --

10 THE COURT: Or they could pursue it through  
11 legislation and Congress; correct?

12 MR. LOVE HUBBARD: They could certainly propose  
13 legislation. They can't do it on their own. And even  
14 if, and that's beyond the gambit of what we need talk  
15 about here today, your Honor. But it's up to the Court  
16 to act as a bullwark to enforce the limits the  
17 Constitution imposes on the Executive Branch's improper  
18 efforts.

19 I'm sorry, your Honor, I'm going to turn back to  
20 standing briefly. The court recognized that the Child  
21 Advocate wasn't a party in the Texas proceeding, had no  
22 opportunity to be heard. The district court there  
23 explicitly did not consider privacy interests.

24 The Government in its opposition argues that the  
25 Child Advocate doesn't have standing because she is not

1 the person to whom the subpoena was issued. But  
2 Section 346 gives the recipient of the subpoena a  
3 statutory mechanism to impose it. It does not silently  
4 extinguish the constitutional rights and authority to  
5 challenge unconstitutional action by nonrecipients  
6 whose own records are sought.

7 THE COURT: And, in fact, my experience is that  
8 in HIPAA subpoenas or subpoenas where there is a HIPAA  
9 issue the individuals under Rhode Island law have to be  
10 given notice by in this case it would have been Rhode  
11 Island Hospital, each individual, and an opportunity to  
12 move to quash the subpoena and so that's sort of  
13 routinely done in state court and in federal court in  
14 Rhode Island, and I'm assume in many, many other  
15 jurisdictions. There's no case law that I could find  
16 that says you can't move to quash a subpoena for your  
17 own information. The Child Advocate stands in the  
18 place of the parents of the children in State care; is  
19 that correct?

20 MR. LOVE HUBBARD: Absolutely.

21 THE COURT: Okay.

22 MR. LOVE HUBBARD: And the Supreme Court issued  
23 a timely opinion about two weeks ago reaffirming that a  
24 subpoena that burdens constitutional rights causes an  
25 injury that is more than enough to establish injury in

1 fact for purposes of standing, and that's the *First*  
2 *Choice Women Resources* case that we cite throughout our  
3 brief in reply.

4 So children who face a dire invasion of their  
5 Fourth Amendment right to be free of unreasonable  
6 search and seizure and of their Fourteenth Amendment  
7 constitutional privacy rights suffer injury in fact  
8 from the subpoena. There can't be any real dispute  
9 about that. And the Child Advocate has independent  
10 litigating authority under Rhode Island law to take  
11 whatever legal action is necessary to protect the  
12 rights of those children.

13 Multiple courts looking at these identical  
14 subpoenas have agreed. As a district court in Maryland  
15 has found, which is patients' case like the interest  
16 the Child Advocate is raising, because the subpoena  
17 plainly threatens to cause immediate injury to movants'  
18 default and concrete right to maintain privacy of their  
19 medical records, they unquestionably have standing to  
20 challenge.

21 The Government also raises the objection that  
22 the Rhode Island Hospital wasn't present here and so  
23 the injury isn't redressable by ordering them to do  
24 anything. That's no longer a concern. I'd also say  
25 the Government's, that the injury is redressable by the

1 Court ordering the Government, who has been a party the  
2 whole time. Quashal is a remedy that runs against the  
3 Government and is the proper remedy in this case and  
4 that would completely redress the injury caused by the  
5 subpoena.

6 THE COURT: And in your reply brief you state as  
7 an alternative ground the Court should modify the  
8 subpoena and enter order barring the Department of  
9 Justice from receiving, using, retaining, or  
10 disseminating patient identifying information or  
11 protected healthcare information, including all  
12 materials responsive to Requests 11 through 15 and any  
13 other materials that identify or reasonably permit  
14 identification of Rhode Island's children. And so that  
15 seems like the remedy sought there is an alternative  
16 remedy that seeks equitable relief.

17 DOJ has been before this Court the entire time,  
18 so certainly I can enjoin the Department of Justice; is  
19 that correct?

20 MR. LOVE HUBBARD: Absolutely. And now that  
21 Rhode Island Hospital is also here I think it would be  
22 appropriate, given the threat from the Government  
23 attempting to seek enforcement elsewhere, to else  
24 enjoin Rhode Island Hospital.

25 THE COURT: Right.

1 MR. LOVE HUBBARD: All right. The Government  
2 also raises the collateral attack doctrine in their  
3 opposition, and I want to briefly walk through that.  
4 First, it's not applicable here because the Child  
5 Advocate was not a party to the Texas proceeding. The  
6 Child Advocate, as we've already discussed, had no  
7 notice, no opportunity to be heard there. The Texas  
8 court specifically said, quote, Rhode Island Hospital  
9 has not shown how it would be harmed, rather than its  
10 patients, who are third parties.

11 Well, those are the patients who are before you  
12 through the Child Advocate, and their rights are at  
13 issue now.

14 The Government argues that the Northern District  
15 -- that the Child Advocate should have gone to the  
16 Northern District of Texas. It's not clear how that  
17 would happen considering that the Northern District of  
18 Texas administratively closed the matter the same day  
19 that it was opened.

20 THE COURT: Within hours.

21 MR. LOVE HUBBARD: Within hours. The Child  
22 Advocate was not a party to that case. It's not clear  
23 how we would even appeal if we wanted to, having had no  
24 role there.

25 THE COURT: Okay.

1 MR. LOVE HUBBARD: One can't be bound by a  
2 judgment *in personam* in a litigation to which she is  
3 not designated as a party. It's a bedrock  
4 constitutional principal. Beyond that, as we've set  
5 forth in our papers, the Northern District of Texas did  
6 not have venue to start with. The collateral attack  
7 doctrine simply does not apply when the original court  
8 lacks jurisdiction.

9 THE COURT: But doesn't the statute give the  
10 Department of Justice the right to move to enforce  
11 either where the parties are, the records are held, or  
12 where the investigation is centered?

13 MR. LOVE HUBBARD: It does.

14 THE COURT: It's asserted in affidavit and  
15 otherwise to this Court that, based on what you said to  
16 NYU that this investigation is centered in the Northern  
17 District of Texas.

18 MR. LOVE HUBBARD: I think, your Honor, what's  
19 important about that is the order of events. If the  
20 Department of Justice's theory is correct here that  
21 they could generate whatever forum they wanted by  
22 issuing subpoenas from D.C. which order production in  
23 D.C. to hospitals around the country, losing in motions  
24 to quash across the country, and then moving part of an  
25 investigation to a district where they think they'll

1 get a more friendly hearing, then the limitations on  
2 the jurisdiction are nonexistent.

3 And you're not writing on a blank slate. As we  
4 cite, the D.C. Circuit set forth eight factors that the  
5 Court could look to to see whether this is a place  
6 where the investigation is carried on such that venue  
7 would have been appropriate. Those factors include  
8 where the hub of national investigative activity took  
9 place; and again, here, all of the investigative  
10 contacts that Rhode Island Hospital had was with D.C.  
11 The subpoena issued from D.C., the place of production  
12 was D.C. And that's important because the second  
13 factor is the agents, the place where the agency made  
14 the decision to authorize the investigation. Again,  
15 temporally when the subpoena was issued, where was the  
16 investigation carried on. They can't overcome that  
17 factor by subsequently saying oh, we moved the  
18 investigation to the Northern District of Texas. The  
19 other factors are where the subpoena is issued. As we  
20 have said, that's D.C. Correspondence from the agency  
21 emanated; again, D.C. The agency believed that the  
22 unlawful actions had occurred; that's Rhode Island.  
23 The documents and witnesses were located; that's Rhode  
24 Island. The headquarters of the subpoenaed company was  
25 located; that's Rhode Island. One state is missing



1 from all of those factors, and that's Texas.

2 So the Government has claimed, and I have not  
3 seen *in camera* filing, but on the record before me  
4 there is zero connection from the investigation, when  
5 it was initiated all the way through April 28th with  
6 the Northern District of Texas, and so venue was not  
7 proper there, and the Court does not have to defer to  
8 the jurisdiction of a place where jurisdiction was  
9 improper to begin with.

10 THE COURT: Under this order, where would these  
11 records be returnable now?

12 MR. LOVE HUBBARD: I imagine -- because records  
13 under the HIPAA subpoena must be within 500 miles of  
14 the place where they're from, they would have to be  
15 returnable to either Rhode Island or D.C.

16 THE COURT: Right. But if the investigation is  
17 in Texas, then I can't order their return to Texas --

18 MR. LOVE HUBBARD: Right.

19 THE COURT: -- where this investigation is  
20 centered.

21 MR. LOVE HUBBARD: Right.

22 THE COURT: Okay. You can continue.

23 MR. LOVE HUBBARD: It's just not what the HIPAA  
24 statute contemplates, your Honor. If that were the law  
25 then there would be no limit on the Government's

1 jurisdiction to bring an enforcement action anywhere it  
2 chooses, and that is not the law.

3 Next is timeliness. I think we've covered that.  
4 If you have any questions about -- there's plenty of  
5 case law in our brief about excusing untimeliness even  
6 if it were to apply. But the return dates in the  
7 statute apply to the recipient of the subpoena and not  
8 to a constitutional claimant who never received the  
9 subpoena, and that's the Child Advocate.

10 Again, so we talked about purpose. I think  
11 that's the end of the inquiry. There is an improper  
12 purpose here, and the Court need to go no further. But  
13 if you want to, the next thing is the information they  
14 sought relevant to any legitimate investigation and is  
15 it reasonably tied to that investigation.

16 Here, the subpoena targets a category of lawful,  
17 state-protected care, and demands children's identities  
18 without a viable FDCA predicate or tailoring. All of  
19 the various and shifting attempts they've offered to  
20 generate an FDCA theory fail. I think the Hospital is  
21 probably in a better position to address each of those,  
22 but I'm happy to answer any questions you have.

23 THE COURT: No, that's fine.

24 MR. LOVE HUBBARD: Okay.

25 Turning to the privacy interest at issue. As we

1 said, they are weighty. The records the Department of  
2 Justice seeks contain the most intimate details of  
3 children's medical health, mental health, gender  
4 identity, sexual development, family relationships,  
5 trauma histories, and struggles with their sense of  
6 self. The subpoena would by definition force the  
7 children whose records DOJ would obtain to disclose  
8 their transgender status, and that on its own would  
9 violate their constitutional privacy rights, as  
10 multiple courts in the First Circuit have found, and we  
11 cited those to you in our brief.

12 The disclosure to DOJ is itself the injury in  
13 this case. And that's important because even if the  
14 improper purpose didn't require quashal as a remedy,  
15 though it does, the only way to protect against that  
16 privacy invasion is to quash the subpoena in its  
17 entirety. Compelled exposure of these children's  
18 medical records would chill their exercise of  
19 constitutionally-protected rights to seek medical  
20 treatment and to associate with providers who would  
21 deliver that care. And that is before you consider the  
22 Department's explicit threat to share these records  
23 with state enforcement agencies in hostile  
24 jurisdictions.

25 THE COURT: Yes, talk to me about that because

1 HIPAA is pretty clear on that as well.

2 MR. LOVE HUBBARD: It doesn't have a limitation  
3 on sharing information with other law enforcement  
4 agencies. And as we cited in our brief, the  
5 Attorney General in Texas has suggested that he's quite  
6 eager to get his hands on this information so that he  
7 can potentially prosecute parents who sought this  
8 medical care for their children.

9 THE COURT: Texas parents?

10 MR. LOVE HUBBARD: Potentially. But, again,  
11 people who have moved from Rhode Island -- moved to  
12 Rhode Island, you know, who knows what theory that they  
13 will generate in terms of threatening.

14 THE COURT: Doesn't the *Scrimetti* the case say  
15 that states have the right to make these decisions  
16 about what healthcare is available in their state and  
17 they don't decide it for other states. Isn't that  
18 essentially how I read *Scrimetti*?

19 MR. LOVE HUBBARD: The very core of that  
20 holding.

21 And, again, I think the Government's purpose  
22 here is relevant to the privacy inquiry because compel  
23 disclosure to investigators who have called the care at  
24 issue had child abuse would create a massive chilling  
25 effect on that patient-physician relationship.

1           And essentially their, the Government's  
2           alternative theory here is they're attempting to  
3           generate leads that they could use to find witnesses in  
4           another investigation. Again, imagine the privacy harm  
5           if you're a parent whose child got this care and thinks  
6           now the Department of Justice is going to send federal  
7           investigators to my house to ask questions about that  
8           care so that it can pursue undefined investigative ends  
9           in the Northern District of Texas. That is an injury  
10          right now and the injury comes from the disclosure to  
11          the Government, and the remedy for it is quashal.

12          The notice of privacy practices argument the  
13          Government raises is I think a nonstarter. A privacy  
14          notice says that records may be disclosed in response  
15          to lawful process. It does not waive constitutional  
16          rights, and it does not authorize an unlawful and  
17          pretextual subpoena.

18          THE COURT: Let's just clarify. Because we are  
19          in the First Circuit, what is the status of the right  
20          to informational privacy in the First Circuit or to  
21          medical privacy; and because it's grounded in  
22          individual privacy interests, I'm assuming, --

23          MR. LOVE HUBBARD: Absolutely.

24          THE COURT: -- how does the Court get to all of  
25          the minor patients rather than just the DCYF children?

1 MR. LOVE HUBBARD: So the privacy rights of the  
2 DCYF children are necessarily embedded in this broader  
3 patient population, right, and so if the Court were to  
4 order relief that went only to DCYF children's records,  
5 that itself would risk exposure of rest of the children  
6 at issue because the Hospital would have to go through,  
7 you know, imagine the administrative burden. Frankly,  
8 that's their issue, not mine. But you can imagine the  
9 administrative burden of trying to go through and work  
10 with the Government, who is hostile to this care, and  
11 the Child Advocate to specifically identify only the  
12 children whose records would be at issue in that order.  
13 That creates and reinforces the disclosure injury that  
14 I've been talking about.

15 THE COURT: And what would be the timeframe?  
16 For example, if somebody was in their parents' or their  
17 guardians' care and then was in DCYF care, maybe went  
18 back to their patients' care or aged out of the system,  
19 who, would the Child Advocate -- is allowing this  
20 relief only to the Child Advocate's children something  
21 that would require this, a determination as to each  
22 patient when decisions were made, who was responsible  
23 for their care?

24 MR. LOVE HUBBARD: Absolutely, your Honor. It's  
25 entirely impractical. And before that quashal is a

1 remedy that runs against the Government because the  
2 defects that we're talking about, the improper purpose,  
3 they infect the entire subpoena. And so before you  
4 even again to the administrative burden and practical  
5 impossibility of carving out that relief the -- in  
6 order to remedy the Government's error here you have to  
7 wash the entire subpoena.

8 THE COURT: And your argument is it doesn't  
9 matter what the Northern District of Texas did because  
10 the Child Advocate wasn't there, wasn't given notice.  
11 We can get to whether Rhode Island Hospital had an  
12 opportunity there or not; but with respect to your  
13 client, excuse me, there was no opportunity to be heard  
14 in Texas.

15 MR. LOVE HUBBARD: Correct.

16 THE COURT: Okay.

17 MR. LOVE HUBBARD: Your Honor, this case is  
18 about whether the federal court can use its  
19 administrative subpoena power to demand the identities  
20 and complete medical records of vulnerable children as  
21 part of a stated campaign to end lawful medical care  
22 the Government disapproves of. Seven courts have said  
23 no. The Government doesn't really engage with any of  
24 those courts in its opposition. The Government's  
25 stated purpose here was an improper one. It has stated

1 so publicly, repeatedly, unambiguously, and brazenly.

2 The constitutional privacy interests of Rhode  
3 Island's children are real and weighty and confirmed by  
4 State law. This Court unquestionably has jurisdiction  
5 to adjudicate them; and for all the reasons we've  
6 talked about needs not defer to the Northern District  
7 of Texas.

8 The Child Advocate, therefore, respectfully asks  
9 this Court to the quash this subpoena in its entirety  
10 and protect the constitutional rights of the children  
11 the Federal Government is targeted here, and, in  
12 addition, to enjoin the Government from taking any  
13 actions to enforce the subpoena elsewhere.

14 THE COURT: Okay. Now, just a question and I  
15 think it's probably tangential, but are you aware of  
16 any specific holding that an administrative subpoena is  
17 final agency action for purposes of 702 of the APA.

18 MR. LOVE HUBBARD: I'm not off the top of my  
19 head, your Honor. The cases we've cited about that  
20 issue are that even if there's not an APA cause of  
21 action specifically, the APA provides relief for  
22 constitutional actions when there is no other relief  
23 otherwise, and that's exactly the situation here.

24 THE COURT: Okay. Thank you.

25 MR. LOVE HUBBARD: Thank you, your Honor.



1 MR. OLSHAN: Good afternoon, your Honor.

2 THE COURT: Good afternoon.

3 MR. OLSHAN: Eric Olshan appearing on behalf of  
4 Rhode Island Hospital.

5 I think I would like to start with how we got  
6 here, Judge. As the Court is the aware, the Hospital  
7 was issued an Administrative Subpoena by the Department  
8 of Justice July 9th of last year. The return date was  
9 August 7th. Rhode Island Hospital retained outside  
10 counsel. Within a couple weeks we engaged with the  
11 Government. We are here all those months later because  
12 we relied on the conduct of the Government in how they  
13 interacted with Rhode Island Hospital with respect to  
14 compliance with the subpoena.

15 As the Court is well aware, subpoenas are issued  
16 all the time, whether it's a grand jury subpoena, an  
17 administrative subpoena. Oftentimes the language in  
18 those subpoena attachments is quite broad because the  
19 Government doesn't necessarily know what things  
20 specifically to ask for, assuming they have a valid  
21 basis to issue the subpoena at all, and so that sparks  
22 negotiations and back and forth between the subpoenaed  
23 entity or individual and the Government. That is sort  
24 of the normal course, and that is how we pursued our  
25 conduct on behalf of the Hospital in this

1 investigation, assuming that we were dealing with a  
2 counterparty that was acting in good faith.

3 We made a production at the Government's request  
4 on August 7th, the return date. And I would note for  
5 the Court that we never heard that there was anything  
6 insufficient about that until they filed their motion  
7 to compel in the Northern District of Texas a couple  
8 weeks ago.

9 THE COURT: Well, you were still negotiating  
10 about search terms; is that correct?

11 MR. OLSHAN: Eventually we were, absolutely. At  
12 the time we made that initial production, that was a  
13 couple weeks after the subpoena was served. We were  
14 not yet negotiating search terms and that related to  
15 one of their requests for marketing communications  
16 involving pharmaceuticals.

17 THE COURT: Right. So they didn't specifically  
18 engage with you about each of the items that they  
19 requested; --

20 MR. OLSHAN: Right.

21 THE COURT: -- I apologize. And so specifically  
22 11 through 15, there was no engagement with them on  
23 that; is that correct?

24 MR. OLSHAN: That's exactly right, your Honor.  
25 So obviously at the center of our objection in the

1 Child Advocate's and the litigation around the country  
2 is the core privacy interests of the patients and their  
3 families at stake here.

4 I will tell the Court that that topic did not  
5 come up in our negotiations. We were talking about  
6 marketing communications, and as we've laid out in our  
7 brief, the cadence of our conversations with the  
8 Government was staggered. Usually in these situations  
9 the Government is driving expectations; it's their  
10 process, they issued it.

11 Here, we would have starts and stops, and so  
12 there were multiple conversations not about Requests 11  
13 through 15. They were never raised by the Government.  
14 We were talking about this other topic.

15 THE COURT: And were you always communicating  
16 with the same person from the Department of Justice?

17 MR. OLSHAN: Primarily. The first two calls I  
18 believe, your Honor, Mr. Campbell was on those calls.  
19 But our subsequent conversations, including the one  
20 that occurred in the e-mail exchange that the Court  
21 referenced starting on April 28th was with primarily  
22 two trial attorneys. I believe one's a trial attorney;  
23 one might be a supervisor in what was the Consumer  
24 Protection Branch that is now part of the Informative  
25 Enforcement and Litigation Branch, I believe it's

1       called, which is still part of the Civil Division.

2               But over time we were dealing directly with two  
3 individuals primarily in our, I'd say, last four to six  
4 calls, neither of whom is here. So our --

5               THE COURT: Okay. And we don't have an  
6 affidavit from any of those; we just have the e-mails.  
7 Correct?

8               MR. OLSHAN: That's correct.

9               THE COURT: Okay.

10              MR. OLSHAN: So our conversations over these  
11 periods of months in 2025, we were focusing on our  
12 efforts to collect e-mail communications that may be  
13 responsive to the marketing request as it relates to  
14 pharmaceutical companies. Never at any time did we  
15 hear your so-called grace period is running out, we are  
16 not happy with the pace of production. We didn't have  
17 any information from the people at the other end at the  
18 Department of Justice that anything like what happened  
19 a couple weeks ago was going to happen.

20              And so you get to January, and the Court is  
21 aware from the e-mail chain and the briefing on this,  
22 you get to January. We had a conversation with an  
23 attorney from the Consumer Protection Branch, or what  
24 is now EALB.

25              THE COURT: Can you tell us who that attorney

1 was .

2 MR. OLSHAN: His name is David Gunn.

3 THE COURT: Okay.

4 MR. OLSHAN: Our conversation with Mr. Gunn  
5 where we talked about providing search terms and in  
6 anticipation of providing a production. The next week  
7 we provided those search terms; the Court is well aware  
8 of this. We didn't hear back even to acknowledge  
9 receipt of those search terms, let alone tell us, hey,  
10 thank you for sending us the search terms, we've got 15  
11 more we think you should add or 30 of them we don't  
12 care about any hits on those; which is sort of the  
13 typical back and forth in that context.

14 THE COURT: In a typical informational discovery  
15 exchange, correct, or a subpoena.

16 MR. OLSHAN: Sure. Absolutely right. And  
17 again, that is typical when you have a very broadly  
18 worded subpoena. And here, as the Court again is well  
19 aware, this isn't just a broadly-worded subpoena. This  
20 is an exceptionally expansive subpoena; not just  
21 Requests 11 through 15, but virtually everything, gets  
22 into the innermost workings of the operation of this  
23 Hospital that's trying to provide care for this very  
24 vulnerable patient population.

25 So, again, in late January offered to provide

1 search terms, we did; they didn't respond. Some  
2 12 weeks passed until April 28. We had the e-mail from  
3 Mr. Gunn, that is in the record, saying that they had  
4 not heard from us since the search terms we sent and  
5 they would request a status. So we responded next day,  
6 which was the 29th of April and said sure, the rest of  
7 this week is not great, how about Monday. We didn't  
8 get a response about scheduling that status call.

9 The next communication we received, and the  
10 Court was exactly right, this happened at 6:10 p.m.  
11 Eastern time, it was Eastern time on Thursday  
12 April 30th, responding to our e-mail about scheduling  
13 the conference that the Department had requested,  
14 saying no need for the call at this time, here's what  
15 we filed.

16 THE COURT: And here's the order that we got;  
17 right?

18 MR. OLSHAN: The order we got the next day.

19 THE COURT: When was the order ordered in Texas?  
20 Texas CM/ECF doesn't allow time. We do.

21 MR. OLSHAN: So that is a little bit of a  
22 mystery here, your Honor. So the order is dated the  
23 same day that the motion to compel was filed. So I  
24 guess technically it must have been within a matter of  
25 hours because the day ended at some point.

1 THE COURT: Well, it had to be, I would imagine  
2 it had to be by 5:00 Texas, Northern District of Texas  
3 time, which I think that's an hour different from Rhode  
4 Island.

5 MR. OLSHAN: Correct.

6 THE COURT: So that would have been 6:00 Eastern  
7 time; correct?

8 And the Government can correct me if I'm wrong  
9 about that, but...

10 MR. OLSHAN: That's correct, the Government  
11 would presumably know when they received the order. It  
12 was docketed the next day before we had even entered an  
13 appearance in the case. So we actually found the order  
14 granting the relief the Government sought essentially  
15 *ex parte* before we were even appearing in the case.

16 But the Government would know whether that order  
17 was actually signed before the close of business on  
18 Thursday the 30th, which would mean not only did we not  
19 get notice that there was a motion to compel until  
20 after the close of business Central and Eastern time,  
21 but that the order granting it was before we ever  
22 received notice. I'm leaving open the possibility,  
23 your Honor, that it might have been signed in the  
24 evening after we got the e-mail from Mr. Gunn attaching  
25 the motion, but --

1 THE COURT: Certainly the Government can respond  
2 to that.

3 MR. OLSHAN: Right. From our standpoint the  
4 motion was, and the record is clear, the motion was  
5 filed and granted the same day, which is the genesis of  
6 our due process argument.

7 THE COURT: Okay. Let's talk about that. I  
8 want to -- a couple of things. So you were in these  
9 negotiations with the Department of Justice, and I  
10 recognize that this is typically how this works in  
11 these cases. But there was nothing preventing Rhode  
12 Island Hospital from filing a motion to quash and  
13 saying to the court hold off on this, we're  
14 negotiating. Is that correct?

15 MR. OLSHAN: That's true, your Honor, it is.  
16 It's an escalation that based on the tenor of our  
17 communications -- again, our reliance on the conduct of  
18 the Government we didn't think was necessary at the  
19 time.

20 Now, the other thing we didn't know as we  
21 were -- well, eventually we knew this -- is that now  
22 it's public because these matters have been unsealed.  
23 Other subpoenaed entities receiving the same exact  
24 subpoena did go to court under seal: Boston  
25 Children's, Children's Hospital of Philadelphia,



1 Seattle Children's, QueerDoc, Colorado Children's, that  
2 was all under -- pardon me?

3 THE COURT: Los Angeles, maybe?

4 MR. OLSHAN: I believe the Los Angeles action,  
5 CHLA, was pursued by patients.

6 THE COURT: Correct. Okay.

7 MR. OLSHAN: But my point is this is happening  
8 in parallel and so as we're negotiating and deciding  
9 next steps, again reacting to the conduct of the  
10 Government. Again, they have not brought up the most  
11 sensitive category, and as the Court knows from our  
12 briefing, the Government voluntarily agreed to  
13 limitations from at least three subpoenaed entities.

14 THE COURT: And there's nothing in the record  
15 that indicates that they gave that information to the  
16 Texas judge. In fact, there's an argument that there  
17 was a misrepresentation to the Texas judge; isn't that  
18 correct?

19 MR. OLSHAN: I am not aware of anything in the  
20 record in the Northern District of Texas that indicates  
21 they told that court that they had agreed to  
22 limitations as to deidentified records, no, your Honor.

23 THE COURT: Okay. And I think they're saying  
24 the deidentified records in their response in Texas  
25 they say, and actually Lisa Hsiao says in her

1 publicly-filed affidavit that, (Reading) Health  
2 benefits programs tied to identified patients could  
3 provide additional information, including claim  
4 records, creating a reinforced evidentiary record. And  
5 then the Government goes on to say in its brief,  
6 (Reading) In sum, without this information the  
7 Government cannot fully determine the scope of  
8 violation, identity patterns of misbranding or  
9 fraudulent billing, or assess whether the conduct was  
10 undertaken with intent to defraud or mislead, as  
11 required for felony liability under 21 USC 333(a)(2).

12 So is it arguably the Texas judge wasn't  
13 informed that they made compromises with other  
14 hospitals to receive deidentified information and, in  
15 fact, I would read that to say that they misled the  
16 Texas judge on that.

17 MR. OLSHAN: I won't disagree with the Court.

18 From my client's standpoint, from Rhode Island  
19 Hospital's standpoint, as you can imagine, Judge, the  
20 recitation of the series of events between issuance of  
21 the subpoena and April 30th when the motion was filed  
22 is something that we object to vigorously. It is not  
23 an accurate recitation. It makes it sound like a  
24 subpoena was issued, we dropped off a six-page  
25 document, we said see you later, and then nothing

1       happened and they decided to go to court.

2               That court was not made aware of the fact until  
3       we moved to the stay the court's order, and the court  
4       there had denied our motion, but we made the court  
5       aware that there was a series of events literally in  
6       the two days before they moved to compel before that  
7       court.

8               THE COURT:   Yeah.

9               MR. OLSHAN:   So here we are, your Honor.   The  
10      Child Advocate, after the court entered the order, we  
11      had no opportunity to be heard.   And we've cited Fifth  
12      Circuit cases, First Circuit cases, Supreme Court cases  
13      making clear that that is a fundamental due process  
14      violation, that the opposing party has to be given the  
15      opportunity to be heard prior to enforcement.

16              THE COURT:   The Department of Justice is saying,  
17      hey, this is a collateral attack by both Child Advocate  
18      and by Rhode Island Hospital.   Can you address Rhode  
19      Island Hospital's argument with respect to why the  
20      Court should not consider this is to be a collateral  
21      attack on the Northern District of Texas order.

22              MR. OLSHAN:   Absolutely, your Honor.   One thing  
23      I would say is if the collateral attack doctrine does  
24      not apply, then it is a direct action, if you will,  
25      against that order because our position is and why

1 we're before this Court is because it's void. And so  
2 there's a case that we cite, it's *Ash v. McNamara*, it's  
3 a First Circuit case that says when the record of a  
4 proceeding, quote, established very clearly that due  
5 process of law had been denied, a court would have been  
6 empowered to entertain the collateral attack.

7 And essentially that's what we're articulating  
8 in our briefing, Judge, is that by the district court  
9 not giving us any opportunity to be heard prior to  
10 enforcement, which could have been immediately, could  
11 have been a couple of hours, we weren't heard; that's a  
12 fundamental due process violation which allows us to  
13 come to court. I agree with Mr. Hubbard that with  
14 respect to the Child Advocate they're not similarly  
15 situated, they were not a party to the matter that led  
16 to that order that way that we are.

17 THE COURT: How do I consider the lack of sort  
18 of a full disclosure in Texas to the judge there what  
19 had gone on between July of 2025 and April 29th of 2026  
20 when I decide -- does that impact the determination as  
21 to whether Rhode Island Hospital was denied due  
22 process?

23 MR. OLSHAN: I think it does because one of the  
24 things that we would be permitted to have done if given  
25 the opportunity to respond on the merits to the motion

1 to compel is exactly that, lay out that this is what  
2 has been happening since the subpoena was issued  
3 July 9th. And the court, this is in our briefing, that  
4 the date on the order the court signed there is  
5 actually wrong. It says that the subpoena was issued  
6 July 3rd. It was issued July 9th.

7 All of that, your Honor, would be hashed out if  
8 we had been given an opportunity, including this  
9 correct series of events.

10 THE COURT: And why isn't the proper order of  
11 operation, so to speak, a motion to reconsider in Texas  
12 before that judge?

13 MR. OLSHAN: Your Honor, given what happened in  
14 the immediate ordering -- and actually now this has  
15 been ratified by the district court there in denying  
16 our motion for a stay -- that essentially the court  
17 viewed any argument as, or any opportunity for us to be  
18 heard on behalf of Rhode Island Hospital as futile.  
19 And so the court there, in issuing that order  
20 immediately, our assessment was the court's mind was  
21 made up, irrespective of whether we had a chance. We  
22 obviously disagree with the court. And so given the  
23 order requiring full compliance with the subpoena,  
24 which the Government knows is not possible, we chose to  
25 ask the court to stay while we appealed his order. The

1 court denied that over the weekend, I believe Sunday  
2 night, and so now we were in the Fifth Circuit which --

3 THE COURT: They denied it, but do you agree  
4 with Mr. Love Hubbard that they've also stayed the part  
5 of the subpoena that deals with the informational  
6 privacy Requests 11 through 15?

7 MR. OLSHAN: I think you could read it that way.  
8 I don't know how the Government reads it, your Honor.

9 THE COURT: I think it's a pretty clear reading  
10 from the order from the judge in Northern District of  
11 Texas.

12 MR. OLSHAN: Even if there is a stay as to let's  
13 say categories or Requests 11 through 15 your Honor, it  
14 only lasts until the Fifth Circuit acts on our motion  
15 for a stay pending appeal.

16 THE COURT: Right.

17 MR. OLSHAN: So, and frankly for all we know  
18 that could have happened already during this hearing  
19 because the government filed their response noon  
20 Central time in the Fifth Circuit. The Fifth Circuit  
21 could act at any moment. So in theory, yes, your  
22 Honor, but as practical matter the court could act  
23 tomorrow, the court could act the next day; and given  
24 the series of events that led us here to this two-week  
25 window -- and I would be curious whether any subpoenaed

1       entity has (1) made full compliance, made full  
2       production and (2) done it on a two-week timeframe  
3       after the Government had led them to believe that their  
4       conversations were an appropriate pace.

5               THE COURT: The record in Texas that goes up to  
6       the Fifth Circuit is not necessarily going to be  
7       complete; is that correct? That there's no motion to  
8       reconsider. So your arguments that are here are not  
9       before the Texas -- the Fifth Circuit Court of Appeals.

10              MR. OLSHAN: They're only in front of the  
11       Fifth Circuit under the likelihood of success prong of  
12       the stay analysis. This is not the full-throated  
13       articulation that you would -- that we have preferred  
14       on direct appeal, excuse me, on reconsideration or on,  
15       if we had been given an opportunity to actually  
16       respond.

17              THE COURT: And because his order denying the  
18       motion to stay says that your, any arguments you made  
19       would be futile, it's Rhode Island Hospital's that it  
20       would be a waste of energy and resources and the  
21       court's time, I would assume, and DOJ's time to file a  
22       motion to reconsider in Texas.

23              MR. OLSHAN: Certainly now, your Honor, now that  
24       the court has entered an order saying that based on  
25       what the Government's one-sided version of events lays

1 out and their one-sided legal arguments, and  
2 notwithstanding that there are seven reasoned decisions  
3 from district courts around the country, our arguments  
4 are few futile, yes.

5 THE COURT: Thank you.

6 MR. OLSHAN: And we're always interested in  
7 conserving judicial resources if we can. I should have  
8 said at the outset, Judge, thank you for letting us  
9 appear at this hearing today. Given the hour obviously  
10 there's significant time pressure that Rhode Island  
11 Hospital is facing.

12 And so I've laid out why from a due process  
13 standpoint we think we have a strong argument not only  
14 in the context of an appeal in the Fifth Circuit, but  
15 why this court can entertain our motion to quash  
16 alongside the Child Advocate's motion to quash.

17 The Child Advocate obviously is representing the  
18 interest she has on behalf of the children she speaks  
19 for, and I join Mr. Hubbard and the Child Advocate's  
20 arguments as to quashal across the board for this  
21 document. Obviously some of those arguments the  
22 Government's raised as to the Child Advocate maybe do  
23 not apply to Rhode Island Hospital. We are the  
24 subpoenaed party. We can ask this Court to quash  
25 across the board. That is what we are seeking at this



1 point.

2 And when the Child Advocate filed we had to --  
3 we made the decision we had to be here in front of this  
4 Court. Rhode Island Hospital cannot be on the sideline  
5 while these issues that not only impact this extremely  
6 vulnerable patient population, as Mr. Hubbard  
7 articulated, but the operations of the Hospital, your  
8 Honor. From any hospital's standpoint, the knowledge  
9 that the Government could come along, the Federal  
10 Government, and obtain the most sensitive patient  
11 records in support of what courts have determined is  
12 invalid and inappropriate investigation is something  
13 that cuts at the core of these hospitals. If patient  
14 populations know that, it might be this vulnerable  
15 patient population today; it's going to be another one  
16 down the road. That's going to affect the ability of  
17 the Hospital to operate.

18 THE COURT: Let me ask you a question, though.  
19 If I agree with you and quash the entire subpoena,  
20 what's the effect on the order in Texas? Does it make  
21 it a nullity because there's no subpoena for them to  
22 order compliance with? What is the practical effect  
23 and what is the procedural sort of impact?

24 MR. OLSHAN: I think the legal effect would be  
25 that this Court would be ruling that that order is

1 essentially void because of the due process issue.

2 We would ask the Court to inquire when the  
3 Government speaks if this Court were to enter order  
4 quashing the subpoena as issued to Rhode Island  
5 Hospital, is the Government going to ask the court in  
6 the Northern District of Texas -- this is assuming  
7 there's no stay. We don't know if there's a stay; this  
8 issue potentially goes away.

9 THE COURT: Uh'huh.

10 MR. OLSHAN: Are they going to go to the  
11 Northern District of Texas and ask to hold Rhode Island  
12 Hospital in contempt in the face of an order that says  
13 the subpoena is quashed? And if they will not commit  
14 to do that, your Honor, we would ask this Court's order  
15 not only quash the subpoena, --

16 THE COURT: But enjoin.

17 MR. OLSHAN: -- but also enjoin Rhode Island  
18 Hospital from producing responsive records to the  
19 Government, and from the Government enjoining the  
20 Government from collecting or taking actions or  
21 collect --

22 (Indecipherable crosstalk)

23 THE COURT: -- to receive responsive records;  
24 right?

25 MR. OLSHAN: Exactly.

1 THE COURT: Okay.

2 MR. OLSHAN: I would hope that the Government --  
3 in the face of any order this Court issues narrowing or  
4 quashing, which we're asking for -- would agree not to  
5 seek that relief in the Northern District of Texas, but  
6 only they can answer that question.

7 I do want to take a few minutes to talk about  
8 the FDCA. The LAMBDA Legal Education Fund, your Honor,  
9 their amicus brief has a very good recitation of the  
10 Government's shifting articulation of what they are  
11 investigating under the FDCA. Is it I believe pages 24  
12 through 27 of their brief which is docket number, one  
13 moment, Docket 15, I believe, in this matter. It lays  
14 out in detail the sort of shifting use of the  
15 terminology from the FDCA, and that's even happened  
16 with respect to Rhode Island Hospital.

17 The affidavit that the Court quoted from for  
18 Ms. Hsiao that was filed in the Northern District of  
19 Texas, this is Document 1-1 from the Northern District  
20 of Texas case 4:26-MC-6, says in paragraph 3, this is a  
21 sworn declaration, "EALB-ES" -- that's this office that  
22 is based in Washington, D.C.

23 THE COURT: Paragraph 3, is that what you're  
24 saying?

25 MR. OLSHAN: Correct, your Honor.

1 THE COURT: Yes.

2 MR. OLSHAN: "...is currently conducting an  
3 investigation of potential violations of the Food,  
4 Drug, and Cosmetic Act, FDCA, relating to the on- or  
5 off-labeling use by manufacturers and distributors of  
6 drugs, including puberty blockers, sex hormones, or any  
7 other drug used to facilitate a child's so-called  
8 gender transition."

9 So the language in that paragraph, your Honor,  
10 speaks about investigations of on- or off-label use by  
11 manufacturers and distributors.

12 Rhode Island Hospital is neither a manufacturer  
13 or a distributor. And as the FDCA makes clear,  
14 off-label use is not prohibited. It's certainly not  
15 prohibited as to Rhode Island Hospital or the  
16 clinicians who prescribe these medications.

17 THE COURT: Right. Do you have clarity on what  
18 the DOJ says it's investigated? Because I read that  
19 too and it indicates that Rhode Island Hospital is  
20 certainly not -- it can't be responsible for  
21 misbranding, which I think is another thing that they  
22 say. And so you're not a manufacturer. You're not  
23 liable for any criminal activity or for off-label use,  
24 and so you also -- they also cannot enforce sort of  
25 these laws that are misbranding laws against you.

1 Did you get any clarity from people you were  
2 working with with the Department of Justice as to what  
3 they specifically were investigating?

4 MR. OLSHAN: No, your Honor. And it is  
5 confusing even in this litigation because I believe the  
6 articulation is one way in response to, I'm sorry, in  
7 this declaration that was submitted in the Northern  
8 District of Texas. It's articulated differently in the  
9 Government's response to the Child Advocate's motion to  
10 quash, and it makes it sound like in their briefing  
11 that there actually could be some kind of liability as  
12 to Rhode Island Hospital, which clearly this  
13 declaration does not support.

14 THE COURT: Right. And it's under oath, this  
15 declaration, it's an affidavit of Lisa Hsiao.

16 MR. OLSHAN: It is. And each of the -- I  
17 believe maybe with one exception, your Honor, Ms. Hsiao  
18 has submitted a declaration, a declaration in every one  
19 of the litigated cases that are unsealed.

20 But I would commend the Court to the brief by  
21 LAMBDA Legal where it kind of lays out each of these  
22 permutations. And this is relevant because it gets to  
23 the argument of what is the -- whether there is an  
24 improper purpose and any bad faith in this  
25 investigation.

1           The way that we read what we think is their  
2       theory is that there cannot be criminal liability  
3       because -- and I'm going to do my best here, Judge.  
4       Physicians prescribe these drugs lawfully off label.  
5       FDCA protects that. Supreme Court said that that is  
6       the law of the land. The Department of Justice has  
7       taken that position in other litigation. It's not a  
8       controversy statement that the doctors routinely  
9       prescribe off-label.

10           THE COURT: I think Wegovy and whatever the  
11       GLP-1 drugs are, that are being prescribed off-label  
12       for everyone.

13           MR. OLSHAN: That's right.

14           THE COURT: Not everyone; I assume some people  
15       are legitimately taking them for diabetes.

16           MR. OLSHAN: But a lot of off-label prescribing.  
17       I believe one of the briefs, it might be the Child  
18       Advocate's reply estimates -- or maybe the state  
19       Attorneys General, I apologize -- 20 to 50 percent of  
20       all drugs are prescribed off-label. In some areas of  
21       medicine I believe the entire standard of care involves  
22       using a drug for an off-label purpose or, excuse me,  
23       prescribing it for an off-label purpose.

24           So what one is left to see is that the  
25       Department of Justice is kind of bootstrapping a

1 shifting theory about why there is statutory basis for  
2 the issuance of these subpoenas under 3486 so that they  
3 can justify what their own statements reflect is a  
4 desire to end gender-affirming care. And as this Court  
5 intimated, there are other ways -- I'm not a doctor, I  
6 don't know if anyone in this courtroom is a doctor; but  
7 the Government is certainly not doctors. If they do  
8 not like the way that certain areas of medicine is  
9 practiced, they can take that up with state  
10 legislatures, they can take it up with licensing  
11 boards.

12 But you do not carry out what appears to be  
13 based on public reporting essentially a nationwide  
14 dragnet through criminal legal process to collect the  
15 most sensitive patient records of what could be tens of  
16 thousands, maybe more, of the most vulnerable children  
17 in the United States.

18 So when the Court kind of tries to parse each of  
19 these FDCA theories, we would argue that's what left,  
20 is that they have not articulated a valid legal theory  
21 under the FDCA, and what they're trying to do is say  
22 that because the original packaging that the  
23 manufacturers produced and the instructions on it for  
24 use do not match with how the drug is actually used  
25 when prescribed off-label by a physician, that somehow

1 establishes some kind of conspiracy to distribute or  
2 promote in on off-label manner.

3 THE COURT: Okay. Who's -- I'll ask the  
4 Department of Justice that. They can answer that.

5 MR. OLSHAN: So again, your Honor, under the  
6 FDCA our view as articulated in our brief and as  
7 ratified by some of the other courts or all of the  
8 other courts prior to the Northern District of Texas'  
9 ruling, there is not a lawful statutory basis, and  
10 that's independent of the evidence in the record of bad  
11 faith and improper purpose.

12 And I will add, your Honor, when the Department  
13 moved to compel, I'd also put on the record there is a  
14 Local Rule in the Northern District of Texas, I believe  
15 it's Local Rule 7.1 that requires conferral before  
16 filing a motion to compel. There was obviously no  
17 conferral here. They do style it as a petition, though  
18 in their actually pleading they say that they are  
19 seeking to compel the records, and I believe the  
20 judge's order, excuse me, denying our motion for stay  
21 refers to it as a motion to compel. But we certainly  
22 did not engage in any conferral prior to their filing,  
23 as the record makes clear.

24 But one of the things, you know, we're left to  
25 consider is why Rhode Island Hospital, and one thing



1 that is relevant to that as it relates to this improper  
2 purpose and bad faith analysis is that one of the  
3 officials involved in this litigation has actually  
4 affirmatively sued Rhode Island Hospital and providers  
5 at Rhode Island Hospital in the years leading up to  
6 now. So Mr. Campbell, prior to joining Department of  
7 Justice, initiated litigation in state court and  
8 federal court in Rhode Island against Rhode Island  
9 Hospital and the some of its providers and has been on  
10 record. I believe the FTC hearing that Mr. Hubbard  
11 mentioned, and the Court has the transcript, that's  
12 where Mr. Campbell appeared and said that they're  
13 working on this with respect to some argument of ending  
14 gender-affirming care by going after providers. That  
15 should be relevant to this Court at least as it relates  
16 to Rhode Island Hospital because we're left wondering  
17 given the nature of our communications with the  
18 Government, how we wound up in this situation that  
19 we're currently in.

20 If the Court will allow me one minute to look at  
21 my notes.

22 (Pause)

23 MR. OLSHAN: One other thing that relates to the  
24 way that the Government has articulated what they are  
25 investigating is they talk about false billing. False

1 billing is not a viable theory under FDCA. That would  
2 be healthcare fraud theory. And so although  
3 Ms. Hsiao's Declaration says they are investigating  
4 violations of the FDCA, I notice in the Government's  
5 brief they say that they are investigating, among other  
6 things, violations of the FDCA. So it is unclear  
7 unless that was an inartful turn of phrase whether or  
8 not the representation that this is just an FDCA  
9 investigation is accurate or if it has expanded to now  
10 encompass billing allegations which really sound in  
11 healthcare fraud, Judge.

12 THE COURT: And that's the other question. Have  
13 you dealt with anybody from the Criminal Division DOJ  
14 or you're only dealing with the Civil Division with  
15 respect to this subpoena?

16 MR. OLSHAN: It's a bit complicated because  
17 there's been some reorganization at the Department of  
18 Justice.

19 THE COURT: I see.

20 MR. OLSHAN: As I understand it, and the  
21 Government can speak to this. The Consumer Protection  
22 Branch which was a part of the Civil Division, but  
23 actually had a civil and criminal mandate, so would be  
24 criminal case coming out of that part of the Civil  
25 Division, has been moved or a lot of it has been moved

1 over to the Criminal Division of main Justice;  
2 although, as we understand it, the lawyers from that  
3 office who are working on this particular investigation  
4 are not in the Criminal Division, they have stayed or  
5 been seconded or detailed back to the Civil Division.

6 THE COURT: And just so that we're clear, in  
7 Texas Ms. Hsiao signed her affidavit as Acting Director  
8 Enforcement and Affirmative Litigation Branch, Civil  
9 Division, United States Department of Justice. So that  
10 answers my question, thank you.

11 MR. OLSHAN: That is accurate. And I did want  
12 to make a point about so it's crystal clear on the  
13 venue question, your Honor. At no time from when we --  
14 the subpoena was served on Rhode Island Hospital, until  
15 the court entered the order on April 30th granting  
16 their motion to compel, were we in touch with anyone in  
17 Texas. Every single person we spoke to was an  
18 attorney, whether there was a career person or a  
19 political appointee at main Justice in Washington, D.C.  
20 No communications with anybody in Texas.

21 Unless the Court has any other questions, I  
22 appreciate Court's time. And if the Court would allow,  
23 depending on what the Government has to say, I would  
24 imagine Mr. Hubbard may want to be heard again, and I  
25 would like to as well.

1 THE COURT: Of course.

2 MR. OLSHAN: Thank you.

3 THE COURT: We are going to take a 10-minute  
4 recess to allow the stenographer to rest her fingers  
5 for a bit, so we'll be back in 10.

6 (Recess)

7 MR. MAYERS: Good afternoon, your Honor.

8 THE COURT: Good afternoon.

9 MR. MAYERS: I tend to speak fast, so let me  
10 know if there's a problem.

11 THE COURT: Yes, just take a deep breath in  
12 between.

13 MR. MAYERS: Yes.

14 THE COURT: You know, it is hard for her to get  
15 the record and I tend to interrupt, so, I also speak  
16 fast. So whenever you're ready.

17 MR. MAYERS: May it please the Court. The  
18 motion before the Court today, I'd like to briefly  
19 renew our motion to transfer. There a few factual  
20 developments that are relevant to the first-filed  
21 rule --

22 THE COURT: Uh'huh.

23 MR. MAYERS: -- that have taken place in the  
24 interim between your Honor's ruling and present.  
25 First, of course, the fact that Rhode Island intervened

1 and so there's --

2 THE COURT: I've denied that motion, --

3 MR. MAYERS: Okay.

4 THE COURT: -- and I've articulated the reason.  
5 The first-filed rule doesn't apply when Rhode Island  
6 Hospital wasn't before the court in Texas. The fact  
7 that they've now been forced to intervene here and in  
8 Texas doesn't bootstrap you into the first-filed rule.

9 MR. MAYERS: Understood, your Honor.

10 So next I'll turn to two threshold arguments  
11 that we made that you discussed with the person on the  
12 other side; first, standing; and second, the collateral  
13 attack doctrine.

14 THE COURT: Okay.

15 MR. MAYERS: Both of those in the Government's  
16 opinion confirm that any relief --

17 (Court Reporter requests pause)

18 THE COURT: The Government submits that both of  
19 those doctrines confirm that any relief the parties  
20 seek should be in front of the Northern District of  
21 Texas and not this Court.

22 So first, standing. The Child Advocate talks  
23 about injury in fact. Your Honor, we don't dispute  
24 injury in fact here as to the Child Advocate's ability  
25 to raise the interests of DCYF.

1 THE COURT: You do, or you do not?

2 MR. MAYERS: We do not.

3 THE COURT: Okay.

4 MR. MAYERS: So with respect to the Child  
5 Advocate in DCYF custody, we agree the Child Advocate  
6 can raise those interests.

7 THE COURT: Okay. We're going to get this to  
8 later, but you should think about how on earth we would  
9 decide who is in DCYF custody and when. And while  
10 we're on the subject, what made the Government choose  
11 January of 2020 through the present day, which I assume  
12 in any present day.

13 MR. MAYERS: Your Honor, that's just the  
14 standard term for a subpoena of this nature.

15 THE COURT: Six years? Five years and three  
16 months, four months, five months? That's your  
17 standard?

18 MR. MAYERS: Yes, your Honor, as far as I'm  
19 aware that is the typical just dating that we would use  
20 in a subpoena like this.

21 THE COURT: Okay.

22 MR. MAYERS: I'll briefly discuss standing and  
23 then we can go to any questions your Honor had. But  
24 our focus in our brief in any case is redressability,  
25 so the point to meet redressability must show that a

1 favorable resolution of her claim likely address the  
2 professed injury. We submit that's not true here.  
3 Regardless of quashal or injunction, which we maintain  
4 would not be permissible on a --

5 THE COURT: Why isn't it? Why isn't the  
6 redressal here?

7 MR. MAYERS: Your Honor, I think regardless of  
8 your Honor's choice of remedy, the Northern District of  
9 Texas' order would still stand. It would still  
10 require --

11 THE COURT: Not if I enjoin DOJ from receiving  
12 any documents.

13 MR. MAYERS: Your Honor, the order compelling  
14 the Hospital to turn over those documents we would  
15 submit would still stand.

16 THE COURT: Okay. But you understand, of  
17 course, that you couldn't receive them.

18 MR. MAYERS: I don't know where I -- it would be  
19 complicated. I don't know where Rhode Island would  
20 send them.

21 THE COURT: Where would you -- well, they  
22 wouldn't send them to Texas because it's more than 500  
23 miles. Where are you from?

24 MR. MAYERS: I'm from Washington, D.C.

25 THE COURT: Okay. And your co-counsel?

1 MR. MAYERS: Washington, D.C. as well.

2 THE COURT: And also at counsel table,  
3 Ms. Zurier is Rhode Island; correct?

4 MR. MAYERS: Yes. Rhode Island, yes.

5 THE COURT: Where is the Northern District of  
6 Texas person?

7 MR. MAYERS: There is no lawyer from the  
8 Northern District of Texas present in the court.

9 THE COURT: Why not?

10 MR. MAYERS: Decided that I would come argue  
11 this motion, your Honor.

12 THE COURT: Uh'huh. Okay. Go ahead.

13 MR. MAYERS: Your Honor, we do think there's a  
14 complication as to redressability for the reason I  
15 stated given the fact that the Northern District of  
16 Texas order would remain on the books regardless.

17 THE COURT: Okay. Now, you heard Mr. Love  
18 Hubbard refer to the NYU press release; correct?

19 MR. MAYERS: Yes, your Honor.

20 THE COURT: And that press release, which I'm  
21 getting a copy of now, dated -- I don't know when it  
22 was dated, but it says that on May 7th NYU was one of  
23 several institutions that received a grand jury  
24 subpoena from the U.S. Attorney's Office in the  
25 Northern District of Texas, and it goes into the



1 request.

2 So I'm assuming that the fact of a grand jury in  
3 the Northern District of Texas is not, is no longer a  
4 secret if you're issuing subpoenas from that grand  
5 jury; correct?

6 MR. MAYERS: Your Honor, we acknowledge that  
7 NYU Langone has put that release out.

8 THE COURT: What, you're disputing it?

9 MR. MAYERS: No.

10 THE COURT: Okay. So that happened.

11 MR. MAYERS: Yes, your Honor.

12 THE COURT: Okay. When was that grand jury  
13 convened? What specific date?

14 MR. MAYERS: Your Honor, I can't come up with  
15 the exact specificity as to the date. I believe that  
16 we can only speak to the extent of what's in the press  
17 release of NYU Langone, it's in the public record.  
18 Your Honor, we submitted the *ex parte* Hsiao declaration  
19 as well.

20 THE COURT: But that doesn't -- okay. I haven't  
21 ordered and I'm going to order as a result of the fact  
22 that now this has been released that you provide a copy  
23 of that affidavit to opposing counsel, and you can do  
24 whatever you need to do to redact it, but redactions  
25 need to be for things like entities being investigated.

1 MR. MAYERS: Understood, your Honor.

2 Second, your Honor, there was a discussion of  
3 the collateral attack doctrine. We think that it  
4 applies with respect to both parties, most apparent  
5 with respect to Rhode Island Hospital.

6 THE COURT: Okay. Let's talk about the  
7 collateral attack doctrine, okay? So you sought  
8 enforcement of a subpoena against Rhode Island Hospital  
9 in Texas.

10 MR. MAYERS: That's correct.

11 THE COURT: Instead of the Washington, D.C.  
12 court which right outside your door; right?

13 MR. MAYERS: Yes, your Honor. We moved there  
14 because that's where the investigation is being carried  
15 on.

16 THE COURT: And that's where you've represented  
17 to this Court and it's been represented under oath that  
18 that has been, not just is now, but has been the center  
19 of the investigation; is that correct?

20 MR. MAYERS: Your Honor, can you point me to a  
21 specific reference that you're pointing to.

22 THE COURT: Looking at Ms. Hsiao's affidavit  
23 that's attached to your filing in Texas, and she says,  
24 she says on page -- nope, a different one. Well, I'll  
25 find that and we can get back to it.

1 But it is it your representation then that it  
2 hasn't always been centered in Northern District of  
3 Texas?

4 MR. MAYERS: Your Honor, it's our representation  
5 that when our petition was filed that that was where  
6 the investigation was being carried on. That is the  
7 locus or -- the focus, excuse me, of subsection (c) for  
8 the purposes of where venue is the proper for a  
9 petition to enforce to be filed.

10 THE COURT: Did you inform the Texas court about  
11 the back and forth that you had with Rhode Island  
12 Hospital over 10 months, or did you simply just tell  
13 them they had only given you six pages?

14 MR. MAYERS: Your Honor, I believe we -- the  
15 focus of representation was on the production.

16 THE COURT: So you did not, you did not inform  
17 them of the actual facts; correct?

18 MR. MAYERS: I wouldn't go that far, your Honor.

19 THE COURT: Well, tell me what you told Texas,  
20 because I have your filings here, and unless you had  
21 *ex parte* communications I know what you told Texas.

22 MR. MAYERS: Yes, your Honor, I would be happy  
23 to. So I'll point the Court to paragraph 46 of the  
24 Hsiao Declaration.

25 THE COURT: The first Hsiao Declaration.

1 MR. MAYERS: Yes, the first one, yes.

2 THE COURT: Uh'huh.

3 MR. MAYERS: It says the return date, you know,  
4 I can read it for your Honor, but that details the --

5 THE COURT: (Reading) Early conversations with  
6 Rhode Island Hospital, the Government communicated that  
7 it would be willing to receive documents responsive to  
8 the subpoena past the return date but that it did not  
9 expect to extend the grace period beyond reason.

10 Is that accurate?

11 MR. MAYERS: I was not on the --

12 THE COURT: Who made those representations to  
13 Rhode Island Hospital?

14 MR. MAYERS: I believe it was on that phone call  
15 or e-mail, but I believe a lawyer from I believe the  
16 then-Consumer Protection Branch, which is now the  
17 Enforcement and Appropriate Litigation Branch.

18 THE COURT: Who?

19 MR. MAYERS: I can't answer that, your Honor,

20 --

21 THE COURT: You don't know?

22 MR. MAYERS: -- who exactly that was. Not that  
23 lawyer that's referred to here. It's one of the member  
24 of the Enforcement Litigation Branch team, but I can't  
25 confirm which one it was at this time. I'd have to get

1       that information --

2               THE COURT:   So when Lisa Hsiao made that  
3       representation, she had information saying that that  
4       was the communication with Rhode Island Hospital;  
5       correct?

6               MR. MAYERS:   Yes, that communication was had,  
7       yes, your Honor.

8               THE COURT:   Okay.   But she said that we "did not  
9       expect to extend the grace period beyond reason;"  
10      correct.

11              MR. MAYERS:   That is what Ms. Hsiao said, yes.

12              THE COURT:   Under oath.

13              MR. MAYERS:   Yes, that's what Ms. Hsiao said.

14              THE COURT:   I'm sorry?

15              MR. MAYERS:   Yes, that is what the declarant  
16      said.

17              THE COURT:   Is that true?

18              MR. MAYERS:   I would have no reason to believe  
19      it's not, your Honor --

20              (Indecipherable crosstalk)

21              THE COURT:   So if Rhode Island Hospital is  
22      saying we had ongoing conversations, then they're  
23      misrepresenting the facts.

24              MR. MAYERS:   I don't think that the fact of  
25      ongoing communications is inconsistent with what

1 Ms. Hsiao said, your Honor.

2 THE COURT: Okay. I want to keep going.

3 "Counsel for Rhode Island Hospital have communicated  
4 several times that it intends to and would be producing  
5 responsive documents."

6 That's true; right?

7 MR. MAYERS: Yes, I believe so.

8 THE COURT: But it's not complete, is it?

9 MR. MAYERS: It is true, and also true that the  
10 last communication was on February -- yes, that's true.

11 THE COURT: That is not true actually. The last  
12 communication wasn't on February 4th. The last  
13 communication was on April 29th, the day before this  
14 was filed; correct?

15 MR. MAYERS: As to potential conferencing, I  
16 believe, but I believe as to when RIH was going to  
17 produce, I have no reason to doubt that that's  
18 accurate.

19 THE COURT: We have e-mails in the record where  
20 the Department of Justice says on the 28th we want to  
21 have a conference, and in response to that in the  
22 apology for being missing a few weeks is because  
23 somebody was on vacation, when it was really like three  
24 months, --

25 (Overlapping crosstalk)

1 MR. MAYERS: And then the next date you send or  
2 somebody from the Department of Justice, and since  
3 you're all one unitary executive you're all the same,  
4 sends an e-mail saying hey, we need to have a  
5 conference on this. Rhode Island Hospital responds on  
6 the 29th, and says okay does this time work or does  
7 that time work, and nobody responds from the Department  
8 of Justice; and you don't represent that to the  
9 Northern District of Texas.

10 Is that correct? That's a yes or no answer.

11 MR. MAYERS: Your Honor, if I could just  
12 briefly, February --

13 THE COURT: No.

14 Yes or no: She says here the last communication  
15 was, she says, let's see, the last communication was on  
16 February 4th. Correct?

17 MR. MAYERS: The last communication where RIH  
18 demonstrated that it intended to and would be producing  
19 responsive documents.

20 THE COURT: I'm going to read the sentence to  
21 you.

22 MR. MAYERS: Yes.

23 THE COURT: "However, the last such  
24 communication" --

25 MR. MAYERS: Yes.

1           THE COURT: -- "was on February 4th, and to date  
2 Rhode Island Hospital has produced only one document  
3 totaling six pages."

4           Now she's referring to "the last such  
5 communication," she says that "Counsel for Rhode Island  
6 Hospital communicated several times that it intends to  
7 and would be producing responsive documents."

8           MR. MAYERS: Yes.

9           THE COURT: Now, you don't see the conversation  
10 where they asked you, Are our search terms okay with  
11 you, and nobody responded? That's not a communication?

12          MR. MAYERS: I believe that is the communication  
13 reference.

14          THE COURT: Okay. And then from there you  
15 didn't, nobody from DOJ responded to them; correct?

16          MR. MAYERS: Yes, because of the paternity  
17 leave.

18          THE COURT: I'm sorry?

19          MR. MAYERS: It's because of the paternity leave  
20 of the --

21          THE COURT: Nobody said "paternity leave". They  
22 said "vacation" in the e-mail. So who was on paternity  
23 leave and when?

24          MR. MAYERS: I believe that was one of the trial  
25 attorneys on our team.



1 THE COURT: In Texas?

2 MR. MAYERS: In Washington, D.C.

3 THE COURT: Why wasn't Texas handling it?

4 MR. MAYERS: Because at this time this was the  
5 communication, the trial attorney assigned to  
6 communicating with Rhode Island Hospital.

7 THE COURT: So there's a trial attorney who is  
8 communicating with Rhode Island Hospital. Where is  
9 that person located?

10 MR. MAYERS: That individual is in Washington,  
11 D.C.

12 THE COURT: Okay. Tell me who has been in touch  
13 with this case who is not in Washington, D.C.

14 MR. MAYERS: Your Honor, I refer you to the, I  
15 believe the signature block in our petition to file,  
16 our petition for enforcement in Northern District of  
17 Texas. I believe that includes...

18 THE COURT: So I see Ryan Raybould, who is the  
19 United States Attorney. Now you're not telling me he  
20 personally participated in this.

21 He's the Dallas and Fort Worth United States  
22 Attorney; correct?

23 MR. MAYERS: That's correct.

24 THE COURT: I'm assuming he's not in Fort Worth,  
25 but is in Dallas.

1 MR. MAYERS: In Dallas, yes, your Honor.

2 THE COURT: Okay. And then we have Brett  
3 Shumate. Where is he?

4 MR. MAYERS: He's in Washington, D.C.

5 THE COURT: Okay. And we have Jordan Campbell.  
6 Where is he?

7 MR. MAYERS: He's in Washington, D.C.

8 THE COURT: Okay. And Lisa Hsiao, where is she?

9 MR. MAYERS: She's in Washington, D.C., as well.

10 THE COURT: So nobody was actually in Fort Worth  
11 who signed off on this.

12 MR. MAYERS: Your Honor, Ethan Womble on the  
13 next page, --

14 THE COURT: Oh, I'm sorry, the next page.

15 MR. MAYERS: -- the U.S. Attorney in Fort Worth.

16 THE COURT: Okay. And he's in Texas; is that  
17 correct?

18 MR. MAYERS: Yes, your Honor.

19 THE COURT: And so he's in charge of this  
20 investigation in Texas.

21 MR. MAYERS: I wouldn't -- he's working in  
22 collaboration with the Enforcement & Litigation Branch  
23 team on this case.

24 THE COURT: Okay. So you don't think that was a  
25 misrepresentation to the Northern District of Texas to

1 say hey, we haven't heard anything from these people  
2 since February 4th. You don't think Ms. Hsiao's  
3 statement in there is, at best, misleading?

4 MR. MAYERS: No, your Honor, I believe that  
5 she's referring to communications in which Rhode Island  
6 Hospital expressed an intent to produce.

7 THE COURT: And did you say -- well, you didn't  
8 see the let's meet next week and talk about the search  
9 terms as an expression of an intent to produce?

10 MR. MAYERS: Not necessarily, your Honor. I  
11 think that what she's referring to is the idea that  
12 Rhode Island Hospital says that a production was  
13 forthcoming. In any case, your Honor, Rhode Island  
14 Hospital --

15 THE COURT: When did they say a production was  
16 forthcoming? After February 4th?

17 MR. MAYERS: No, your Honor. Those are the  
18 communications she's referencing.

19 THE COURT: What I'm stuck with here is that,  
20 what I see is that in February Rhode Island Hospital  
21 sends search terms to the Department of Justice.  
22 Somebody goes on paternity leave, we're not sure who,  
23 although they said I was on vacation for a couple of  
24 weeks.

25 The next communication is April 28th, which I'm

1 assuming you had already been in touch with Northern  
2 District of Texas and had already at least drafted this  
3 motion on April 28th.

4 MR. MAYERS: Yes, your Honor, there are  
5 communications Northern District of Texas extended  
6 before that date, yes.

7 THE COURT: When?

8 MR. MAYERS: I can't pinpoint the exact date.  
9 It's when we first discussed this investigation  
10 Northern District Texas. I believe it was mid-March,  
11 your Honor.

12 THE COURT: So moving to compel was decided  
13 before April 28th; right?

14 MR. MAYERS: No, your Honor, not the final  
15 decision, I don't believe.

16 THE COURT: Okay. So that as decided when?

17 MR. MAYERS: I don't know the exact date for  
18 your Honor.

19 THE COURT: Can you ask your co-counsel.

20 (Counsel confer)

21 THE COURT: When was that drafted? When was it  
22 written?

23 (Counsel confer)

24 MR. CAMPBELL: Your Honor, I don't think either  
25 of us specifically recalls when it was drafted, but it

1 was drafted very near the date of filing.

2 THE COURT: Was it before or after April 28th?

3 MR. CAMPBELL: Likely after April 28th.

4 THE COURT: Well, it was filed the 30th, so you  
5 think it was after the 28th, after that 5:00 or so p.m.  
6 communication from your agency to Rhode Island Hospital  
7 saying hey, let's have a meeting, sorry I was out for  
8 two weeks?

9 MR. CAMPBELL: Excuse me, your Honor. It was  
10 drafted during that week.

11 THE COURT: Which day?

12 MR. CAMPBELL: I don't specifically -- couldn't  
13 tell you the first day that it was picked up.

14 THE COURT: Okay. So you were in the process of  
15 drafting that when somebody from the Department of  
16 Justice sent an e-mail to Rhode Island Hospital saying  
17 hey, sorry, I've been out, I was on vacation for a  
18 couple of weeks, and let's talk about this this week or  
19 next week or whatever the issue was; right? This was  
20 already being drafted?

21 MR. MAYERS: It was being drafted that week.

22 THE COURT: Okay. And you don't see that as  
23 misleading the Texas judge who's relying on the  
24 ordinary sort of procedure of the Federal Government to  
25 provide relevant and full information to the court, as

1 we are, and we've been burned by it recently; and so in  
2 this case I think has he.

3 MR. MAYERS: Your Honor, I would point out that  
4 Rhode Island Hospital in its motion for a stay did  
5 include the April e-mails that your Honor referenced,  
6 and the Northern District of Texas considered that  
7 submission and denied the motion to stay.

8 THE COURT: They denied the motion to stay, but  
9 they didn't -- okay, fine, that's a motion to stay that  
10 has --.

11 All right. Go ahead.

12 MR. MAYERS: And I would note also, your Honor,  
13 that Rhode Island Hospital could have moved for  
14 reconsideration.

15 THE COURT: Did you tell Rhode Island Hospital  
16 that you were going to file a motion to enforce in  
17 Texas?

18 MR. MAYERS: No, your Honor.

19 THE COURT: Why not?

20 MR. MAYERS: I don't recall the exact discussion  
21 as to when we made that decision.

22 THE COURT: But you didn't tell them you made a  
23 decision affirmatively not to let them know that you  
24 were moving to enforce it; correct?

25 MR. MAYERS: I don't know if that was the

1 decision. I believe the decision was just, you know,  
2 file the motion.

3 THE COURT: You had communications with them two  
4 days before and you didn't say hey, we're in the  
5 process of filing a motion to enforce; right?

6 MR. MAYERS: Your Honor, the subpoena was also  
7 live for 10 months and we got one document.

8 THE COURT: Well, no, because you were  
9 negotiating with them. That's the norm in a HIPAA  
10 subpoena. You're going to tell me every subpoena that  
11 you've received has been complied with in the timeframe  
12 fully?

13 MR. MAYERS: No, your Honor. I will note,  
14 though, they mention negotiations as to I believe only  
15 a few of the requests.

16 THE COURT: Did you suggest that you needed some  
17 other stuff?

18 MR. MAYERS: Yes, your Honor, I believe so.  
19 Again, I wasn't on every phone call.

20 THE COURT: Were you on any of the phone calls  
21 with the hospital?

22 MR. MAYERS: No, your Honor.

23 THE COURT: So when you say I wasn't on every  
24 phone call, you mean you weren't on any phone calls.

25 MR. MAYERS: Yes; I don't recall a phone call I

1 was on with them. I'd joined the Department relatively  
2 recently so I believe I --

3 THE COURT: When did you join the Department?

4 MR. MAYERS: Late November.

5 THE COURT: And from where?

6 MR. MAYERS: I was clerking.

7 THE COURT: For whom?

8 MR. MAYERS: A judge in the Middle District of  
9 Florida.

10 THE COURT: And before that you were in law  
11 school?

12 MR. MAYERS: I was clerking.

13 THE COURT: For how many years?

14 MR. MAYERS: So I clerked for three years for  
15 three great jurists in Florida; first Florida Supreme  
16 Court for Justice John Couriel, and then for Judge  
17 Barbara Lagoa in the Eleventh Circuit, and then Judge  
18 Kathryn Kimball Mizelle in the Middle District of  
19 Florida.

20 THE COURT: Okay. And then you came to the  
21 Department of Justice in November?

22 MR. MAYERS: Your Honor, I had a brief stint in  
23 private practice. Sorry, that was during the shutdown  
24 and they moved, so I had a brief stint in private  
25 practice, and then I joined the Department.



1 THE COURT: Brief, like weeks?

2 MR. MAYERS: It was a month.

3 THE COURT: Okay. Thank you.

4 MR. MAYERS: Yes.

5 Turning briefly to the collateral attack  
6 doctrine we submit that applies here.

7 THE COURT: So I feel like I'm -- this isn't  
8 really fair to you because I feel like they're putting  
9 somebody brand new out here to argue this, and I think  
10 that's intentional. But tell me what does the  
11 collateral attack doctrine require you to show.

12 MR. MAYERS: So the *Celotex Corp. v. Edwards* --

13 THE COURT: I'm sorry, say that again.

14 MR. MAYERS: So the *Celotex* case we cite, you  
15 know, we also cite *Pratt v. Buntis*.

16 THE COURT: Where are the cases?

17 MR. MAYERS: The Sixth Circuit.

18 THE COURT: We're the First Circuit here, so  
19 talk to me about First Circuit case law.

20 MR. MAYERS: Yes. Your Honor, I believe we set  
21 a few of those in our motions as well, but essentially  
22 the essence is that the doctrine forbids a party from  
23 seeking to circumvent an earlier ruling of one court by  
24 filing a subsequent action in another court.

25 THE COURT: Okay. But what about your own party

1 preclusion, because neither party was before the Texas  
2 court. Let's start with the Child Advocate.

3 MR. MAYERS: Uh'huh. Yes, your Honor. So I  
4 believe the Sixth Circuit case the Child Advocate cites  
5 discusses, you know, reference to *res judicata*. It  
6 would be our submission that the patients in the  
7 hospital were in privity and therefore the judgment  
8 against the hospital would also reach the patients.  
9 The hospital raises the patients' interest and so we  
10 would argue that that is what applies with respect to  
11 the Advocate.

12 THE COURT: Okay. Let's talk about them then.  
13 Did you give notice to Rhode Island Hospital?

14 MR. MAYERS: Your Honor, we served Rhode Island  
15 Hospital I believe on Saturday -- maybe actually the  
16 Monday following. So we received the order, and there  
17 were some questions earlier about when the Department  
18 received, you know, the Northern District of Texas  
19 order. We did so on Friday, and we served that on  
20 Rhode Island Hospital on the following Monday.

21 THE COURT: After the order was issued.

22 MR. MAYERS: Yes, your Honor, we were -- as your  
23 Honor noted the issue was --

24 THE COURT: Okay. Did you provide the Texas  
25 court with any facts supporting the court's

1 jurisdiction before it granted your petition to  
2 enforce?

3 MR. MAYERS: I believe the supplemental Hsiao  
4 Declaration came after.

5 THE COURT: So, no.

6 MR. MAYERS: Yes, your Honor, I believe we  
7 included the relevant subsection in our petition to  
8 enforce.

9 THE COURT: I'm talking about jurisdiction --

10 MR. MAYERS: Yes.

11 THE COURT: -- for the Northern District, not  
12 jurisdiction over the statute.

13 So did you provide before the judge signed off  
14 on your order any information to that judge that  
15 supported jurisdiction in the Northern District of  
16 Texas?

17 MR. MAYERS: Your Honor, personal jurisdiction,  
18 subject matter, both?

19 THE COURT: Jurisdiction of that court to issue  
20 an order so, yes, jurisdiction.

21 MR. MAYERS: Yes, your Honor. So we cited  
22 subsection (c) which we think (indecipherable) Texas  
23 with jurisdiction. We did not submit the Hsiao --

24 THE COURT: You said section (c), so you also  
25 need to tell the court I'm investigating this entity or

1       that entity that is in Texas or Texas is the center of  
2       the investigation; right?

3               MR. MAYERS: Yes, those facts which we  
4       ultimately did provide in which --

5               THE COURT: After the order.

6               MR. MAYERS: Correct, your Honor.

7               THE COURT: Okay. That's what I'm trying to get  
8       it. So you didn't provide them beforehand; correct?

9               MR. MAYERS: Your Honor, the relevant facts were  
10      in existence before the order was entered.

11              THE COURT: It's not a matter of whether the  
12      facts were in existence. The judge needs to know the  
13      facts to make a decision. Just like I can't ask you  
14      questions about meetings you weren't at with Rhode  
15      Island Hospital.

16              MR. MAYERS: Your Honor, the Northern District  
17      of Texas, the court there concluded that it had enough  
18      in front of it to issue the order.

19              THE COURT: But has to make an independent  
20      determination to determine the collateral attack  
21      doctrine and whether it applies; and you've asked me to  
22      rule that this is a collateral attack. And with  
23      respect to Child Advocate, I don't think you have  
24      standing for that.

25              But with respect to Rhode Island Hospital, I'm

1       trying to ascertain if the Department of Justice misled  
2       the judge in Texas, which it seems clear it did, about  
3       certain facts. And we haven't even gotten into the  
4       specifics of other things that I think are misleading.

5               MR. MAYERS: Your Honor, I disagree that we  
6       misled the judge.

7               THE COURT: Okay.

8               MR. MAYERS: And I would submit that, again, I  
9       don't -- the Rhode Island Hospital specifically did not  
10      put forth the case that says the, you know, facts that  
11      existed prior to court's order but that, you know, were  
12      submitted to the court after somehow negates a finding  
13      of proper venue or jurisdiction.

14              THE COURT: But he has to make that finding, and  
15      he's basing it on what he has in front of him.

16              MR. MAYERS: Yes, your Honor, he did, and we  
17      would submit it was a correct finding.

18              THE COURT: Based on the facts only known to  
19      you.

20              (Indecipherable crosstalk)

21              MR. MAYERS: -- that we provided to your Honor  
22      under seal.

23              THE COURT: Afterwards.

24              MR. MAYERS: Correct, but those facts existed  
25      beforehand so --

1 THE COURT: But did they?

2 MR. MAYERS: Yes, your Honor.

3 THE COURT: Okay. That better be true.

4 Okay. Go ahead.

5 MR. MAYERS: Thank you. And so to touch on one  
6 of the responses to the collateral attack doctrine's  
7 due process --

8 THE COURT: Uh'huh.

9 MR. MAYERS: -- your Honor discussed that with  
10 Rhode Island Hospital. As we point first to the fact  
11 that service of summons under 3486(e) established  
12 personal jurisdiction over Rhode Island Hospital, and  
13 also we would direct your Honor to the case law in the  
14 Section 1782 context where petitions are often granted  
15 *ex parte* and respondents show up after and move for  
16 reconsideration, and certain courts have concluded that  
17 that process, that allowing the respondent to move for  
18 reconsideration satisfies.

19 THE COURT: Can you give me a case --

20 MR. MAYERS: Yes, your Honor.

21 THE COURT: -- in this circuit or Supreme Court.

22 MR. MAYERS: The one case I have in front of me,  
23 your Honor, is Second Circuit, but I'd be happy to --

24 THE COURT: Second Circuit is not our circuit.

25 MR. MAYERS: Yes, understood. But I would note,

1 your Honor, that I looked through those cases. I  
2 believe there's First Circuit case, I'd be happy to  
3 provide it after, don't hold me to it necessarily, but  
4 the cases I read have uniformly concludes that that  
5 process satisfies due process.

6 I would note also that given the window of time  
7 with which Rhode Island Hospital was given to comply,  
8 there was enough time for them to move for  
9 reconsideration or move to relief as they have. So the  
10 enforcement has not occurred yet, and so the  
11 deprivation has not occurred yet, and there's time, as  
12 Rhode Island Hospital has illustrated, by litigating in  
13 two -- three courts.

14 THE COURT: What three courts?

15 MR. MAYERS: The Northern District of Texas, the  
16 Fifth Circuit, and in front your Honor.

17 THE COURT: Did the Fifth Circuit make a  
18 decision while we've been here?

19 MR. MAYERS: My phone has been off, so I don't  
20 know.

21 THE COURT: Okay.

22 MR. MAYERS: So your Honor, that's the  
23 collateral attack doctrine. We submit that it applies  
24 at least with respect to Rhode Island Hospital.

25 THE COURT: If they weren't present in Texas,

1 I'm not sure how you apply it. First of all, nonparty  
2 preclusion with respect to the Child Advocate, you  
3 don't have it; right? I mean you can agree they  
4 weren't a party there.

5 MR. MAYERS: They were not a party, we argue  
6 they were privity, they are a party to that action, we  
7 would submit. Of course they could have moved for  
8 reconsideration as well.

9 THE COURT: Why should they have to go to the  
10 Texas because the Government chose Texas. She is the  
11 Child Advocate for the State of Rhode Island and the  
12 children in DCYF care, some of our most vulnerable  
13 children; and we're going to get to how you propose  
14 that we separate them out later.

15 But why on earth, when she was not a party  
16 there, you didn't make her a party there. I'm assuming  
17 that Rhode Island Hospital must have known that some  
18 kids must have in State care at some point in the five,  
19 six years that you've asked for records for. It's a  
20 little more than six years.

21 So I mean I think, you know, there's no reason  
22 to require her to go to Texas to litigate a subpoena in  
23 Rhode Island for the information from a Rhode Island  
24 hospital that you sought from D.C., that you move to  
25 Texas for what I think we can all agree you sought a



1 favorable forum or what you believe to be a favorable  
2 forum, and so there's absolutely no reason for this  
3 Court to make a finding that they're precluded by the  
4 collateral attack doctrine.

5 Talk to me about Rhode Island Hospital.

6 MR. MAYERS: Yes, your Honor. So we would  
7 argue, again, that they were a party and that, you  
8 know, essentially what they're seeking to do here is to  
9 undue an order that was entered against them. Their  
10 response as to why the collateral attack doctrine  
11 (indecipherable) apply is due process, and that's why I  
12 walked through with your Honor the holdings of one  
13 case, I cited others, that find an opportunity for  
14 reconsideration and the 1782 context satisfies due  
15 process. So we argue here that they had that  
16 opportunity. They forewent it.

17 THE COURT: Well, they didn't have an  
18 opportunity. How can you possibly say they had an  
19 opportunity to appear in Texas when you sought the  
20 order -- what time did you file that order in Texas?

21 MR. MAYERS: I believe it was early afternoon,  
22 your Honor.

23 THE COURT: Give me an proximate.

24 MR. MAYERS: I'll probably say 2:00 or  
25 3:00 p.m., although I don't, you know...

1 THE COURT: What time did you get the order?

2 MR. MAYERS: Got the order the next day.

3 THE COURT: The order was issued that day. So  
4 when did the order issue?

5 MR. MAYERS: Your Honor, Judge O'Connor signed  
6 the order on April 30th. However, we received the  
7 order?

8 THE COURT: I'm not interested in when you  
9 received it. When was it effective?

10 MR. MAYERS: I believe when he signed the orders  
11 that would be April 30th.

12 THE COURT: What time?

13 MR. MAYERS: I'm not aware of the exact time he  
14 signed it. However, I will note as this past Sunday  
15 indicates Judge O'Connor does issue orders late at  
16 night so, you know, we can't exactly approximate when  
17 he signed it on the 30th, so I don't have any more  
18 specific information --

19 THE COURT: Understood.

20 MR. MAYERS: -- as to time.

21 THE COURT: And he issued the order without  
22 Rhode Island Hospital being notified that the motion  
23 had been filed; correct?

24 MR. MAYERS: I believe, and I can double-check  
25 on this; I believe we notified Rhode Island Hospital of

1 the motion and then once we got the order we did that  
2 as well.

3 THE COURT: 6:12 p.m. Rhode Island time;  
4 correct?

5 MR. MAYERS: I'll take your word for it, your  
6 Honor.

7 THE COURT: And so you notified them that you  
8 had already filed this when you said never mind, we  
9 don't need a conference that we just asked for two days  
10 ago; correct.

11 MR. MAYERS: I believe that's what the e-mail  
12 said, yes.

13 THE COURT: Okay. Go on.

14 MR. MAYERS: Again, your Honor, my point is that  
15 the due process argument we don't think is a successful  
16 one or a meritorious one or one that has merit because of  
17 the 1782 cases. So those say, you know, if you can  
18 move for reconsideration, you can show up and contest  
19 production before production is required, that that  
20 satisfies due process.

21 THE COURT: Well, why not tell Rhode Island  
22 Hospital? Don't you think that looking at it from  
23 Rhode Island, where you're subpoenaing Rhode Island  
24 Hospital records from Rhode Island children, who are  
25 protected by the Rhode Island Child Advocate, and you

1 go to Northern District of Texas and arguably center  
2 your investigation there, which I don't buy; but at  
3 some point you decide to center it there and you go to  
4 the court there and you ask for the order. Why not  
5 tell Rhode Island Hospital? Did you not want them to  
6 have an opportunity to object?

7 MR. MAYERS: Your Honor, we are happy to  
8 litigate this out as our, you know, papers show we --

9 THE COURT: Well, you didn't want to litigate it  
10 here; right?

11 MR. MAYERS: Well, we want to litigate where the  
12 investigation was carried out?

13 THE COURT: Is that true? Didn't you litigate  
14 others in other places, and you're 0 for 7 in those  
15 other places?

16 MR. MAYERS: Those are all motions to quash, --

17 THE COURT: Right.

18 MR. MAYERS: -- correct, so --

19 THE COURT: You didn't move them to the Northern  
20 District of Texas, did you?

21 MR. MAYERS: No, because the statute allows the  
22 subpoena recipient to move to quash in a district in  
23 which they reside,

24 THE COURT: Okay.

25 MR. MAYERS: -- so --

1 THE COURT: Did you move to compel NYU to  
2 provide it in the Northern District of Texas?

3 MR. MAYERS: No, your Honor, we did not.

4 THE COURT: Go ahead. So the reason not to,  
5 just so we're clear, the process works if everybody is  
6 transparent with each other and if we're up front and  
7 we don't file things under oath that are misleading at  
8 best and we don't mislead opposing counsel. So in a  
9 position now, I would tell anybody you have to file a  
10 motion to quash if you're dealing with the Government  
11 every single time and every single time I will require  
12 the Government to file something, because you can't  
13 rely on the Government to do what they've done over the  
14 last 50 years to deal with these, 30 years that HIPAA  
15 has been in place. So understand that I take a very  
16 negative view to playing fast and loose by telling  
17 people one thing and filing other things with the  
18 court, and then taking the position like, oh, well, we  
19 didn't tell you, but we did tell you afterwards. That  
20 is dirty pool, in my opinion, and the Department of  
21 Justice have willfully done that in this case. And we  
22 haven't gotten to the things that I think you've  
23 misrepresented in your filings in Texas; well, some of  
24 them we have. Go ahead.

25 MR. MAYERS: Your Honor, I would note also that

1 we would expect, as Rhode Island said, that they would  
2 comply with the subpoena.

3 THE COURT: And they did, and they sent you  
4 search terms, and nobody responded. Why not?

5 MR. MAYERS: They had provided us with one  
6 document in 10 months and now --

7 THE COURT: How many documents do you need?

8 MR. MAYERS: If there's only one document  
9 responsive to the subpoena, again, your Honor noted I'm  
10 new to this practice, but I'd be surprised.

11 THE COURT: Well, but we don't know, do we,  
12 because you never had that conversation with Rhode  
13 Island Hospital; correct?

14 MR. MAYERS: Your Honor, Rhode Island Hospital  
15 never told us that the one document they provided was  
16 the entirety of the responsive documents.

17 THE COURT: Right; because they were working  
18 with you on search terms for things like advertising,  
19 billing, that kind of stuff; right?

20 MR. MAYERS: Your Honor, the idea that Rhode  
21 Island Hospital would have complied with the subpoena  
22 that they now argue is entirely --

23 THE COURT: Oh, I think it's pretty clear that  
24 they would have. They may have negotiated like you did  
25 in Los Angeles, and we're going to talk about that

1 because you didn't tell the Texas court about the  
2 anonymized data that you agreed to there, or other  
3 places. So that's another falsehood or arguably  
4 leading filing in Texas.

5 MR. MAYERS: I disagree, your Honor, but --

6 THE COURT: Based on what?

7 MR. MAYERS: Your Honor pointed to a provision  
8 of the Hsiao Declaration that says the patient records,  
9 generally the patient records, --

10 THE COURT: Uh'huh.

11 MR. MAYERS: -- are important or essential to  
12 the investigation.

13 THE COURT: So you're saying that anonymized  
14 data is fine; you don't need the actual identifiable  
15 data. Is that what you're saying?

16 MR. MAYERS: Your Honor, it has been our  
17 practice to the extent that I'm aware of offering  
18 anonymized data request or an anonymized data  
19 production to recipients.

20 THE COURT: When did you offer that to Rhode  
21 Island Hospital?

22 MR. MAYERS: I was informed that we -- to the  
23 best of my recollection I was informed that we had, but  
24 I can't confirm that or confirm the date of that.

25 THE COURT: Can you confirm who would have made

1       that offer?

2               MR. MAYERS: Who would have made that offer  
3 would be a member of I believe either the Enforcement  
4 and Affirmative Litigation Branch or a member of our  
5 team in Northern District of Texas.

6               THE COURT: Okay.

7               MR. MAYERS: I believe the offer in this case,  
8 if one was made, and I can't confirm that without  
9 double-checking would be --

10              THE COURT: Can you double-check with  
11 co-counsel? I think he's running this case generally;  
12 right?

13              (Counsel confer)

14              MR. MAYERS: Your Honor, it would have been  
15 David Gunn, --

16              THE COURT: When?

17              MR. MAYERS: -- who was the trial attorney in  
18 the case. He's in Washington, D.C.

19              And to be clear, if Rhode Island Hospital were  
20 to come to us and say would you be willing to go and  
21 asked the court for, you know, anonymized records, that  
22 would be fine with us.

23              THE COURT: But you -- oh, so you'll do that  
24 now?

25              MR. MAYERS: Yes, your Honor, we would still



1 take -- if they agree to produce anonymized records,  
2 patient records, we would take those.

3 THE COURT: And that wouldn't be a violation of  
4 the Texas judge's order?

5 MR. MAYERS: We would go to Judge O'Connor and  
6 say the parties have discussed in the light of your  
7 Honor's order and we would take anonymized.

8 THE COURT: But when I asked you before if you  
9 could agree to an extension of that judge's order you  
10 said no because it was court order; didn't you?

11 MR. MAYERS: Your Honor, I believe we said that  
12 we could not guarantee how Judge O'Connor would rule on  
13 such order and that we were not in a place to request  
14 such an order at this time.

15 THE COURT: But then you can't make that  
16 representation to Rhode Island Hospital of whether  
17 anonymized data would work.

18 MR. MAYERS: We could make the representation  
19 that we would agree to go to the court and say that we  
20 have discussed and that pursuant to our approach in the  
21 other investigations we would accept anonymized patient  
22 data.

23 THE COURT: I'm going to ask counsel for Rhode  
24 Island Hospital to address when and if that was stated,  
25 and I'm going to ask for an affidavit from Mr. Gunn by

1 the beginning of tomorrow, under oath, telling when it  
2 was offered to Rhode Island Hospital, by whom it was  
3 offered, to whom it was offered, and in what capacity,  
4 and I'd like that filed by tomorrow morning at 9:00.  
5 Go ahead.

6 MR. MAYERS: Okay, your Honor. And just to be  
7 clear, that is my recollection. I cannot speak for  
8 Mr. Gunn.

9 THE COURT: And you actually told Texas actually  
10 in addition to that, and I don't mean to interrupt, but  
11 in your filing in the Northern District of Texas you  
12 cite to Ms. Hsiao's affidavit and you also say that  
13 they -- you didn't say we've asked for anonymized data  
14 and they refused, they didn't agree to provide it.  
15 Correct?

16 MR. MAYERS: It is not in the affidavit, your  
17 Honor. Again, I could be wrong in remembering that and  
18 so I don't want to tie Mr. Gunn to my statements here.  
19 It is, you know, this is an investigation involving  
20 many parties and many conversations, so I can't commit  
21 Mr. Gunn to that statement.

22 THE COURT: But you did. You said he said it.

23 MR. MAYERS: Your Honor, I said that to the best  
24 of my recollection --

25 THE COURT: The Department of Justice cannot say

1 we're going to send somebody who's brand new and has no  
2 contact with this case other than being the new guy in  
3 Washington -- and it's not fair to you and I recognize  
4 that this is going to make you never want to go to  
5 court again, and I can tell you I had similar  
6 experiences in my practice. But --

7 MR. MAYERS: Your Honor, I don't mind, I'm happy  
8 to be --

9 (Indecipherable crosstalk)

10 THE COURT: -- go to court again.

11 MR. MAYERS: I'm happy to be back --

12 (Indecipherable crosstalk)

13 THE COURT: But is unfair for the Department of  
14 Justice to sit there and say we don't know, we don't  
15 know, we don't know, because we're sending somebody who  
16 has had no contact with the case.

17 MR. MAYERS: Your Honor, I'd be happy to ask  
18 Mr. Gunn. That is what I can commit to. I can't  
19 commit to him saying something.

20 THE COURT: Well, if it's not true, then I want  
21 that too, if nobody made that representation.

22 MR. MAYERS: We can provide a statement as to  
23 the extent of our communications with RIH on patient  
24 records, your Honor.

25 THE COURT: Great.

1           What are you investigating in the Northern  
2   District of Texas?

3           MR. MAYERS: Your Honor, so, again, there are  
4   multiple as I (indecipherable) static or not a stagnant  
5   investigation. There are multiple prongs to it. This  
6   specific subpoena related to the FDCA --

7           THE COURT: Okay.

8           MR. MAYERS: -- and to our --

9           THE COURT: Tell me what specifically is the  
10   FDCA.

11          MR. MAYERS: So your Honor, the main theory  
12   we've espoused, and I'll push back a little bit on the  
13   idea that our theories have been shifting. If you look  
14   back at, for example, our first filing in the District  
15   of Massachusetts, we say there are two or at least two  
16   potential things we're investigating. First is  
17   off-label promotion and misbranding by pharmaceutical  
18   companies.

19          THE COURT: Okay. But Rhode Island Hospital  
20   can't be liable for that; correct?

21          MR. MAYERS: Your Honor --

22          THE COURT: There could be a witness potentially  
23   or a holder of information, but not themselves liable  
24   for misbranding.

25          MR. MAYERS: So Rhode Island Hospital can be a

1 witness, and we think Rhode Island Hospital can also be  
2 liable under a conspiracy theory. The Government has  
3 charged that in the past.

4 THE COURT: In these kinds of cases.

5 MR. MAYERS: Yes, your Honor. So the theory  
6 works in that pharmaceutical company provides financial  
7 incentives to doctors to prescribe off-label and  
8 therefore that has been viewed as a conspiracy.

9 THE COURT: Can you give me the cites of where  
10 you've charged that.

11 MR. MAYERS: There is a case I believe in the  
12 Eastern District of New York called *Gleason*.

13 THE COURT: I'm sorry?

14 MR. MAYERS: *United States vs. Gleason*. I'll be  
15 happy to get --

16 THE COURT: Do you know approximately when that  
17 case was?

18 MR. MAYERS: I believe that case was probably  
19 early 2010s.

20 THE COURT: And any others?

21 MR. MAYERS: That is the one I know of off the  
22 top of my head, your Honor.

23 THE COURT: And who was charged in the *Gleason*  
24 case? The hospital?

25 MR. MAYERS: So Mr. Gleason was a doctor. And

1       there was also the case, the *Caronia* case that my  
2       friends on the other side cite as First Amendment  
3       context. I believe *Caronia* was a pharmaceutical  
4       company employee that was indicted in this similar, you  
5       know, scheme or in this same scheme, excuse me.

6               THE COURT: Uh'huh.

7               MR. MAYERS: So the idea would be that the  
8       pharmaceutical company is providing incentives through  
9       off-label protection and through certain incentives to  
10      doctors, and those doctors turn around and be  
11      remunerated for the amount of prescribing they would do  
12      and so that you --

13              THE COURT: Do you have any evidence to support  
14      that theory?

15              MR. MAYERS: Yes, your Honor, not in -- I'd  
16      double-check with respect to specific RIH employees.  
17      We do have evidence that this has happened.

18              THE COURT: Where?

19              MR. MAYERS: In this specific context, I believe  
20      the case I'm thinking about is in California.

21              THE COURT: In Los Angeles? Is that the  
22      Los Angeles County one where you agreed to the  
23      anonymized data?

24              MR. MAYERS: I believe that the individual I'm  
25      thinking is, the set of facts I'm thinking of does

1 relate to CHLA.

2 THE COURT: Okay. Go ahead.

3 MR. MAYERS: So your Honor, that is the idea.  
4 It's not, you know, off-label prescribing. We're  
5 not -- we've never argued that it's an FDCA violation.  
6 Instead it is both RIH as a witness and then this  
7 conspiracy idea and then --

8 THE COURT: But that's a criminal investigation,  
9 the conspiracy idea.

10 MR. MAYERS: Yes, your Honor.

11 THE COURT: Okay. And what specific conspiracy  
12 are you investigating? Because there are different  
13 kinds of conspiracy.

14 MR. MAYERS: So it would be a conspiracy to,  
15 well, so in this instance, right, so again as I said  
16 there are multiple prongs to investigation; right? So  
17 there are other potential theories that aren't spoken  
18 to in this case with the subpoena, you know, there's  
19 ideas of false billing which we think is relevant to  
20 the extent it speaks to --

21 THE COURT: But that's a healthcare violation;  
22 right? That's not a FDCPA or whatever you call it  
23 violation; correct?

24 MR. MAYERS: Your Honor, it is, it can be  
25 evidence in an FDCA case of fraudulent intent, but we

1 agree that false billing alone is not --

2 THE COURT: And if Rhode Island law -- and  
3 states administer Medicaid; correct?

4 MR. MAYERS: Yes, your Honor.

5 THE COURT: Okay. And so if Rhode Island allows  
6 for off-label use and billing of Medicaid for off-label  
7 use of drugs, then how do you get to a criminal  
8 conspiracy? Criminal is a little bit of a higher  
9 standard, you may have heard, than civil case, so --

10 MR. MAYERS: I know of criminal and civil in my  
11 clerkship.

12 THE COURT: Okay, there you go then. So you  
13 know it's beyond a reasonable doubt and there needs to  
14 be probable cause to charge.

15 MR. MAYERS: To charge, yes.

16 THE COURT: And not a fishing expedition.

17 MR. MAYERS: And not to issue a subpoena.

18 THE COURT: Well, subpoenas are not supposed to  
19 be fishing expeditions, are they?

20 MR. MAYERS: We would contend that ours is not,  
21 your Honor.

22 THE COURT: Okay. So you have direct  
23 information that supports a subpoena to Rhode Island  
24 Hospital for each of the 15 things you've requested.

25 MR. MAYERS: Your Honor, we have the Hsiao



1 Declaration speaks to generally the relevance in each  
2 request.

3 THE COURT: Uh'huh.

4 MR. MAYERS: The Hsiao Declaration also  
5 identifies certain instances what we think is billing  
6 fraud by Rhode Island Hospital, kids with central  
7 precocious pubic billing over the age of --

8 THE COURT: Wait. Say that again.

9 MR. MAYERS: Yes, let me just pull up this.

10 THE COURT: Yes. Tell me where you're referring  
11 to this.

12 MR. MAYERS: Your Honor, I refer to you  
13 paragraph 36 for Hsiao Declaration.

14 THE COURT: Hang on, I'm looking.

15 MR. MAYERS: Page 15 --

16 THE COURT: Okay.

17 MR. MAYERS: -- on the footer number.

18 THE COURT: Okay.

19 MR. MAYERS: So there it says, quoting now, "For  
20 example, based on diagnosis codes it appears between  
21 2020 and 2025 there were at least four minors first  
22 diagnosed at RIH with central precocious --

23 (Court Reporter requests clarification)

24 MR. MAYERS: "For example, based on diagnosis  
25 codes it appears that between 2020 and 2025 there were

1 at least four minors first diagnosed at RIH with  
2 central precocious puberty at age 12 or older."

3 THE COURT: Okay. So I don't know where you  
4 have that information from but, you know, you're not a  
5 doctor; right?

6 MR. MAYERS: I'm not.

7 THE COURT: Okay. And I'm assuming you're too  
8 young to have children who've gone through puberty.

9 MR. MAYERS: That is a correct assumption.

10 THE COURT: But as somebody who has premature  
11 babies in their family, their precocious puberty can be  
12 diagnosed for a preemie later because of growth  
13 retardation; isn't that correct?

14 MR. MAYERS: Again, I'm not a doctor, so I --

15 THE COURT: Neither am I, but I'm facing this on  
16 very old knowledge because my kids are older.

17 MR. MAYERS: Yes. So as to what I can say as to  
18 central precocious puberty itself is what is in the  
19 follow-on sentence, right, where it says, "Precocious  
20 puberty is usually defined as the onset of puberty  
21 before age eight in girls and before age nine boys."

22 THE COURT: Usually.

23 MR. MAYERS: So -- yes. So I would agree with  
24 your Honor that perhaps there are completely lawful  
25 reasons why each of these individuals was diagnosed

1 with central precocious puberty at age 12 or older;  
2 however, I would submit we can investigate whether  
3 there are legitimate reasons or not.

4 THE COURT: Well, what would be the violation?  
5 Let's say a doctor does diagnose somebody who  
6 is 12 or older with precocious puberty and it is for  
7 the purpose of gender-affirming care. Why is that  
8 something that the Federal Government, as distinguished  
9 from the State of Rhode Island -- and I again refer you  
10 to the *Scrimetti* decision. Why does the Federal  
11 Government get to decide that and not Rhode Island?

12 MR. MAYERS: So the Federal -- (A) *Scrimetti* said  
13 the Fourteenth Amendment does not prohibit states from  
14 deciding to, you know, preclude this.

15 THE COURT: Or allow, or allow. The corollary  
16 is "or allow." I know you want to focus on "preclude,"  
17 but *Scrimetti* said it was the State's decision.

18 MR. MAYERS: I will agree, I will agree it's for  
19 "allow" as well. I agree the corollary is, can follow  
20 on *Scrimetti*.

21 THE COURT: A hundred percent.

22 MR. MAYERS: I will say that *Scrimetti* does not  
23 say, And the federal government can investigate  
24 potential violations of federal law in the case --

25 THE COURT: What is the federal law? That's

1 what you haven't answered.

2 MR. MAYERS: Your Honor, happily. So for  
3 example, (1) false statements in a healthcare case, so  
4 18 USC 1035.

5 THE COURT: False statements...

6 MR. MAYERS: In a healthcare case. So 18 USC,  
7 so I can speak both to, I'll speak to --

8 THE COURT: But that's healthcare fraud; right?

9 MR. MAYERS: Your Honor, I will speak both to  
10 the FDCA and others. So I took your question to be  
11 asking generally what could be. So in the FDCA space,  
12 we agree that the FDCA on its own does not speak or  
13 does not criminalize the act of false billing in and of  
14 itself; however, we believe that false billing can be  
15 evidence of an intent to mislead or fraud. I think  
16 that's a, you know, pretty basic statement. I don't  
17 think anyone disagrees with that. You know, a  
18 fraudulent statement in a billing record could speak to  
19 that intent.

20 THE COURT: Who is the fraudulent statement to?

21 MR. MAYERS: To the healthcare -- to the  
22 insurance company; excuse me.

23 THE COURT: I see. So in the case of the Child  
24 Advocate, I would assume it's most Medicare or  
25 Medicaid.

1 MR. MAYERS: Yes. And your Honor, you raise a  
2 point, well, you know, it's covered in Rhode Island so  
3 why would they do this? Exactly. We don't know.

4 THE COURT: So unlikely; right?

5 MR. MAYERS: All we can speak to is what we've  
6 seen.

7 THE COURT: So, but you understand, like take a  
8 step back. I understand you have your position you're  
9 an advocate, and I give you credit for it especially  
10 because I think they threw you up here.

11 MR. MAYERS: I'm happy to be here, your Honor,  
12 there's no throwing --

13 (Indecipherable crosstalk)

14 THE COURT: I'm sure you are, and I'm sure  
15 you're required to say that, but --

16 MR. MAYERS: I'm not, I'm not paid to say --

17 THE COURT: I have law clerks; I know what they  
18 say.

19 But here's the thing. So Rhode Island gets to  
20 decide, you have four, arguably four cases you said  
21 where, for example, and this is under oath based on  
22 diagnostic codes it appears that between 2020 and 2025,  
23 so for five years. There were at least four minors  
24 first diagnosed at Rhode Island Hospital -- I don't  
25 know how you know this, but I assume it's from records

1 from other hospitals like in Texas -- with central  
2 precocious puberty at age 12 or older.

3 Okay. How many patients were treated at Rhode  
4 Island Hospital with gender -- with puberty blockers  
5 during that time?

6 MR. MAYERS: Your Honor, before I answer, also  
7 we rely on paragraphs 37 and 38 which speak to a spike  
8 in the number of claims with an "unspecified endocrine  
9 disorder," and so it would be odd around the time that  
10 the number of claims for gender dysphoria increase that  
11 there's the similar spike in endocrine disorder.

12 THE COURT: Could it not also be with respect to  
13 their being either a limitation of gender-affirming  
14 care facilities and a centralized sort of Rhode Island  
15 Hospital and Brown Health being the sort of centralized  
16 medical provider in Rhode Island? Couldn't it also be  
17 that smaller agencies that provided that care were  
18 folded into Rhode Island Hospital?

19 MR. MAYERS: That could speak to a rise in  
20 gender dysphoria claims.

21 THE COURT: And gender-affirming care.

22 MR. MAYERS: No, but the number of claims for  
23 "unspecified endocrine disorder" also increased.

24 THE COURT: But if Memorial, Pawtucket Memorial  
25 Hospital closes and those patients who were being

1 treated for endocrine -- and by the way it did and I  
2 think it was in this time frame -- and so the patients  
3 being treated for endocrine disorder have to go  
4 somewhere else; right?

5 MR. MAYERS: Yes.

6 THE COURT: And the most likely place would be  
7 Rhode Island Hospital, which also encompasses Miriam  
8 Health, I believe. Brown Health is all of those  
9 things. So there could be a very innocent reason for  
10 that.

11 MR. MAYERS: There could be, but again --

12 THE COURT: So why do you need highly-sensitive,  
13 personalized, individually-identifying information  
14 about the most vulnerable children in order to follow  
15 up on a hunch based on things where you don't seem to  
16 have a real Rhode Island understanding of what's  
17 happened in our healthcare in the last five years, six  
18 years.

19 MR. MAYERS: Your Honor, there could be a  
20 completely innocuous explanation, but *Morton Salt*, for  
21 example, says we can investigate to determine whether  
22 there is or not. There is a point in an investigation  
23 --

24 THE COURT: Right. Investigate away.

25 Why do you need individual personalized

1 information about individual children?

2 MR. MAYERS: Because, again, how would we tell,  
3 for example, whether this child with central precocious  
4 puberty diagnosis, how would we tell whether that was a  
5 legitimate one, maybe they were born prematurely, or  
6 how would we tell it's false billing. We would have to  
7 look at the patient records.

8 THE COURT: And you think the Government has the  
9 right to look at everybody's patients' records to see  
10 if those four cases, and you can't tell me how many  
11 people were treated with puberty blockers during that  
12 time.

13 MR. MAYERS: I don't believe it's an  
14 exponentially higher number. I can --

15 THE COURT: Well, it's more than four; right.

16 MR. MAYERS: Yes, I would agree it's more than  
17 four.

18 THE COURT: Okay. Go ahead.

19 MR. MAYERS: But again, your Honor, we would not  
20 be able to tell whether a potential explanation that  
21 you offered or kids coming in with unspecified  
22 endocrine disorders is right or whether, again, a  
23 doctor to, you know, insurance coverage or to hide up  
24 or to, you know, to hide some off-label promotion  
25 scheme.



1 THE COURT: Off-label is not illegal.

2 MR. MAYERS: Again, we agree off-label  
3 prescription is not illegal in and of itself. Our  
4 position though is that --

5 THE COURT: I'm sure you don't know my  
6 background. I spent 25 years as a criminal defense  
7 attorney, including in the Federal Defender's Office;  
8 and it seems that the Government is having a really  
9 hard time articulating what it is they're  
10 investigating.

11 So I'm going to ask you again specifically what  
12 are you investigating? And bear in mind what Lisa  
13 Hsiao represented to the Northern District of Texas.

14 MR. MAYERS: Right. So Lisa Hsiao's Declaration  
15 speaks to our FDCA investigation. It speaks to the  
16 relevance of each request. And your Honor, I'll back  
17 up first and say First Circuit, I know you want  
18 First Circuit cases, so I will, so *Sturm Ruger* and  
19 *Ricco Jonas*, all these cases say a stay summary  
20 proceeding and we don't need to hash out, you know, the  
21 exact specifics of an agency's authority to reg --

22 THE COURT: Oh, I complete agree; but I have to  
23 make a finding that you had a legitimate law  
24 enforcement purpose and that you didn't mislead the  
25 judge in Texas; correct?

1 MR. MAYERS: To make what finding, your Honor?

2 THE COURT: For him to order the issuance of  
3 the, the compliance with the subpoena; correct?

4 MR. MAYERS: I'm not sure about that. I would  
5 think you would have to conclude in this proceeding --

6 THE COURT: Uh'huh.

7 MR. MAYERS: -- that the effects of this order  
8 is void, which we don't think it is.

9 THE COURT: Or that there can be a collateral  
10 attack based on the fact that these parties were not in  
11 Texas and we're not in Texas.

12 MR. MAYERS: Yes, your Honor would have to find  
13 a route to conclude that the Northern District of  
14 Texas' order on the same subpoena can be set aside in  
15 this court.

16 THE COURT: I don't need to set it aside; I can  
17 just quash the subpoena and then there's nothing for  
18 the Texas court to enforce.

19 MR. MAYERS: Well, your Honor, that's a  
20 (indecipherable).

21 THE COURT: But I don't need to decide that the  
22 Texas judge did something wrong; I can just quash --.  
23 See, the problem I'm having here is that it's pretty  
24 clear to me that this was shopped to Texas, that's  
25 fine, you have the right to investigate wherever you

1 want, but these indictments that come out of Texas, if  
2 they ever come, because every person has signed an  
3 affidavit in this court and is going to be before me to  
4 explain it if they don't. That's one.

5 MR. MAYERS: Your Honor, --

6 THE COURT: Two -- no.

7 MR. MAYERS: Your Honor, I don't believe the  
8 investigation is out there, grand jury investigations  
9 are, you know --

10 (Indecipherable crosstalk)

11 THE COURT: It's in Texas, the grand jury is in  
12 Texas.

13 MR. MAYERS: Yes, your Honor. But I'm saying  
14 any investigation can be transferred, right --

15 THE COURT: Right, so we'll just check to see if  
16 you transferred it, but it better come out of Texas.  
17 What I'm saying is if this was done and you lied to  
18 this Court or misrepresented the facts to this Court  
19 and convened that grand jury after this was filed,  
20 there will be issues with false representations to this  
21 Court; and we're at the end of our tether with the DOJ  
22 making false representations in this District. So I'm  
23 going to say that, and that is just a warning.

24 But if I, I make a finding that you did not,  
25 that you violated the due process of Rhode Island

1 Hospital and certainly the -- I think the Child  
2 Advocate is pretty clear, it's not a precluded  
3 collateral attack; correct?

4 MR. MAYERS: We think the analysis is cleaner  
5 understanding in our opinion with respect to the Child  
6 Advocate.

7 THE COURT: Okay. And you say nobody has  
8 standing to move to quash the subpoena?

9 MR. MAYERS: We would argue that in order to,  
10 again, set aside functionally this --

11 THE COURT: I'm not setting aside. We're  
12 dealing with something they were not a party to, so  
13 talk about what they're asking.

14 MR. MAYERS: Yes, your Honor. Again, I think  
15 it's well established that district courts cannot set  
16 aside or interfere, et cetera, with another district  
17 court's order, and I think that is what will be  
18 required here to provide the Child Advocate or Rhode  
19 Island Hospital with redress.

20 THE COURT: Why?

21 MR. MAYERS: Because the order still stands  
22 regardless, the order compelling Rhode Island, ordering  
23 Rhode Island Hospital to comply would stand regardless.

24 THE COURT: But did you provide the relevant  
25 information to the judge in Texas?

1 MR. MAYERS: Yes. And he concluded after --  
2 assuming your Honor thinks the April e-mails --

3 THE COURT: I'm sorry?

4 MR. MAYERS: Assuming your Honor thinks the  
5 April e-mails between the Department and Rhode Island  
6 Hospital are relevant to the district judge's  
7 determination, he reviewed those e-mails. Rhode Island  
8 Hospital provided them --- -

9 THE COURT: But didn't he also --

10 MR. MAYERS: -- and reached the same conclusion.

11 THE COURT: But they provided them after the  
12 fact and they weren't -- he didn't assert jurisdiction  
13 with a jurisdictional nexus during the time; you just  
14 said it and he signed off and, in fact, I think he  
15 signed the order that you produced.

16 But the health benefit program that's in  
17 Ms. Hsiao's affidavit, you didn't tell him certain  
18 relevant facts, right, that you had negotiated with  
19 Rhode Island Hospital over the period of 10 months,  
20 that you had been in touch with them two days.

21 Any of that provided to that judge?

22 MR. MAYERS: Your Honor, not with our  
23 petition -- what Ms. Hsiao's Declaration said, of  
24 course, was provided; however, I don't read in 3486 any  
25 of those facts being necessary, you know, a necessary

1 prerequisite.

2 THE COURT: So you're saying you have kind of  
3 mislead the court to get what you want under 3586.

4 MR. MAYERS: I'm not saying that, your Honor.

5 THE COURT: Okay. Go ahead.

6 MR. MAYERS: We've discussed it briefly, but to  
7 go to the factors the First Circuit has set out for the  
8 enforcement of a subpoena, there are four of them.  
9 Subpoenas issued for a congressionally-authorized  
10 purpose.

11 THE COURT: I'm sorry, say that again.

12 MR. MAYERS: The subpoena is issued for a  
13 congressionally-authorized purpose. I'm quoting from  
14 *Sturm Ruger & Co.*, First Circuit 84 F.3d, this is at  
15 page 4.

16 THE COURT: Go ahead.

17 MR. MAYERS: So this is *Sturm*, and there's other  
18 cases that speak to the same standard, right, "the  
19 subpoena is issued for a congressionally-authorized  
20 purpose."

21 We think here, we know here that 3486(a)  
22 authorizes the Attorney General to issue subpoenas to  
23 investigate violations of federal healthcare offenses.  
24 (2) the information sought is relevant to the  
25 authorized purpose. We think Ms. Hsiao's Declaration

1 speaks to the relevancy of the request. And also I've  
2 outlined to your Honor two theories, one being that  
3 Rhode Island Hospital possesses, could possess evidence  
4 relevant to potential misconduct by pharmaceutical  
5 companies and (2) Rhode Island Hospital could have  
6 engaged in a conspiracy with said pharmaceutical  
7 companies.

8 THE COURT: Right.

9 MR. MAYERS: So we think that each subpoena  
10 requests --

11 THE COURT: Well, that doesn't get you to  
12 11 through 15, but we'll address that later.

13 MR. MAYERS: I'm happy to address it --

14 THE COURT: How do you get to 11 through 15?

15 MR. MAYERS: Well, your Honor, you know, as  
16 we've discussed --

17 THE COURT: And why can't it be deidentified, as  
18 I think HSS requires under the CFR HSS rules say that  
19 in order to get that information or give that  
20 information, Rhode Island Hospital's responsible for  
21 deidentifying that data and you're responsible for  
22 saying why it can't be deidentified.

23 MR. MAYERS: So if Rhode Island Hospital takes  
24 the position that they will produce deidentified  
25 patient information to the extent it is possible for us

1 to carry out our investigation, we would accept those  
2 records

3 THE COURT: And did you tell the Texas judge  
4 that?

5 MR. MAYERS: We didn't tell the Texas judge one  
6 way or the other.

7 THE COURT: And did you tell the Texas judge  
8 essentially that you needed the information, without  
9 disclosing to the Texas judge that you had agreed to  
10 deidentified information in several other places?

11 MR. MAYERS: We told the Texas judge that  
12 patient records, and again I can quote from -- I want  
13 to be sure I'm precise here.

14 (Judge confers with Clerk)

15 MR. MAYERS: So we said, your Honor, just  
16 referring to patient records generally.

17 THE COURT: Where is this?

18 MR. MAYERS: This is, I believe your Honor  
19 quoted earlier in paragraph 44 of the initial Hsiao  
20 Declaration.

21 THE COURT: Okay.

22 MR. MAYERS: So we say, patient records:  
23 Generally without this information we cannot fully  
24 determine the scope of violations, identify patterns,  
25 or assess whether conduct was taken with intent to



1 defraud or mislead. Now, yes --

2 THE COURT: Well, you go on in that paragraph I  
3 think: Linking each patient's clinical record to  
4 corresponding billing and insurance claims can  
5 demonstrate whether diagnoses were miscoded, which can  
6 prove fraudulent intent...blah, blah, blah.

7 This is Ms. Hsiao's, again, under oath  
8 affidavit. And so: Absence or minimization of such  
9 warnings, multiple patient outcomes...blah, blah,  
10 blah...Finally, providing patient records can provide  
11 essential investigative leads, parents may be witnesses  
12 about which disclosures were made, patients --.

13 How were parents -- are you investigating fail  
14 to disclose the side effects or like -- how are parents  
15 involved with off-label prescriptions?

16 MR. MAYERS: We think that the representations,  
17 again, we're not saying that off-label prescription  
18 alone is an FDCA violation. We think that  
19 communications with parents perhaps could be relevant  
20 to this idea that the hospital and its employees acted  
21 in concert with pharmaceutical companies.

22 THE COURT: Okay. But this is where Ms. Hsiao I  
23 think may have a problem. On page 18, further down in  
24 the paragraph she says: The Government cannot fully  
25 determine the scope of the violation, identify patterns

1 of misbranding or fraudulent billing, or assess whether  
2 the conduct was undertaken with intent to defraud or  
3 mislead, as required for felony liability; and she says  
4 that with respect to needing the individualized patient  
5 information. And so she says that, but she doesn't  
6 represent in there that, in fact, she had agreed to or  
7 you, the Department of Justice had agreed to  
8 deidentified information in several other cases.  
9 Correct?

10 MR. MAYERS: Your Honor, I think that the  
11 important word to focus on is "fully". I think our  
12 position is that, of course, de-anonymized records  
13 would allow us to more fully determine the scope of any  
14 potential violations. Again, as your Honor noted  
15 earlier, there are negotiations that happen between a  
16 subpoena recipient and the Government, and in those  
17 negotiations we have agreed to accept anonymized  
18 records.

19 THE COURT: Okay. We're going to find out from  
20 Rhode Island Hospital if you've done that with them,  
21 and we're going to get an affidavit from Mr. Gunn,  
22 right, saying one way or the other.

23 MR. MAYERS: Yes, one way or the other whether  
24 those conversations --

25 THE COURT: Ever took place, and with whom.

1           Okay. Go ahead, continue.

2           MR. MAYERS: So your Honor, I was going through  
3 the First Circuit's factors for.

4           THE COURT: So let's agree to disagree on  
5 whether 11 through 15 are relevant.

6           MR. MAYERS: Yes. Your Honor, just to reiterate  
7 for your Honor's benefit, we think they're relevant  
8 both to show intent to mislead, and also if we're  
9 investigating off-label promotion oftentimes it is  
10 important to determine where those drugs ended up and  
11 so we think also the patient records are relevant for  
12 that.

13           THE COURT: And so are you -- is the DOJ going  
14 to go follow up and find parents and patients and  
15 interview them about what they were told?

16           MR. MAYERS: Potentially, yes.

17           THE COURT: And you don't think that's an  
18 incredible invasion based on a hunch when DOJ has  
19 nothing more? You don't think that's part two? If  
20 you've got something then, you know, then maybe you get  
21 that information, maybe. But since you're just  
22 starting with this broad sweep you don't think that's a  
23 little bit invasive? Can this Court issue an order for  
24 somebody who says, you know what, I don't think that  
25 Viagra should be prescribed and I want to find

1 everybody in the state of Rhode Island who has been  
2 prescribed Viagra --

3 MR. MAYERS: Your Honor --

4 THE COURT: -- and while we're at it, everybody  
5 in the DOJ.

6 MR. MAYERS: Your Honor, we are not, again,  
7 targeting only the prescriptions; right? We are  
8 targeting this potential scheme and we're trying to  
9 figure out how it worked or if it worked.

10 THE COURT: Right; the patients would have no  
11 relevant information unless there's a scheme.

12 MR. MAYERS: The point of the investigation is  
13 to you know, again, we've laid out why we think  
14 there --

15 THE COURT: Do you understand why the parties  
16 are saying that this is an intentionally broad effort  
17 to chill the rights of these minors in Rhode Island  
18 which have a statutory protection for gender-affirming  
19 care. You can agree with it, I can disagree with it,  
20 anybody in this courtroom can disagree with it; but our  
21 Legislature has protected it. And it is ridiculous to  
22 say that you're going to find 14- and 15-year-olds who  
23 are undergoing gender reassignment or gender treatment  
24 and question them about what was told to them by their  
25 doctor. How invasive is that? And on a hunch that we

1 might have an investigation into false billing  
2 practices that may or may not include four people.

3 MR. MAYERS: Your Honor, I would claim there are  
4 horrific stories pointing the other way as well. And I  
5 would also note --

6 THE COURT: In what other way?

7 MR. MAYERS: Indicating the damage done to  
8 children by these very --

9 THE COURT: But that's getting into whether you  
10 agree with it or not. I don't care whether you agree  
11 with it or not, I don't care at all.

12 Rhode Island, according to Justice Alito in  
13 *Scrimetti*, has the right to decide -- and by the way,  
14 also in *Dobbs* and in many other cases, states are best  
15 situated to protect the health of their citizens. They  
16 say it in *Dobbs*, they say it in *Scrimetti*, they've  
17 probably said it in other cases. It doesn't really  
18 matter whether you think it's a good idea or not,  
19 because you're not a scientist and neither am I. It  
20 doesn't matter if anybody here thinks it's a great idea  
21 or not. There are stories on both sides. Mr. Love  
22 Hubbard told you stories about children who were, who  
23 had suicidal ideation until they received the care.  
24 That is not what this Court is deciding and frankly  
25 that's not what the Department of Justice is deciding;

1 correct?

2 MR. MAYERS: Correct, your Honor. Congress has  
3 enacted -- Congress has decided to criminalize  
4 misbranding.

5 THE COURT: Misbranding can happen by whom? Who  
6 can misbrand?

7 MR. MAYERS: So as I explained, there are,  
8 again, two potentials: So (A) it is typically the  
9 manufacturer --

10 THE COURT: Define "misbranding" for me, please.

11 MR. MAYERS: So there are multiple ways a drug  
12 can be misbranded. That is found in 352, 21 USC 352.  
13 The ones we have discussed in our papers most are, I'm  
14 just quoting from the statute: A drug shall deemed to  
15 be misbranded in its labeling is false or misleading.

16 THE COURT: Okay. Who labels drugs?

17 MR. MAYERS: Your Honor, typically the  
18 manufacturer.

19 THE COURT: Okay. So that's not Rhode Island  
20 Hospital and that's not the parents or children.

21 So tell me the other ways.

22 MR. MAYERS: So also there is, you know, and I  
23 want to clarify after I point to the other section or  
24 subsection, excuse me. It's 35 -- 352(f) says unless  
25 the labeling's adequate directions for use, is also the

1 other one, the other subsection we had pointed to.

2 Your Honor, again --

3 THE COURT: I'm sorry, say that again.

4 MR. MAYERS: There's 352(f) talks about adequate  
5 directions for use.

6 THE COURT: Again, that comes from the  
7 manufacturer; correct?

8 MR. MAYERS: Yes, most often the manufacturer  
9 will in the first instance decide --

10 THE COURT: Just so that you know, the  
11 Fifth Circuit denied the stay in a one-sentence order.

12 MR. MAYERS: So that means that Judge O'Connor's  
13 order is in effect in (indecipherable).

14 THE COURT: Unless I quash subpoena --

15 MR. MAYERS: Which would be --

16 THE COURT: -- or enjoin the Department of  
17 Justice, or enjoin Rhode Island Hospital, or all of the  
18 above.

19 MR. MAYERS: So your Honor, yes, a manufacturer  
20 distributor can misbrand a drug. They decide the  
21 labeling. Often in the first instance it goes through  
22 the FDA approval process. Our argument here is (A),  
23 that can happen by a manufacturer, and Rhode Island  
24 Hospital would have evidence of that.

25 THE COURT: How? How on earth would they have

1 -- were they the place where these drugs were  
2 officially tested and approved by the FDA? Were they  
3 the center?

4 MR. MAYERS: So your Honor, under 352(f),  
5 adequate directions for intended use, the intended use  
6 under the CFR provision we cite.

7 THE COURT: Then don't we get into Ozempic and  
8 Wegovy. You know, I mean so basically you're saying  
9 that it would be okay if the Department of Justice went  
10 and got everybody's records who's taking those drugs;  
11 correct?

12 MR. MAYERS: Your Honor, that is not my position  
13 and I --

14 THE COURT: Why not? It could be misbranding.  
15 (Indecipherable crosstalk)

16 THE COURT: Or is it because of the people who  
17 are taking them that are less vulnerable?

18 MR. MAYERS: No, your Honor, that is not the  
19 case. But I'm still trying to explain how a drug can  
20 be misbranded. That was your Honor's question, --

21 THE COURT: Go ahead.

22 MR. MAYERS: -- so I'm explaining false or  
23 misleading any particular and also directions adequate  
24 for intended use.

25 THE COURT: Okay. And that comes from?



1 MR. MAYERS: This is in 21 USC 352.

2 THE COURT: Who misbrands?

3 MR. MAYERS: So again, in the first sentence the  
4 manufacturer distributor decides the labeling, and that  
5 goes through the FDA approval process.

6 THE COURT: Okay.

7 MR. MAYERS: Our position is with respect to  
8 Rhode Island Hospital's potential witness, they may  
9 have communications from the pharmaceutical company  
10 that are evidence of the intended use.

11 THE COURT: Right. Rhode Island Hospital  
12 lawyers sent you terms to find those, and you didn't  
13 respond; right?

14 MR. MAYERS: I believe that's correct as to the  
15 search terms.

16 THE COURT: That was in February, no response;  
17 except hey, let's have a meeting; right?

18 MR. MAYERS: Your Honor, I don't believe that  
19 that exempts Rhode Island Hospital from collecting  
20 those documents or from --

21 THE COURT: They have the documents. They're  
22 asking you how -- what if I said to you I want  
23 everything that the Department of Justice has written  
24 that includes the word "preempt".

25 MR. MAYERS: It would be a lot of paper.

1 THE COURT: Yeah. So that's what they're  
2 saying, let's get some much search terms to narrow down  
3 the search. They offer that, and you ghosted them.

4 MR. MAYERS: Your Honor, I don't think that  
5 their e-mail exempts them from attempting to comply in  
6 the meantime. We know from their filing in the  
7 Northern District of Texas --

8 THE COURT: They did intend to comply. They  
9 gave you six pages, which you haven't produced to this  
10 Court. I don't know what's in those six pages, and I'm  
11 sure the Texas judge didn't. But you also didn't  
12 respond to their search terms.

13 MR. MAYERS: Your Honor, again --

14 THE COURT: I mean they're undergoing this  
15 process in good faith, and you can understand why as a  
16 judge I would take it if a party says we're negotiating  
17 with this other party; and then the other party comes  
18 to court, that I think it's misleading the court not to  
19 tell the court -- whether in Texas or here or Ohio or  
20 wherever -- the facts, the real facts about the  
21 communication. And I recognize that you weren't there,  
22 and it was the gentleman sitting behind you and the  
23 other people who were part of those communications.  
24 But that was misrepresented in Texas, and so that  
25 record in Texas is based on misrepresentations.

1 MR. MAYERS: Your Honor, Judge O'Connor's order  
2 did not --

3 THE COURT: Based on misrepresentation.

4 MR. MAYERS: No, your Honor, it's not -- Judge  
5 O'Connor --

6 THE COURT: It wasn't? It wasn't? It was a  
7 motion to stay. It was not a motion to reconsider.

8 MR. MAYERS: Your Honor, and he said if he would  
9 have had that record beforehand when he first ruled.

10 THE COURT: Yeah, but we don't know -- first of  
11 all, you chose Judge O'Connor in Texas. Let's just  
12 admit that. At least be honest enough to admit that.

13 MR. MAYERS: Admit what, your Honor?

14 THE COURT: That you chose Fort Worth where  
15 there's two judges intentionally knowing that you were  
16 going to get a forum, since you had lost seven of  
17 these, every single one of them that were filed in  
18 other cases; right?

19 MR. MAYERS: Your Honor, there were many reasons  
20 why the investigation is being carried on in the  
21 Northern District of Texas. As the affidavit that you  
22 received yesterday *ex parte* indicates, there are  
23 potential targets, potential witnesses there. I  
24 believe there are certain --

25 THE COURT: There are potential targets and

1 witnesses here.

2 MR. MAYERS: Yes.

3 THE COURT: We have a court of three judges, so  
4 we can offer you an extra judge. Why not file here?

5 MR. MAYERS: Well, the investigation was not  
6 carried on here necessarily. We are given --

7 THE COURT: But you can't tell me when it went  
8 to Texas.

9 MR. MAYERS: When what went to Texas?

10 THE COURT: The investigation. When did it go  
11 to Texas? Because it was in D.C. until, when?

12 MR. MAYERS: Your Honor, the investigation,  
13 again the statute says "carried on"; right?

14 THE COURT: Where is it being carried on?

15 MR. MAYERS: So, again, our submission is it's  
16 being carried on in the Northern District of Texas.

17 THE COURT: Great. When? When did it start  
18 there?

19 MR. MAYERS: The investigation I believe there  
20 were few months ago, maybe a little bit, I don't  
21 remember the exact date, but --

22 THE COURT: In April; right?

23 MR. MAYERS: No, your Honor.

24 THE COURT: In March?

25 MR. MAYERS: Before April. If I remember

1       correctly I believe there were, yes, communications in  
2       March.

3               THE COURT:   Okay.   So not in July of 2025.

4               MR. MAYERS:   I can't speak for, again, every  
5       member of the team.   I don't believe there were any  
6       specific conversations in July 2025.

7               THE COURT:   But the investigation wasn't being  
8       carried on there.

9               MR. MAYERS:   At that time, your Honor -- again,  
10      your Honor, the investigation shifts all the time.

11              THE COURT:   I know, you said that.

12              MR. MAYERS:   Well, I mean I think that's true.

13              THE COURT:   Well, they shift for reasons, and if  
14      you're telling me that now this is centered in the  
15      Northern District of Texas as an officer of the court,  
16      I am taking your representation of that.   And I'm  
17      taking Ms. Hsiao's under oath representations that  
18      that's correct.   But as I already indicated, if I ever  
19      find out that that's not correct you and Ms. Hsiao and  
20      anybody else who filed false representations to this  
21      Court -- I can't speak to the judge in Texas, but if I  
22      were him I would be furious that you didn't tell him  
23      the full landscape before he decided things; and he  
24      didn't have a jurisdictional nexus at the time he  
25      decided.   You gave him that after the fact.   And I

1 understand that on a motion for a stay he said it  
2 wouldn't have made a difference to me anyway. But you  
3 know what, doing that while not telling him, to this  
4 date you haven't told him that, hey, by the way, we  
5 were in ongoing conversations on FaceTime or whatever  
6 with Rhode Island Hospital.

7 MR. MAYERS: Yes, the Hsiao Declaration does  
8 speak to those. And again, Rhode Island Hospital  
9 submitted those to the court in both the Northern  
10 District of Texas and to the Fifth Circuit now.

11 THE COURT: Well, the Fifth Circuit was deciding  
12 on a stay and they did it in one sentence, so I'm not  
13 impressed.

14 MR. MAYERS: Regardless, the Fifth Circuit has  
15 reviewed the record, including those April e-mails, and  
16 concluded that Rhode Island Hospital is not likely to  
17 succeed on the merits.

18 THE COURT: Great, in Texas. Now we're here.

19 Tell me what's going on with the rest of your  
20 argument here because I have some questions and we're  
21 getting late.

22 MR. MAYERS: Yes, your Honor. So those are, I  
23 believe we were walking through the First Circuit's  
24 factors for subpoena (indecipherable).

25 THE COURT: Yup.

1 MR. MAYERS: We've discussed at length.

2 THE COURT: You didn't give me the third or  
3 fourth factor.

4 MR. MAYERS: Yes, I was getting there. I  
5 recognize that the second factor your Honor and I  
6 disagree on, that Requests 11 through 15.

7 THE COURT: Right.

8 MR. MAYERS: So I would ask, you know, even if  
9 your Honor concludes those are, that we still have  
10 1 through 10.

11 THE COURT: I think the time to negotiate that  
12 was before today, don't you?

13 MR. MAYERS: Not necessarily, your Honor.

14 THE COURT: Okay.

15 MR. MAYERS: On alternative factor 3 or element  
16 3, however you look at it, whether the information is  
17 adequately described, we point to the Supreme Court in  
18 *McPhaul* which says, you know, there's a relatively  
19 broad inquiry, permissible scope of materials that  
20 could reasonably be sought if necessarily broad.

21 I won't cite the D.C. Circuit case because I  
22 know your Honor has a preference for First Circuit law,  
23 but I think that Supreme Court decision recognizes  
24 that --

25 THE COURT: Well, it's not just that I just have

1 a preference. I'm required to follow First Circuit  
2 law.

3 MR. MAYERS: Completely understood, your Honor.  
4 But the Supreme Court here has said that, you know, a  
5 Government investigation that is relatively broad means  
6 that there is a, you know, again on the back end a  
7 relatively, you know, broad permissible scope of  
8 materials that the Government can seek.

9 THE COURT: Okay.

10 MR. MAYERS: And then fourth, your Honor, the  
11 fourth factor, excuse me, is whether proper procedures  
12 had been employed in issuing the subpoena. The parties  
13 dispute that that fourth factor is met here.

14 THE COURT: How did you issue the subpoena?

15 MR. MAYERS: So the Assistant Attorney General  
16 for the Civil Division signed the subpoena early July  
17 and it was served by e-mail I believe on the, on Rhode  
18 Island Hospital.

19 THE COURT: Is that proper service?

20 MR. MAYERS: We asked if they would accept  
21 service by e-mail.

22 THE COURT: But is it proper service? Because  
23 now they said they would accept it, but maybe they're  
24 not bound by that, right, by the rules of this case.  
25 Are they bound by that?



1 MR. MAYERS: By accepting service of the  
2 subpoena --

3 THE COURT: By saying they would accept it by  
4 e-mail.

5 MR. MAYERS: -- in July 2025?

6 THE COURT: By saying they would accept it by  
7 e-mail.

8 MR. MAYERS: I believe they, I believe the  
9 e-mail responded that they accepted it, so I believe --

10 THE COURT: Okay.

11 MR. MAYERS: I don't think they disputed they  
12 were not properly served with the subpoena in July.

13 THE COURT: But you're calling into question any  
14 informal communications that you had with Rhode Island  
15 Hospital. You understand that; right?

16 MR. MAYERS: Your Honor, I believe we submitted  
17 the e-mail, that acceptance as far as e-mail is  
18 (indecipherable)?

19 THE COURT: They also submitted the e-mail about  
20 the search terms that nobody responded to, and until  
21 they asked for a meeting that they never had any  
22 intention of holding; right?

23 MR. MAYERS: Your Honor, whose intention of  
24 holding?

25 THE COURT: DOJ.

1 MR. MAYERS: I don't know when the e-mail was  
2 sent, whether we had (indecipherable) or not. I  
3 believe --

4 THE COURT: It was sent on the 28th. So you're  
5 telling me you think on the 28th you hadn't already  
6 decided to go to the Northern District of Texas?

7 MR. MAYERS: Oh, I believe the decision to file  
8 the petition had not been determined when we, you know,  
9 reach out about it.

10 THE COURT: Okay.

11 MR. MAYERS: So the fourth element, again, no  
12 one disputes it, so I think that one is satisfied here.

13 THE COURT: Uh'huh.

14 MR. MAYERS: So I'll turn to some of the  
15 counter-arguments.

16 THE COURT: I have a bunch of questions, so go  
17 ahead.

18 MR. MAYERS: Yes. So we've discussed statutory  
19 authority and the relevance factors a decent amount.

20 I will also note that on the overbreadth  
21 arguments, if your Honor agrees that some of the  
22 requests are overbroad the proper remedied we would  
23 submit is narrowing the subpoena rather than quashing  
24 it.

25 THE COURT: But you're saying I don't have the

1 authority do that.

2 MR. MAYERS: Your Honor, I'm assuming that you  
3 disagree with us on that point. So of course we  
4 maintain that we think that any further litigation  
5 should take place in Texas; however, if your Honor  
6 disagrees with us we submit that narrowing rather than  
7 quashal is the right.

8 THE COURT: Who bears the cost of litigation in  
9 Texas? The taxpayers of the State of Rhode Island?

10 MR. MAYERS: Would it be Rhode Island Hospital,  
11 I believe, so.

12 THE COURT: But what about the Child Advocate.

13 MR. MAYERS: Yes, your Honor, the Child Advocate  
14 in Texas, I believe, I don't know exactly how she's  
15 funded.

16 THE COURT: It's state funding. So the  
17 taxpayers of the State of Rhode Island, you submit,  
18 should be required to go to the forum that you chose.

19 MR. MAYERS: Yes, your Honor, we think that is  
20 the proper way to challenge the order of --

21 (Indiscernible crosstalk)

22 THE COURT: Okay. I just want the record to be  
23 clear that that is what the DOJ is suggesting.

24 MR. MAYERS: We are. We just think that as a,  
25 you know, especially with standing, we think the only

1 way to really set aside the order of Judge O'Connor is  
2 to go to the Northern District of Texas for the Fifth  
3 Circuit. That is our position. I think that's --

4 THE COURT: But they weren't in there, so I know  
5 you take the position that they can't collaterally  
6 attack an order that they weren't a party to and that  
7 they weren't notified of until after of the fact; but I  
8 think you have kind of a difficult row to hoe on that  
9 one.

10 Why should the Child Advocate be precluded from  
11 challenging the subpoena here, when it wasn't a party  
12 in Texas? Can you answer that specifically.

13 MR. MAYERS: Yes. I think, as I've discussed  
14 with your Honor, we don't think any remedy here can  
15 result in the undoing of Judge O'Connor's order, and so  
16 we think as a matter of redressability at the least any  
17 relief from Judge O'Connor's order needs to be sought  
18 either in front of him or in the Fifth Circuit.

19 THE COURT: But if I quash the subpoena there is  
20 nothing, and if I enjoined the Department of Justice,  
21 which is what the Child Advocate has asked, then they  
22 don't have to -- then nothing can be provided to you  
23 because you would be enjoined from receiving it;  
24 correct?

25 MR. MAYERS: That would be we the -- or I

1 believe your Honor believes would be the effect of that  
2 injunction. But again, the order would still be,  
3 Judge O'Connor's order would still be live and  
4 enforceable.

5 THE COURT: But if a judge orders somebody to  
6 show up for trial, and then they cut a deal and they  
7 plead to the case, that order to show up for trial is  
8 void because that doesn't exist anymore; right?

9 MR. MAYERS: Yes, if we voluntarily cut a deal.

10 THE COURT: I'm not talking about voluntarily.

11 MR. MAYERS: If we cut a deal, sure.

12 THE COURT: I don't care about the voluntarily.  
13 What I'm saying is that court orders become nullities  
14 all the time; right?

15 MR. MAYERS: By agreement of the parties.

16 THE COURT: No. Sometimes by operation of law,  
17 of the court quashing of subpoenas.

18 MR. MAYERS: Again, they haven't pointed to a  
19 case, movants haven't, where a district court, a  
20 federal district court enters an order enforcing a  
21 subpoena and another federal district court entered  
22 one, you know, quashing that same subpoena afterwards.

23 THE COURT: Have you, do you have a case that's  
24 similar to this one where the Department of Justice  
25 went to an inconvenient forum to enforce a subpoena

1 without giving notice to the party?

2 MR. MAYERS: We have cases that stand for the  
3 general proposition that one district court cannot  
4 essentially review the work of another.

5 THE COURT: I wouldn't be reviewing his work;  
6 right? I'm reviewing the subpoena.

7 MR. MAYERS: Your Honor, we've been talking  
8 about his work for quite a while now.

9 THE COURT: Well, we are because I think the  
10 Department of Justice intentionally mislead the judge  
11 in the Northern District of Texas.

12 MR. MAYERS: I strongly disagree, and Judge  
13 O'Connor does too.

14 THE COURT: Well, I don't know if he disagrees.  
15 I don't think he knows about all of the other stuff  
16 that you've said here about the conversations about  
17 deidentified data. That wasn't provided to him. In  
18 fact, Lisa Hsiao specifically said you couldn't have  
19 deidentified data, and part of his finding is based on  
20 that. And that was untrue at the time she wrote it,  
21 and it remains untrue today, and that representation  
22 made in an affidavit in the Northern District of Texas;  
23 and that judge has the right to call her in and ask her  
24 to explain it. Now, will he, I don't know. But if it  
25 turns out that that misrepresentation has been made

1 here, then I will.

2 Now, putting that aside, it doesn't matter what  
3 he does. We're talking about separate motions to quash  
4 that are brought before this Court, and I'm trying to  
5 find out why you think the collateral attack doctrine  
6 would apply against the Child Advocate when they had no  
7 notice, no opportunity to be heard, and certainly it  
8 can't be the scheme that the taxpayers of the State of  
9 Rhode Island are responsible for going to Texas to  
10 litigate something.

11 MR. MAYERS: Your Honor, we think the cleanest  
12 way to think about it is probably with respect to Rhode  
13 Island Hospital would be the collateral attack  
14 doctrine.

15 THE COURT: But they weren't in Texas either;  
16 right?

17 MR. MAYERS: They are in Texas. They've  
18 litigated -- again, they could have gone for  
19 reconsideration.

20 THE COURT: But they haven't moved for  
21 reconsideration. They chose to appeal --

22 MR. MAYERS: They could have.

23 THE COURT: -- because the time was short;  
24 correct?

25 MR. MAYERS: I don't know, I can't speak to

1       their motives or their thought processes as to why not  
2       move for reconsideration and instead move for a stay of  
3       that appeal, or appeal and then move for a stay. But  
4       again, I think that --

5               THE COURT: Don't you think this was complicated  
6       by your choice of forum?

7               MR. MAYERS: How so, your Honor?

8               THE COURT: No?

9               MR. MAYERS: I'm trying to understand.

10              THE COURT: Well, if you had come here for a  
11       motion to enforce, then they would have responded and  
12       we would be here, where they are.

13              But instead you came to a district and didn't  
14       provide notice and had the order issued the same day  
15       you filed it without an opportunity to be heard in a  
16       foreign -- in a forum that they can't even be required  
17       to provide the records in because it's too far away,  
18       under HIPAA. So you created this morass, believe me,  
19       and Rhode Island Hospital helped; and in the future I'm  
20       sure Rhode Island Hospital is not going to make that  
21       mistake, they will always file a motion to quash, as  
22       will everybody, and I think the Department of Justice  
23       is going to spend a lot of time responding to motions  
24       to quash.

25              MR. MAYERS: Your Honor, we exercised our



1 authority under 3486 to move to enforce in a district  
2 in which it --

3 THE COURT: I understand that.

4 MR. MAYERS: -- was carried on and so --

5 THE COURT: That's not the question. The  
6 question is the collateral attack. You're trying to  
7 put the collateral attack doctrine up front and say  
8 everybody is precluded because of this Texas ruling  
9 that where the judge wasn't provided all of the  
10 information and the parties weren't there.

11 MR. MAYERS: Your Honor, I think that our choice  
12 of venue, the correctness of it under 3486 is relevant  
13 to whether the collateral attack doctrine applies.

14 THE COURT: I don't think so, not if they  
15 weren't parties.

16 MR. MAYERS: Again, they appeared in front of  
17 Judge O'Connor. They sought relief in front of  
18 Judge O'Connor.

19 THE COURT: After the fact. And the Child  
20 Advocate has never appeared in front of Judge O'Connor.

21 MR. MAYERS: Yes, but as we covered earlier,  
22 your Honor, 1782 says that motion for reconsideration  
23 after the fact complies with due process.

24 THE COURT: Okay. So let's say you gave due  
25 process to Rhode Island Hospital. How does that

1 preclude the Child Advocate from collateral attack?

2 MR. MAYERS: Your Honor, we think it precludes a  
3 collateral attack like this one because regardless of  
4 the relief your Honor orders, the order of  
5 Judge O'Connor will remain, and that order directs  
6 Rhode Island Hospital to produce the documents.

7 THE COURT: In 14 days; in two days from now.

8 MR. MAYERS: Yes.

9 THE COURT: And you guys are not talking about  
10 any kind of like reality as to whether they can  
11 actually happen.

12 MR. MAYERS: We haven't had those discussions  
13 yet.

14 THE COURT: When did you plan on having them?

15 MR. MAYERS: Assuming we will. My point --

16 THE COURT: Today, I would suggest.

17 MR. MAYERS: But my point is, your Honor --

18 THE COURT: Okay.

19 MR. MAYERS: -- that the order will remain  
20 regardless. Regardless of the remedy they've  
21 requested, that order will remain and it will  
22 essentially require as of now Rhode Island Hospital to  
23 turn over those documents.

24 THE COURT: But if I preclude you from receiving  
25 them and I preclude them from giving them -- let's say

1 I preclude you from receiving them, then what? You're  
2 going to violate my order?

3 MR. MAYERS: We will not violate your order,  
4 your Honor.

5 THE COURT: Okay. Then what?

6 MR. MAYERS: We will go likely First Circuit.  
7 We will not --

8 THE COURT: Great, go to the First Circuit. Let  
9 them decide. There's already a case in front of the  
10 First Circuit because every other court that has  
11 decided this besides the Northern District of Texas has  
12 quashed these subpoena; correct?

13 MR. MAYERS: I know in Green (phonetic) I did  
14 brief that case, so I'm aware of the BCH appeal and I  
15 am the one litigating it, so, yes.

16 THE COURT: Okay. Great. When is your  
17 argument? Your brief is not due with them until July.

18 MR. MAYERS: So the answer is due in July. We  
19 filed ours in April, mid April, and Boston Children's  
20 basically asked for a three-month extension, and so as  
21 of now oral argument has not been set.

22 THE COURT: So why shouldn't we just hold this  
23 and wait to see what they decide? If the subpoena is  
24 overbroad, then it's overbroad in the First Circuit and  
25 Rhode Island Hospital would have to comply with

1 First Circuit law as I do.

2 MR. MAYERS: Your Honor, because we have one in  
3 order in front of Judge O'Connor that we think is  
4 enforceable.

5 THE COURT: That you wrote and that he granted  
6 after four hours.

7 MR. MAYERS: That he granted.

8 THE COURT: After four hours.

9 MR. MAYERS: Your Honor, with respect, I don't  
10 think any district judge would take kindly to, oh, you  
11 considered this only for a few hours.

12 THE COURT: Well, you withheld information from  
13 him. Of course he --

14 (Indecipherable crosstalk)

15 MR. MAYERS: I disagree, your Honor.  
16 Judge O'Connor --

17 THE COURT: I don't, and I'm making the finding  
18 that the Department of Justice withheld relevant  
19 information from Judge O'Connor, just so you know.

20 MR. MAYERS: So I will turn to the privacy  
21 argument, and again the --

22 THE COURT: Let's get there. I have questions,  
23 so let's move because we're after 5:00.

24 MR. MAYERS: We will, yes. So yes, the  
25 First Circuit in *Whelan v. Roe* and some of the

1 follow-on cases do speak to this idea of informational  
2 privacy. But at the same time the First Circuit has  
3 said that such a right must often give way to  
4 considerations of public interest.

5 THE COURT: What's the public interest in  
6 identifiable information?

7 MR. MAYERS: In enforcing --

8 THE COURT: Identifiable information.

9 MR. MAYERS: Your Honor, the public interest is,  
10 as our declaration explains, as we've discussed,  
11 determining the extent of any false billing scheme that  
12 informs the relevant intent under the FDCA, at least as  
13 to the FDCA.

14 THE COURT: So you're saying that a statutory --  
15 that an investigation into a statutory civil or minor  
16 criminal offense supersedes constitutional rights?

17 MR. MAYERS: No, your Honor. I think the  
18 determination as to what the Constitution protects is  
19 informed by considerations of public interest, just as  
20 it was in *Whelan*, for example, and so my position is,  
21 our position is there is a public interest that weighs  
22 heavily in favor of enforcing currently existing  
23 federal law and that is what we are pursuing.

24 THE COURT: But you're pursuing that with  
25 respect to -- do you understand the disconnect between

1 we're pursuing this because we think maybe somebody  
2 might have conspired with the drug manufacturers or the  
3 labelers or the issuers or the doctors or the hospital  
4 to mislabel, misbrand, mislead people about this drug,  
5 and so therefore we need the mental health records of  
6 children in DCYF care who have been diagnosed with  
7 gender dysphoria. Do you not see that that is a leap  
8 that you haven't connected?

9 MR. MAYERS: So, your Honor, this is -- if you  
10 will allow, this is not our FD theory, but just imagine  
11 that we were in the false billing context, --

12 THE COURT: Uh'huh.

13 MR. MAYERS: -- and there it is, you know,  
14 perhaps you would think more apparent as to why patient  
15 records were needed, --

16 THE COURT: Uh'huh.

17 MR. MAYERS: -- and there, if you would agree  
18 with that then presumably under these cases you would  
19 also agree that the privacy interest is different.

20 THE COURT: The privacy interest in what?  
21 You're asking for all of their records. Do you  
22 understand how broad your subpoena is? I've never seen  
23 a subpoena quite that broad in 25 years of criminal  
24 work.

25 MR. MAYERS: My understanding is that it's

1 pretty basic language. It is also --

2 THE COURT: Basic language for these subpoenas  
3 in this case where you're seeking these drugs, records.

4 MR. MAYERS: I believe that this is typical  
5 language used in the FDCA context and subpoenas like  
6 this is one.

7 THE COURT: Uh'huh.

8 MR. MAYERS: But what I was saying, your Honor,  
9 is that if there is a relevant need, which we submit  
10 there is for patient records in the FDCA context to  
11 inform (A) who got misbranded drugs and (B) --  
12 potentially misbranded drugs, and (B) whether there was  
13 false billing which informs fraudulent intent, that  
14 that need, that investigatory need constitutes a public  
15 interest that affects the privacy, you know, inquiry.

16 THE COURT: Okay. Okay. You've answered it.

17 MR. MAYERS: Your Honor --

18 THE COURT: I think that the difference between  
19 a constitutional right and a statutory right is  
20 something that the DOJ is failing to address, and I  
21 think it's pretty clear the First Circuit has an  
22 informational privacy right, and I would argue that  
23 Justice Alito in *Dobbs* reaffirmed that right. I think  
24 it's pretty clear in *Dobbs* that he says there's a  
25 difference, there is a decisional privacy and there's

1 informational privacy and here's why *Roe* was misguided  
2 in its original decision, because it focused on  
3 decisional privacy and there isn't one, and here but  
4 there is an informational one.

5 MR. MAYERS: Your Honor, a few responses. So  
6 the *Dowry* case, which is 842 F.2d 913 --

7 THE COURT: Where is that?

8 MR. MAYERS: First Circuit.

9 THE COURT: Uh'huh.

10 MR. MAYERS: -- is a constitutional privacy case  
11 and it says often that such privacy interests must  
12 often give way to considerations of public interest.

13 THE COURT: But don't you have to narrowly  
14 construe those things? Don't you have to tailor that  
15 narrowly?

16 MR. MAYERS: Tailor what narrowly, your Honor?

17 THE COURT: Your request, when you're going to  
18 get documents that are protected by a constitutional  
19 right. Let's say I wanted to know every gun owner in  
20 the state of Rhode Island. I want a list everybody who  
21 owns a gun, everybody who bought one at a gun show,  
22 everybody who has one that they registered, everybody  
23 who goes to a shooting gallery, or anything like that.  
24 Why can't -- can I just get those records? They have a  
25 constitutional right to bear arms. Can I if I'm



1 investigating, you know, mislabeling of bullets as  
2 whatever, you know, the ones that break apart and the  
3 ones that don't; I can't remember the name, but you  
4 know what I'm talking about. Why can't I get all of  
5 their records?

6 MR. MAYERS: Your Honor, if a party came before  
7 you seeking such records and put forward a valid  
8 investigatory reason --

9 THE COURT: Uh'huh.

10 MR. MAYERS: -- for it, right, for example, you  
11 know the --

12 THE COURT: I want to investigate, I want to  
13 talk to every gun owner in the state of Rhode Island,  
14 and I want to find out from every gun owner whether or  
15 not they've ever bought bullets that said they were not  
16 hollow-point bullets, but were hollow-point bullets.

17 MR. MAYERS: So say, for example, that that case  
18 was in front of you, --

19 THE COURT: Yeah.

20 MR. MAYERS: -- and say, for example, there are  
21 also statements from the party requesting such  
22 records --

23 THE COURT: Uh'huh.

24 MR. MAYERS: -- that said, you know, work for a  
25 machine gunman, right --

1 THE COURT: No, no. There's a machine gun ban.  
2 I'm not talking about that.

3 I'm talking about your absolutely constitutional  
4 right, I've got my little pistol in my nightstand table;  
5 I'm investigating whether or not bullets have been  
6 mislabeled as hollow-point or non-hollow point. Hollow  
7 points are legal, non-hollow -- or the other way  
8 around; whatever. I'm investigating whether these  
9 bullets have been misbranded, so I want to know how  
10 many guns you have and when you've bought ammunition.  
11 Don't I have the right to it under your theory?

12 MR. MAYERS: If that again was a, assuming its  
13 for (indecipherable) investigatory purpose, --

14 THE COURT: Uh'huh.

15 MR. MAYERS: -- and again the relevance standard  
16 is quite, you know, quite forgiving in the subpoena  
17 context.

18 THE COURT: Uh'huh.

19 MR. MAYERS: And if there was a reason, a law  
20 enforcement reason put forward --

21 THE COURT: Investigating potential, I don't  
22 have any proof, but I have a hunch that some of these  
23 bullets are being misbranded, and I have four people  
24 from Texas now who say that their bullets were  
25 misbranded when they were in Rhode Island.

1 MR. MAYERS: Your Honor, to clarify, I believe  
2 the patients were Rhode Island Hospital patients.

3 THE COURT: At the time. I bought bullets in  
4 Rhode Island when I lived there.

5 MR. MAYERS: Yeah, if that was the facts in  
6 front of the court I think that the court would have to  
7 consider whether those communications or whether  
8 interviewing potential, you know, owners of bullets  
9 were reasonably relevant to the investigation. If the  
10 court concluded yes, that's fine; if the court  
11 concluded no, we would argue, and there's a  
12 First Circuit case I meant to mention to your Honor on  
13 the relevance side of this. It's 554 F.2d 498, 503.

14 (Court Reporter requests clarification)

15 MR. MAYERS: It's *Usery*, U-s-e-r-y.

16 THE COURT: What's the page cite? 554 F.2d...

17 MR. MAYERS: So 554 F.2d 498, 503, we read to  
18 suggest that even if the Court concludes that a  
19 subpoena is overbroad, the right remedy is narrowing  
20 rather than quash. So we would suggest in that  
21 circumstance that if the government put forward a valid  
22 need for request purchase of certain bullets, for  
23 example, under the analogous circumstances --

24 THE COURT: But if the Department of Justice  
25 came before me with an affidavit and they didn't notify

1 anybody, they don't notify the Second Amendment  
2 coalition or the gun owners of Rhode Island or D&B Guns  
3 or any of those places, they just come before me with a  
4 subpoena that says hey, by the way, we're investigating  
5 a possibility that -- this is DOJ coming to me -- that  
6 we issued an administrative subpoena to all these  
7 places and we want to know everybody who's ever bought  
8 bullets from them for the last six years and who owns a  
9 gun, we want the State of Rhode Island to provide us a  
10 list of all gun owners that they're aware of, and  
11 that's it, it's an enforcement order; I have no choice  
12 but to enforce it; right?

13 And so the Department of Justice is conceding  
14 that the Department of Justice could get the  
15 information as it relates to the constitutional right  
16 in the Second Amendment; right? But that  
17 constitutional right gives way.

18 MR. MAYERS: Your Honor, I'm not conceding. I  
19 think the rights are a little different.

20 THE COURT: Why are they different?

21 MR. MAYERS: So I think, so it might be more  
22 relevant in the informational privacy context, right,  
23 because there isn't necessarily an analogous privacy  
24 interest in Second --

25 THE COURT: Constitutional issue.

1 MR. MAYERS: Agreed. I have not read a case  
2 saying that there is some sort of Second Amendment  
3 privacy right that is analogous to the privacy right  
4 claimed here.

5 THE COURT: Let me go back then. Let's say it's  
6 the Department of Justice and they're saying you know  
7 what, we want a list of everybody who's gotten guns  
8 because we want to start enforcing the  
9 you-can't-lie-on-it and we want to know who's got  
10 medical marijuana, which is legal in the state of Rhode  
11 Island.

12 MR. MAYERS: Yes, your Honor, if the Federal  
13 Government was investigating violations, potential  
14 violations of federal law and requested those records,  
15 we don't -- and again, I haven't cited  
16 (indecipherable), haven't cited cases in that context  
17 where there's Second Amendment cases speaking to some  
18 sort of privacy interest in gun ownership.

19 But again, we think that the -- and the  
20 First Circuit and the Supreme Court said this, that the  
21 relevant inquiry is whether the request is relevant to  
22 the needs of the investigation.

23 THE COURT: The needs of the investigation. So  
24 tell me now why you can negotiate with L.A. County  
25 Children's Hospital, or whatever they call themselves,

1 and say we don't need the identified data, but you do  
2 need it here, and you told the Texas court you need it;  
3 at least Lisa Hsiao did in her under oath affidavit.

4 MR. MAYERS: Your Honor, Lisa Hsiao said that  
5 the patients' records, that we need patient records,  
6 generally patient records to carry out our  
7 investigation. She did not say --

8 THE COURT: But doesn't HIPAA enforcement under  
9 the CFR, doesn't it say that you need to, doesn't HHS  
10 and HIPAA enforcement statute say that you have to show  
11 that nonanonymized data is necessary. You have to make  
12 that showing.

13 MR. MAYERS: That issue has not come up in this  
14 case or any of the others that I've worked on.

15 THE COURT: Well, it's coming up now. So, why  
16 not?

17 MR. MAYERS: Can your Honor point me to a...

18 THE COURT: Yup. It's a Code of Federal  
19 Regulations so the Department of Health and Human  
20 Services enforcement, and let's see.

21 Is it in our Teams from earlier today, folks?

22 (Pause)

23 THE COURT: We'll get it to you, but it's 615 in  
24 CFR, it's, whatever -- it's HSS's implementation of  
25 HIPAA, and I don't think you made that showing; do you?

1 MR. MAYERS: Your Honor (indecipherable) --

2 (Court Reporter requests clarification)

3 THE COURT: I'm arguing it. I'm asking you  
4 about it. You're saying that they have to come up with  
5 every possible argument and if they don't tell you what  
6 the law is then...

7 MR. MAYERS: Your Honor, as we've discussed at  
8 length, your Honor discussed the adversarial process.

9 THE COURT: So it's 45 CFR 164.512. It's not an  
10 adversarial process, is it? I thought it was just an  
11 Administrative Subpoena.

12 MR. MAYERS: No; my point is, your Honor, that I  
13 have not considered the application of that here and  
14 the others have not, --

15 THE COURT: Okay.

16 MR. MAYERS: -- given that it has not been  
17 briefed.

18 THE COURT: Gotcha.

19 MR. MAYERS: I'd be happy to look at it. I'd be  
20 happy to submit something to your Honor as to our  
21 opinion of it, but as of now given that it has not been  
22 briefed or at this point raised, I'm not in a position  
23 to address that regulation.

24 THE COURT: Let me find it for you so I can read  
25 it to you, so you can see what it says.

1 (Pause)

2 THE COURT: 45 CFR 64. This computer is so  
3 slow; that's why I print everything out. So, let's  
4 see. It tells Rhode Island Hospital that they have  
5 to -- they can only provide anonymized data unless  
6 there's been a showing that, I can't find the exact  
7 language because I can't read on this thing. Let me  
8 see.

9 (Pause)

10 THE COURT: Subsection, guys? Anyone? Okay, so  
11 it says basically -- oh, that's employer.

12 At any rate, it talks about what's required, and  
13 one of the requirements is a showing that anonymized  
14 data can't be used and it goes through different  
15 disclosures, victim of crimes, victims of child abuse,  
16 when people must be informed, which they must be.  
17 Okay. It says permitted disclosures: A covered  
18 entity, which I believe Rhode Island Hospital is, may  
19 disclose protected health information to a health  
20 oversight activity agency authorized by law, which I  
21 think is what you're arguing. Exceptions to health  
22 oversight activities for purposes of disclosure  
23 permitted by (indecipherable) oversight activity -- no,  
24 that's different. This is on my desk I should have  
25 just taken it with me. At any rate -- oh, here it is.



1 It's in part -- I don't know.

2 (Reading) In response to a subpoena, discovery  
3 request, or other lawful process that is not  
4 accompanied by an order of a court or administrative  
5 tribunal -- which is what your order is -- the covered  
6 entity receives satisfactory assurance as described in  
7 the other paragraphs from the party seeking the  
8 information that reasonable efforts have been made to  
9 ensure, to supply such parties to ensure that the  
10 individuals who is subject to protected health  
11 information that has been requested has been given  
12 notice -- which you haven't -- that the covered entity  
13 receives satisfactory assurance, blah, blah, blah;  
14 reasonable efforts have been made by such party to  
15 secure qualified protective order that meets the  
16 requirements of subsection whatever; and that a party  
17 requesting such information has made a good faith  
18 attempt to provide written notice. We already did  
19 that. Anyway, there is a point where they say that the  
20 Rhode Island Hospital has to make a finding that  
21 anonymized data doesn't satisfy it.

22 Disclosures for law enforcement purposes: The  
23 covered entity may disclose protected health  
24 information for a law enforcement purpose, to a law  
25 enforcement official if the conditions in paragraphs

1 F-1 through F-6 of the section are met as applicable.  
2 So pursuant to process as otherwise required, a covered  
3 entity may disclose information as required by law, by  
4 a court order in compliance with a subpoena, a grand  
5 jury subpoena, an administrative request for which  
6 response is required by law, and under that it says the  
7 information sought is relevant. They have to make a  
8 determination for law enforcement -- which is what you  
9 are -- the information sought is relevant and material  
10 to a legitimate law enforcement inquiry; the request is  
11 specific and limited in scope to the extent reasonably  
12 practicable in light of the purpose for which the  
13 information is sought -- not sure you have that; and  
14 then (3), deidentified information could not be,  
15 reasonably be used. And that is subsection F, standard  
16 disclosures for law enforcement purposes.

17 So why don't you have to follow that?

18 MR. MAYERS: Again, your Honor, I would hesitate  
19 to opine on that regulation, it's the first it's come  
20 up; I don't have it in front of me. I would also note  
21 that if Rhode Island Hospital had concerns to that  
22 effect they could have raised them in the past  
23 10 months.

24 THE COURT: Okay. All right. Go ahead.

25 MR. MAYERS: Your Honor, briefly I'll wrap up

1 and let madam court reporter...

2 THE COURT: Yes, we have some replies too from  
3 the other side, and I have questions for you too.

4 MR. MAYERS: Yes, so your Honor, I would be  
5 happy to answer those questions now.

6 THE COURT: Okay. Let me make sure I have them.  
7 I think you already answered who or what entities can  
8 be held liable for misbranding; is that correct?

9 MR. MAYERS: Yes, I have.

10 THE COURT: And you don't need -- we're agreed  
11 you don't need patient's name, Social Security number,  
12 home address to investigate billing fraud or off-label  
13 promotion or misbranding; correct?

14 MR. MAYERS: We think that that information  
15 would assist in our investigation.

16 THE COURT: I'm asking if you need it.

17 MR. MAYERS: Again, it would assist. Is it  
18 absolute every circumstance? As we've discussed we  
19 have accepted anonymized data in other cases, in other  
20 interactions requested of other subpoena recipients, so  
21 we would say that we're willing to accept that, we have  
22 been so far; that it is not -- that the information you  
23 read off is not necessarily irrelevant to our  
24 investigation.

25 THE COURT: But you agreed to not -- to forego

1 it in other cases where you made deals, I think it's  
2 Pittsburgh, Los Angeles, Maryland; I don't know.

3 MR. MAYERS: Yes, we have, and I believe  
4 Judge O'Connor said that he had reviewed other courts  
5 (indecipherable), so presumably in, for example --

6 THE COURT: When did he say he reviewed other  
7 court's orders?

8 MR. MAYERS: He said in his order on the motion  
9 for stay.

10 THE COURT: I have that somewhere. Tell me  
11 where. Okay, so it's document 12 in his case.

12 MR. MAYERS: He says on page 4, (Reading)  
13 Enforcing the instant subpoena, the Court consider  
14 RIH's long-term noncompliance with the subpoena and the  
15 arguments in opposition that have been made to other  
16 district courts.

17 THE COURT: Where is that? On page 4?

18 MR. MAYERS: This is the second full...

19 THE COURT: Second full paragraph?

20 MR. MAYERS: Yes.

21 THE COURT: Oh, okay. (Reading) The court  
22 considered Rhode Island Hospital's long-term  
23 noncompliance -- which we've agreed now isn't a hundred  
24 percent accurate.

25 MR. MAYERS: This is after Judge O'Connor

1 reviewed their submission.

2 THE COURT: -- (Reading) with the subpoena and  
3 the arguments in opposition have been made to other  
4 district courts. And he says Petition 12 -- no -- 4,  
5 ECF 1, so he just read it from Rhode Island Hospital's  
6 filing. Is that correct?

7 MR. MAYERS: I believe he might be citing to our  
8 petition there.

9 THE COURT: I see. Okay.

10 MR. MAYERS: But I will note that there is  
11 public briefing on the anonymization point that  
12 Judge O'Connor could have reviewed and considered,  
13 again.

14 THE COURT: But did you tell him that you had  
15 accepted anonymized data as part of a deal in other  
16 states and that you had -- you told us you offered it  
17 to Rhode Island Hospital; and we'll get an affidavit  
18 from Mr. Gunn, and Rhode Island Hospital is going to  
19 answer that.

20 MR. MAYERS: Again, your Honor, just to clarify,  
21 I have said that to the best of my recollection that  
22 offer was made. I cannot confirm what Mr. Gunn will  
23 say. I cannot confirm that --

24 THE COURT: No, I'm not holding you to that.  
25 You weren't there.

1 MR. MAYERS: And I don't want to hold - I can't  
2 hold Mr. Gunn to that either.

3 THE COURT: Well, he's going to file an  
4 affidavit under oath saying one way or the other;  
5 right?

6 MR. MAYERS: That's what we have discussed.

7 THE COURT: That's what I ordered.

8 MR. MAYERS: Yes, please, your Honor.

9 THE COURT: Okay. Go ahead.

10 MR. MAYERS: I can't remember exactly the  
11 question I was answering. My point is there is public  
12 briefing on this anonymization point that  
13 Judge O'Connor had accessible to him when reviewing our  
14 petition.

15 THE COURT: Okay. Go ahead. Did you have  
16 anything else you wanted to say with respect to that?

17 So we've already gone over the fact that you  
18 didn't inform the Texas court that you had been in  
19 ongoing negotiations with Rhode Island Hospital. You  
20 told them that the last communication was February,  
21 which wasn't accurate.

22 MR. MAYERS: The last such communication.

23 THE COURT: If Ms. Hsiao is going to hang her  
24 hat on that as far as representation being accurate,  
25 I'm not hopeful for her chances.

1 But you didn't inform them that it was still  
2 ongoing up like that day and the day before. Why not?

3 MR. MAYERS: I can't speak to why that decision  
4 was made or not. I don't think that that decision was  
5 necessarily or that those communications are relevant  
6 to the standard in front of the court.

7 Ultimately we got one document, six pages, over  
8 10 months.

9 THE COURT: But doesn't it go to due process,  
10 whether they were afforded due process in Texas?

11 MR. MAYERS: Your Honor, as we've discussed, the  
12 ability for Rhode Island Hospital to appear and move  
13 for reconsideration, which they forewent, we think that  
14 satisfies due process. Again, they were heard on their  
15 arguments.

16 THE COURT: We're going to hear them about  
17 whether they --. They weren't heard on their  
18 arguments; they were heard on their arguments with  
19 respect to the motion to stay.

20 Now, so you're saying that post hoc notice to  
21 Rhode Island Hospital satisfies due process? That's  
22 Government's argument?

23 MR. MAYERS: Yes. The ability to appear and  
24 move for reconsideration we think here, as in 1782  
25 cases we cite discussed, we think that ability for

1 Rhode Island to show up pre the date on the  
2 miscellaneous calendar and makes their arguments, that  
3 opportunity, which they forewent, satisfies due  
4 process.

5 THE COURT: Well, I don't think they forewent it  
6 forever. Do you?

7 MR. MAYERS: They have not moved for  
8 reconsideration, your Honor, as far as I'm aware.

9 THE COURT: So Rhode Island Hospital is  
10 challenging the subpoena here and saying it needs to be  
11 quashed, and it's clear that they didn't know you were  
12 filing in Northern District of Texas and would have no  
13 reason -- there's 94 Districts in the United States so  
14 would be no reason for them to assume there was filing  
15 in the Northern District of Texas. Can we at least  
16 agree on that?

17 MR. MAYERS: Yes.

18 THE COURT: Okay. Good.

19 So the collateral attack doctrine is similar to  
20 *res judicata*; right? Isn't that essentially what it  
21 is?

22 MR. MAYERS: Yes, there's the Sixth Circuit  
23 case -- I'm sorry, that Child Advocate cited which  
24 relies on *res judicata*.

25 THE COURT: Okay. But that's what it is



1 essentially; right? It's saying issue preclusion, you  
2 can't come here and attack in a different court an  
3 order of a separate court where you are a party in that  
4 case; correct?

5 MR. MAYERS: Litigated and (indecipherable) the  
6 decision on the merits, et cetera, yes.

7 THE COURT: I'm sorry, say that again.

8 MR. MAYERS: Yes, yes, where it was litigated  
9 and there was a decision on the merits, which there was  
10 here.

11 THE COURT: Correct. So that's what you're  
12 arguing.

13 MR. MAYERS: Yes, with respect to that doctrine  
14 that is what we are arguing here. And as your Honor  
15 and I discussed earlier, the response is that because  
16 Rhode Island Hospital did not appear before  
17 Judge O'Connor entered the order, that affects and  
18 nullifies the application of the collateral attack  
19 doctrine, to which we responded; it's not because they  
20 had the responsibility to come in and litigate via a  
21 motion for reconsideration.

22 THE COURT: But the Child Advocate didn't -- oh,  
23 that gets me to two other things: (1) are there  
24 similar cases that you know of other than class  
25 actions, which are obviously not similar here, where

1 nonparties to prior litigation will be precluded from  
2 challenging the consequences flowing from that  
3 litigation? And I will give you the example of  
4 *Martin v. Wilks* where the Supreme Court allowed  
5 nonparties to a court-ordered consent decree to  
6 challenge the employment decisions made pursuant to  
7 that decree.

8 MR. MAYERS: Your Honor, I acknowledge *Wilks*;  
9 however, I would point the Court to *Taylor v. Sturgell*  
10 which does seem to suggest that adequate  
11 representation, that doctrine could apply beyond the  
12 context of that class action.

13 THE COURT: Right. I mean like in a consent  
14 decree, right, that's what *Wilks* was, it was a consent  
15 decree; and the court said no, you can't be bound by a  
16 consent decree that you weren't a party to; right?

17 MR. MAYERS: Yes, I believe that is the holding  
18 in *Wilks*.

19 THE COURT: Okay. All right. Good.

20 Now, how do you propose that Rhode Island  
21 Hospital decide who was in DCYF care, and who wasn't  
22 during what relevant period. How are you defining DCYF  
23 care in order to -- if I made a finding that just the  
24 Child Advocate has that, wouldn't the Child Advocate's  
25 argument and Rhode Island Hospital's argument that but

1 it necessitates Rhode Island Hospital identifying their  
2 patients and their clients and their client's medical  
3 records to separate them out.

4 MR. MAYERS: Yes.

5 THE COURT: Okay.

6 MR. MAYERS: The Child Advocate has appeared, in  
7 the Declaration says that there are some, you know,  
8 patients in DCYF custody, --

9 THE COURT: Uh'huh.

10 MR. MAYERS: -- so we would propose that she  
11 would provide that list to the hospital.

12 THE COURT: She cannot provide that list to  
13 you --

14 MR. MAYERS: I'm not saying --

15 THE COURT: -- or to the hospital. When were  
16 they in DCYF custody? You have a six-plus year span of  
17 your subpoena. Are you saying anybody who was in DCYF  
18 custody for any time? Is there a relevant time? Are  
19 you -- is there a relevant determination? People go in  
20 and out of the care, children who are vulnerable  
21 because of either parental neglect or parental abuse or  
22 mental health problems that their parents can't handle  
23 go in and out of State care.

24 How do you propose -- it's your subpoena -- that  
25 we separate it out?

1 MR. MAYERS: Your Honor, we would propose that  
2 it is those children currently in DCYF custody --

3 THE COURT: Today?

4 MR. MAYERS: -- or those that the Child Advocate  
5 has standing to represent. That is our understanding  
6 of Rhode Island law.

7 THE COURT: She can represent people for  
8 issues -- so if they were in DCYF February of 2022, she  
9 can represent them with respect to informational  
10 privacy for that time period; right?

11 MR. MAYERS: Your Honor, it is my understanding  
12 of Rhode Island law that she represents those currently  
13 in DCYF custody. Now, if your Honor concludes that the  
14 quashal order -- of course we don't agree it should be  
15 quashal -- but if your Honor reaches that point and  
16 concludes that the scope of relief that your Honor can  
17 provide is quashal for DCYF and those in DCYF custody  
18 currently or those covered by DCYF, or if there's a  
19 question, for example, if we maintain it's custody  
20 currently, Child Advocate puts forth Rhode Island law  
21 that says it applies --

22 THE COURT: You're not deciding this; I am,  
23 right?

24 MR. MAYERS: Yes, your Honor. That's what I'm  
25 proposing. So if that was your Honor's conclusion,

1 that it was a, you know, quashal tie to those in DCYF  
2 custody, we would be happy to consider any Rhode Island  
3 authority that says the Child Advocate has standing to  
4 represent both those currently in custody and those who  
5 were. If that is what Rhode Island law says, if Rhode  
6 Island law provides --

7 THE COURT: What if I just say it.

8 MR. MAYERS: Your Honor, if Rhode Island law, if  
9 that's what Rhode Island law says...

10 THE COURT: Ms. Medeiros is here and can  
11 probably answer that question if I put her on the spot.

12 MR. MAYERS: And again, if that's what Rhode  
13 Island law says, and we'd agree it's not an  
14 Article III, but that's what the Child Advocate has  
15 standing to represent. So it's a question of Rhode  
16 Island law that, you know, we'd be happy to look at it  
17 if that's your Honor's conclusion.

18 THE COURT: And how are you going to separate  
19 out those children? And don't say give us a list.

20 MR. MAYERS: Your Honor, I think that is a -- we  
21 will, we will allow Rhode Island Hospital to make that  
22 decision. We will take them on their word that they  
23 applied your Honor's order in line with those terms.

24 THE COURT: Okay.

25 Does anybody want to be heard.

1 MR. LOVE HUBBARD: Yes, your Honor.

2 (Judge confers with Court Reporter).

3 THE COURT: Today, or tomorrow morning?

4 MR. LOVE HUBBARD: Your Honor, I think I need  
5 three minutes.

6 MR. MAYERS: About the same, your Honor.

7 (Judge confers with Court Reporter)

8 THE COURT: We're still taking a break, about  
9 five minutes.

10 (Recess)

11 THE COURT: All right.

12 MR. OLSHAN: Yes, your Honor. I believe I'll go  
13 first and then Mr. Hubbard will follow me, and I will  
14 be brief in the interest of time because it's very real  
15 for Rhode Island Hospital. The Fifth Circuit has now  
16 denied our request for a stay and we would ask the  
17 Court, if the Court is inclined, to quash the subpoena  
18 both as to the request from the Child Advocate, but on  
19 behalf of Rhode Island Hospital in full.

20 I think today's argument has made clear that the  
21 basis for the issuance of the subpoena, the statutory  
22 basis as well as the indicia of improper purpose and  
23 bad faith is sufficient for this Court to conclude,  
24 similar to other courts around the country, that this  
25 subpoena should be quashed in full.

1           We'd also ask the Court to order, if the Court  
2           is inclined on the record today, that the Government be  
3           enjoined from seeking to collect, receive -- whichever  
4           verb the Court chooses -- records that are responsive  
5           to the subpoena issued to Rhode Island Hospital last  
6           July and that Rhode Island Hospital is similarly  
7           enjoined from producing to such responsive to the  
8           subpoena.

9           I would note and I'd ask the Court, if the Court  
10          is inclined, to inquire of the government the proposed  
11          order that the Government submitted to Judge O'Connor  
12          that Judge O'Connor signed on April 30th, the second  
13          paragraph says that, Failure to fully comply with the  
14          subpoena or show just cause for continued noncompliance  
15          may result in sanctions up to and including this court  
16          holding at witness in contempt.

17          Those are the sanctions that Rhode Island  
18          Hospital is facing. I'd ask the Court to confirm with  
19          the Government that it is "just cause" for Rhode Island  
20          Hospital to not produce records if there is a court  
21          order issued by this Court prohibiting that and  
22          quashing the subpoena.

23                 MR. MAYERS: Okay. Why don't you answer that  
24                 now on the record, Government.

25                 MR. CAMPBELL: What's the question, your Honor?

1 If you could just restate it.

2 THE COURT: If I issue an order enjoining the  
3 Government from receiving the records and enjoining  
4 Rhode Island Hospital from producing the records, is  
5 that just cause for Rhode Island Hospital not complying  
6 with the Texas order?

7 MR. CAMPBELL: I think that determination would  
8 be made by Judge O'Connor in Texas and --

9 THE COURT: Well, are you going to be seeking to  
10 hold Rhode Island Hospital in contempt?

11 MR. CAMPBELL: We fully intend to comply with  
12 whatever order this Court issues.

13 THE COURT: Okay.

14 MR. OLSHAN: I understand Government counsel to  
15 be saying, your Honor, if this Court enters an order  
16 prohibiting the Government from seeking to enforce the  
17 subpoena further or collecting responsive records to  
18 the subpoena, that the Government will abide by that  
19 order, just as Rhode Island Hospital will comply with  
20 any order that prohibits our production of those  
21 records responsive to the subpoena.

22 THE COURT: That's what I understood the  
23 Government to be saying, as well.

24 MR. CAMPBELL: Just to be clear and for the  
25 record, your Honor, the Government will follow whatever



1 order this Court issues and potentially appeal it if  
2 the Government determines so. I will simply note for  
3 the record that the current action before the Court is  
4 a Miscellaneous Action on a motion to quash. We don't  
5 necessarily agree that the Government or -- excuse  
6 me -- that the Court can enjoin the parties in this  
7 context. The relief before the Court is whether to  
8 grant the motion to quash.

9 THE COURT: The Child Advocate asked for  
10 injunction.

11 MR. CAMPBELL: She asked for it in their  
12 papers --

13 (Court Reporter requests clarification)

14 THE COURT: You need to come to the podium.

15 (To Mr. Olshan) You can stay there because he's  
16 only going to be a minute, at most.

17 MR. CAMPBELL: Certainly, your Honor. I'm  
18 simply noting for the record that the Government  
19 believes that an injunction issued in connection with a  
20 Miscellaneous Action that is a motion to quash is  
21 outside the scope of the relief that should be afforded  
22 the proper vehicle --

23 THE COURT: Do you have any citations?

24 MR. CAMPBELL: The proper vehicle would have  
25 been a civil action seeking an injunction.

1 THE COURT: Okay. You can be seated.

2 MR. OLSHAN: Your Honor, a few more points. I  
3 did just want to put on the record that at no time in  
4 our conversations with the Government was an offer made  
5 to accept deidentified records like it has been asked  
6 to others. And I would note the question of patient  
7 identities is not just something that implicates  
8 Requests 11 through 13 or 15. It implicates multiple  
9 additional requests. For example, Request 2 deals with  
10 billing records. That's going to have information  
11 about patients. Request 3 deals with all documents  
12 relating to the use of diagnosis codes.

13 THE COURT: So the Government's representations  
14 that they made that offer to Rhode Island Hospital is  
15 inaccurate.

16 MR. OLSHAN: Correct.

17 THE COURT: And so Mr. Gunn will get us an  
18 affidavit today or by 9:00 tomorrow Eastern time, that  
19 whether he did or didn't and to whom he made that; and  
20 if he didn't, then that leaves this Court with a  
21 question about what was told to the judge in Texas, and  
22 I think that, you know, there's been ample evidence  
23 that the judge in Texas was not given all of the  
24 relevant information. Go ahead.

25 MR. OLSHAN: Thank you, your Honor.

1           With respect to the analysis on venue, there's  
2           important information that appears to have just been  
3           made public in this hearing, which is that I believe  
4           Government counsel said that there were discussions or  
5           communications that started in mid March with the  
6           Northern District of Texas and that there was -- they  
7           are working in, quote, collaboration with the Northern  
8           District of Texas.

9           The *Cooper Tire* case from the District of  
10          Columbia circuit that deals with these factors relevant  
11          to where something is being carried on that talks about  
12          the hub, et cetera, the eight factors that Mr. Hubbard  
13          mentioned, Love Hubbard; excuse me.

14          Our view is based on that additional  
15          information; it underscores the lack of an appropriate  
16          venue in the Northern District of Texas.

17          I'll also confirm for the Court that there were  
18          no facts put in front of the court there. It was just a  
19          reference in one line in the petition or motion to  
20          compel that said under 3486(c) the investigation is  
21          being carried on. The Hsiao Declaration did not speak  
22          to that. Only subsequently did they provide something.  
23          The Court has I believe ordered the Government to  
24          provided a redacted copy of that to the parties.

25          THE COURT: Right. And I'd like that done

1 before tomorrow morning, and you can redact only that  
2 which is confidential law enforcement privilege.

3 MR. OLSHAN: I do want to just highlight that  
4 the discussion the Government had with Government  
5 counsel about the FDCA theory was all over the place.

6 THE COURT: Uh'huh.

7 MR. OLSHAN: There was discussion about  
8 endocrine disorder and gender dysphoria, billing  
9 coding, there was discussion about promoters. I do  
10 want to highlight for the Court the *Gleason* case that  
11 my colleague referenced is 576 F.Supp. 2nd 385, it's  
12 *U.S. v. Caronia*, C-o-r-o-n-i-a (verbatim). The doctor  
13 in that case, I believe that's Dr. Gleason, was  
14 essentially a paid sales rep, as we can glean from, of  
15 the manufacturer. This is not a case that was about  
16 the prescribing practices of any doctor. It was  
17 basically a doctor who was acting as a sales rep to  
18 promote off-label to maybe other doctors or other  
19 entities. So we would argue that that's  
20 distinguishable.

21 And as to the point about the opportunity to  
22 reconsider an order that we were never able to be heard  
23 on in the first instance as a valid basis for this  
24 Court not to invoke the collateral attack doctrine, we  
25 disagree with. Getting a judge to revisit a decision

1 that was made without due process cannot be the same  
2 thing as getting a judge to consider it in the first  
3 instance.

4 THE COURT: And, in fact, there's federal rules  
5 that sort of speak to what a court can and cannot  
6 reconsider; correct?

7 MR. OLSHAN: That's correct.

8 THE COURT: Okay. Go ahead.

9 MR. OLSHAN: Your Honor, I think those are the  
10 few points I wanted to make just again to stress given  
11 where things are in the court's order that has not been  
12 stayed, obviously Rhode Island Hospital requests as  
13 soon as this Court is able to make a reasoned,  
14 determined, excuse me, a decision, we would ask the  
15 Court to act, quash the subpoena in full and enjoin the  
16 parties in the way that we described a few minutes ago.  
17 Thank you.

18 THE COURT: Thank you.

19 Mr. Love Hubbard.

20 MR. LOVE HUBBARD: Thank you, your Honor.

21 Very briefly, the Government's argument with  
22 respect to the Child Advocate and the collateral attack  
23 doctrine was, I think I heard him say that the patients  
24 are somehow in privity with the hospital and/or that  
25 they were adequately represented.

1 THE COURT: I think he abandoned that later and  
2 said essentially that it's not the same argument as the  
3 Hospital with respect to the collateral attack and  
4 Child Advocate.

5 MR. LOVE HUBBARD: Just to be clear, the court  
6 in the Northern District of Texas said, "Rhode Island  
7 Hospital cannot show how it" in italics "would be  
8 harmed, rather than its patients, who are third  
9 parties."

10 So very basis for the court's order in Texas was  
11 that the patients were not present there and that their  
12 interests were not considered and so --

13 THE COURT: And so the record is abundantly  
14 clear, they weren't notified.

15 MR. LOVE HUBBARD: Correct. And about notice,  
16 your Honor, one point on that. I found out about this  
17 order because the Department of Justice issued a press  
18 release on May 1st publicizing it before it was served  
19 on Rhode Island Hospital, which they say happened the  
20 following Monday. So when we consider that, with all  
21 of the other things that we've talked about, improper  
22 purpose, I think what I want to end with is that enough  
23 is enough. The Government's investigative power is  
24 massive, and it depends on good faith actors acting in  
25 good faith to accomplish legitimate law enforcement

1 purposes.

2 I think the record is clear here that that is  
3 not what happened, and so when you're having a  
4 conversation with them about narrowing scope or  
5 deidentifying data, on the deidentifying point I'll  
6 note that the UPMC Court specifically rejected the  
7 offer to receive anonymized data which the DOJ made  
8 there, again, only in response to the motion to quash;  
9 and the court said no, you don't get the benefit of a  
10 normal procedure when you don't follow that normal  
11 procedure. And I think that's what the Court should do  
12 here. The Government is going to continue to press  
13 these investigations unless the Court stops it.

14 THE COURT: Okay. I think you indicated that  
15 NYU had received a subpoena from a grand jury in the  
16 Northern District of Texas, and that's the press  
17 release that was issued today? Yesterday?

18 MR. LOVE HUBBARD: Late last night, I believe.

19 THE COURT: Okay. So clearly if that's the case  
20 there's a grand jury in the Northern District of Texas  
21 and that's not a secret anymore; correct?

22 MR. LOVE HUBBARD: Yes, your Honor.

23 THE COURT: So I'm going to order the Government  
24 to provide also notice to this Court about when, which  
25 specific date that was convened.

1 MR. LOVE HUBBARD: And just --

2 THE COURT: For purposes of this case.

3 MR. LOVE HUBBARD: For the purposes of  
4 jurisdiction as well.

5 THE COURT: Correct.

6 MR. LOVE HUBBARD: I think there's some gliding  
7 on their part; they're saying nationwide investigation.  
8 It can't be the basis for an enforcement action against  
9 Rhode Island Hospital for them to have a nationwide  
10 investigation into these generalized practices. And  
11 really what it comes down to, when you try and hear  
12 them articulate a proper FDCA theory, they don't  
13 gender-affirming is legitimate.

14 THE COURT: Right.

15 MR. LOVE HUBBARD: They don't get to make that  
16 decision.

17 THE COURT: Correct. This is not policy and I  
18 think that that's where, you know, and mean I know  
19 you're very familiar with the Department of Justice and  
20 how it operates, and we have always had a usual course  
21 with the Department of Justice where we can rely on  
22 what was presented to the Court; but this is the second  
23 time now that a party has found out by a press release  
24 the status of their case. And was it the DOJ that  
25 issued the press release?



1 MR. LOVE HUBBARD: Yes, your Honor.

2 THE COURT: In the other case I believe it was  
3 HHS. But it's, you know, sort of not the ordinary  
4 course and that's why I say, you know, they should be  
5 prepared to field thousands of motions to quash, tens  
6 of thousands maybe, because I don't know how any party  
7 can rely on a conversation with the Department of  
8 Justice that they're working on compliance, given the  
9 tract of this case. And I so mean I'm not a  
10 practitioner, but as a judge I would say to anybody you  
11 should be filing motions to quash in every case where  
12 the Department of Justice is seeking information and  
13 you're trying to negotiate it, and then they can  
14 respond. It's unfortunate that the process comes down  
15 to this level of adversarial process.

16 MR. LOVE HUBBARD: And just to --

17 THE COURT: It never was, but...

18 MR. LOVE HUBBARD: Just to emphasize, your  
19 Honor, that's exactly what happened here.

20 THE COURT: Yeah.

21 MR. LOVE HUBBARD: I found about the subpoena  
22 and had a motion filed within 49 hours.

23 THE COURT: Yup.

24 MR. LOVE HUBBARD: And we did everything in our  
25 power to prevent this from happening as soon as it

1 became -- as soon as we had notice of it.

2 THE COURT: I understand that. I'm just saying  
3 it's a cautionary tale.

4 MR. LOVE HUBBARD: Absolutely. Thank you, your  
5 Honor.

6 THE COURT: Okay. Is there anything further  
7 from any party?

8 Just so that we're clear, I want the Government  
9 to provide the sealed document to the parties on the  
10 other side. That should be done before tomorrow  
11 morning at 9:00. Mr. Gunn's affidavit under oath,  
12 filed and given to the parties by 9:00 tomorrow morning  
13 about the discussions that you represent to the Court  
14 were had with anonymized data with Rhode Island  
15 Hospital, and Rhode Island Hospital has now disputed  
16 that, so I want an affidavit under oath from somebody  
17 who can testify, if need be; and if it's not Mr. Gunn  
18 then find the person who it is. And then the third  
19 thing is notice of when the grand jury began the  
20 investigation, when they first sat on this case in the  
21 Northern District of Texas. And I don't mean when you  
22 decided among you to take it to the Northern District  
23 of Texas. I mean when did the first witness appear  
24 before the grand jury in the Northern District of  
25 Texas.

1           Is there anything else?

2           MR. OLSHAN: Not for Rhode Island Hospital.

3       Thank you.

4           THE COURT: Okay. All right. We're in recess.

5           (Adjourned)

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C E R T I F I C A T I O N

I, Denise P. Veitch, RPR, do hereby certify  
that the foregoing pages are a true and accurate  
transcription of my stenographic notes in the  
above-entitled case.

/s/ Denise P. Veitch  
Denise P. Veitch, RPR  
Federal Official Court Reporter

May 17, 2026  
Date