No. 26-1568

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

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

CHILD ADVOCATE FOR RHODE ISLAND, et al.,
Petitioners-Appellees

v.

UNITED STATES OF AMERICA,
Respondent-Appellant

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

BRIEF FOR THE APPELLEE THE CHILD ADVOCATE FOR THE STATE OF RHODE ISLAND

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, Appellee the Child Advocate for the State of Rhode Island hereby makes the following disclosures:

The Child Advocate for the State of Rhode Island is appointed by the Governor of Rhode Island and confirmed by the state Senate. The Office of the Child Advocate is a state agency. No publicly held corporation owns 10% or more of its stock.

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STATEMENT IN SUPPORT OF ORAL ARGUMENT

This appeal presents important issues relating to the limits of the federal government's authority to subpoena information from health care providers under the Federal Food, Drug, and Cosmetic Act; the federal government's intrusion into states' authority to regulate the practice of medicine; and the illegitimate purposes behind the government's subpoenas to gender-affirming care providers. Appellee the Child Advocate for the State of Rhode Island respectfully requests that the Court schedule oral argument.

STATEMENT OF JURISDICTION

Appellee agrees with the jurisdictional statement in appellant's brief.

STATEMENT OF THE ISSUES

1. Whether the District Court correctly exercised jurisdiction over a motion to quash a subpoena brought by an entity that was not a party to, nor represented by any party in, a previous proceeding to enforce the subpoena in the Northern District of Texas?

2. Whether the District Court abused its discretion when it quashed a subpoena (1) that lacked a congressionally authorized purpose, (2) where the materials requested were not relevant to those purposes in any event, and (3) where the District Court did not clearly err in determining that the subpoena was issued in bad faith?

3. Whether the District Court's decision should be affirmed on the independent basis that enforcement of the subpoena would intrude on the privacy of children seeking medical treatment for gender dysphoria?

4. Whether the District Court abused its discretion when it quashed the entirety of the subpoena and enjoined the government from accessing protected health information obtained from the subpoena?

STATEMENT OF THE CASE

A. Medical Care for Gender Dysphoria is Medically Necessary and Legally Protected in Rhode Island

Gender-affirming care refers to the evidence-based provision of medical care for individuals, including minors, who experience gender dysphoria. Gender dysphoria occurs when there is a conflict between the sex a person is assigned at birth and the gender with which they identify. *United States v. Skrmetti*, 605 U.S. 495, 501–03 (2025). All major medical associations agree that the use of medications is central to the standard of care for individuals with gender dysphoria. JA16–17. As the Supreme Court recognized just last year, "[l]eft untreated, gender dysphoria may result in severe physical and psychological harms." *Skrmetti*, 605 U.S. at 503. Gender-affirming care can take various forms, including puberty suppressants or hormone therapy, depending on the need of the individual patient. JA17. Medical care is thus a "vital lifeline" for individuals with gender dysphoria, who without

treatment may experience severe distress, anxiety, depression, and suicidal ideation. JA17–18.

Reflecting this widespread medical consensus, Rhode Island law provides explicit guarantees of a patient's ability to receive medical care for gender dysphoria, including in R.I. Gen. Laws § 23-101, the Healthcare Provider Shield Law. That law defines "Legally protected healthcare activity" in Rhode Island to include "gender-affirming healthcare services." R.I. Gen. Laws § 23-101-2. The Healthcare Provider Shield Law was enacted 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. *See* R.I. Gen. Laws § 23-101-5(b) (creating a cause of action for any recipient of a subpoena seeking information regarding protected healthcare activity).

B. The Trump-Vance Administration's Actions to End Gender-Affirming Care

The Trump-Vance administration has made it a mission to eradicate all gender-affirming care. On the day of his inauguration for his second term, President Trump issued Executive Order 14168, "Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government," which declared that the United States "recognize[s] two sexes, male and female[, and t]hese sexes are not changeable and are grounded in fundamental and incontrovertible

reality." JA15 n.1. Soon after taking office, President Trump issued Executive Order 14187, "Protecting Children from Chemical and Surgical Mutilation," to suppress the medical treatment of individuals who require gender-affirming care. JA21 n.11. That Executive Order equated "gender affirming care" with "chemical and surgical mutilation" and 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." *Id.* The Order went on to declare that "[t]his dangerous trend will be a stain on our Nation's history, and it must end." *Id.* Executive Order 14187 spurred a full-throttle attack on gender-affirming care, directing the Attorney General to prioritize investigations related to such care. *Id.* § 8.

Following the President's marching orders, on April 22, 2025, then-Attorney General Pam Bondi issued a memorandum to Department of Justice leadership titled "Preventing the Mutilation of American Children."[1] 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." *Id.* It also directed the Department of Justice (DOJ) to investigate healthcare providers offering medical care for gender

[1] *Memorandum from Attorney General, Preventing the Mutilation of American Children*, Office of the Attorney General, at 3–4 (April 22, 2025) (hereinafter "Bondi Memo"), https://tinyurl.com/2b9kaja7 (last visited July 15, 2026).

dysphoria, purportedly for alleged violations under the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.*, and the False Claims Act (FCA), 31 U.S.C. § 3729 *et seq. Id.* Bondi concluded the memo with the Department's mission in conducting these investigations: "bring[ing] [gender-affirming care] practices to an end." *Id.*

Following the Attorney General's directive, 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.[2] The memorandum explicitly referenced the Attorney General's directive to "hold accountable those who mutilate [children] under the guise of care." *Id.*

C. DOJ's Attacks on Gender-Affirming Care Providers

Department officials wasted no time in acting. In July 2025, DOJ announced that it had "sent more than 20 subpoenas to doctors and clinics involved in performing transgender medical procedures on children." JA23 n.23. DOJ's focus on direct providers of gender-affirming care, rather than pharmaceutical manufacturers or distributors who actually market drugs used by those providers,

[2] *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 "Shumate Memo"), https://tinyurl.com/mr3bym4f (last visited July 15, 2026).

demonstrates that DOJ's strategy is to coerce and frighten providers into abandoning treatment for gender dysphoria. Indeed, as a result of DOJ's ongoing efforts to end gender-affirming care, eighteen hospitals have already significantly curtailed their medical care for gender dysphoria programs—a result about which the White House has boasted. JA24 n.26. DOJ has announced settlements with at least two providers as a result of its investigations.[3] Both providers entered agreements that require them to cease providing gender-affirming medical care for up to twenty years and provide "detransition" services in its place.[4] A DOJ supervisor of these investigations further touted the administration's efforts to end gender-affirming care altogether, responding to a comment that "there's a very good chance [medical care for gender dysphoria] will stop even in blue states" by stating that DOJ was "[w]orking on it." JA24 n.27.

RIH was one of many providers that received an administrative subpoena from DOJ under Section 248 of the Health Insurance Portability & Accountability

[3] U.S. Dep't of Just., Off. of Pub. Affairs, *Justice Department Secures Resolution with Cleveland Clinic to End Pediatric "Gender-Affirming Care"* (June 5, 2026), https://perma.cc/Z9XW-4NQT; U.S. Dep't of Just., Off. of Pub. Affairs, *Justice Department Secures Landmark Resolution to End Pediatric "Gender-Affirming Care" and Create Detransition Clinic* (May 15, 2026), https://perma.cc/3YSZ-6XXU.

[4] *Supra* n.3; *See also* Settlement Agreement between Cleveland Clinic Foundation, the U.S. Dep't of Just., and the Ohio Att'y Gen. Off., at ¶ III.7(a), https://perma.cc/YR9Z-VTPT ("CCF agrees to not provide Sex-Reject Procedures"); *id.* at ¶ III.24 ("The Parties agree that CCF's obligations under Paragraphs III.7(a) . . . will persist for twenty (20) years from the Effective Date of this Agreement").

Act of 1996 (HIPAA), Public Law No. 104-191, 18 U.S.C. § 3486. JA60. DOJ's authority to issue a Section 3486 subpoena (sometimes called a HIPAA subpoena) is limited to investigations of alleged violations of the healthcare offenses specified in 18 U.S.C. § 24—and, as particularly relevant here, section 301 of the FDCA, 21 U.S.C. § 331, which prohibits misbranding of drugs in interstate commerce. JA88 ¶ 5; *see also In re Subpoena No. 251431-014 (CHOP)*, 810 F. Supp. 3d 555, 569 & n.56 (E.D. Pa. 2025).[5] The FDCA concerns "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 them." *CHOP*, 810 F. Supp. 3d at 579. Nor does the FDCA govern violations of the FCA. *See infra* p. 25.

As with the other subpoena recipients, the government demanded that RIH provide a vast amount of information about the individual children it treated, information which has no apparent connection to any possible FDCA violation. JA60–67. The information sought about the children included their names, dates of birth, Social Security numbers, addresses, diagnoses, clinical histories, and familial information. *Id.* In addition to requiring information about every minor patient who received medical care for gender dysphoria at RIH over more than five years, the

[5] Even then, a Section 3486 subpoena may be issued to investigate a violation of the FDCA only if the possible violation "relates to a health care benefit program[,]"—that is, public or private health insurance. 18 U.S.C. § 24(a)(2), (b); JA88 ¶ 5.

subpoena demands medical records that contain some of the most private and intimate details about these minors, including mental health struggles, sexual development, and trauma histories. JA66–68.

D. DOJ's Enforcement of the Subpoena on Rhode Island Hospital in a Venue with Which the Hospital Had No Connection

In the months after DOJ's issuance of a subpoena on RIH, other hospitals began challenging the almost-identical subpoenas that DOJ had issued to them—and they were succeeding. Before DOJ sought to enforce its subpoena on RIH, at least six different district courts had quashed materially identical subpoenas, and none had ruled in DOJ's favor.[6] Having lost before every court that had reviewed the subpoenas, DOJ soon switched its strategy. After several months of negotiations and active engagement with RIH on the proper search terms and parameters, DOJ abruptly ceased communicating with RIH in February 2026. JA238–39. DOJ reinitiated contact with RIH on April 28, 2026, and requested that the parties conference "this week" about RIH's next production. JA200–01.

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[6] *In re Admin. Subpoena No. 25-1431-019 (Boston Children's)*, 800 F. Supp. 3d 229 (D. Mass. 2025), *appeal pending*, No. 26-1093 (1st Cir.); *QueerDoc, PLLC v. U.S. Dep't of Just.*, 807 F. Supp. 3d 1295 (W.D. Wash. 2025), *appeal pending*, No. 25-7384 (9th Cir.) (argued and submitted March 19, 2026); *CHOP*, 810 F. Supp. 3d at 607; *In re 2025 UPMC Subpoena (UPMC)*, No. 2:25-MC-01069-CB, 2025 WL 3724705 (W.D. Pa. Dec. 24, 2025), *judgment entered*, 2026 WL 570419 (W.D. Pa. Mar. 2, 2026); *In re Children's Nat'l Hosp. (Children's Nat'l)*, No. 1:25-cv-03780, 2026 WL 160792 (D. Md. Jan. 21, 2026); R&R, *In re Dep't of Just. Admin. Subpoena No. 25-1431-030 (Children's Hosp. Colo.)*, No. 25-mc-00063-SKC-CYC, 2026 WL 33398 (D. Colo. Jan. 5, 2026).

Instead of conferencing with RIH, however, DOJ filed an unannounced enforcement action in the Northern District of Texas, Fort Worth Division on April 30, 2026. *In the Matter of Administrative Subpoena No. 25-1431-032*, No. 4:26-mc-00006-O, JA156 (N.D. Tex. 2026). To its petition, DOJ attached a declaration from the Acting Director of the Enforcement & Affirmative Litigation Branch of DOJ Civil, Lisa K. Hsiao. *Id.*, JA87–105. Aside from "15 pages of her assertions of what the law is," *Children's Nat'l*, 2026 WL 160792, at *7, Hsiao claimed that DOJ issued the subpoena to investigate "fraudulent billing practices," the off-label prescribing and promotion of medications, and the failure of providers to "supply adequate labeling" to patients. JA99–100, 103. She further alleged RIH's use of certain diagnostic codes "raised questions" about its provision of medical care. JA100–01.

The court overseeing the administrative subpoena enforcement action granted the petition on the same day, without notice to, or a response from, RIH. JA169–70. The order commanded that RIH provide all records responsive to the subpoena by May 14, 2026, and warned that failure to do so or to show just cause for noncompliance could result in sanctions. *Id.* On May 10, 2026, the Texas court denied RIH's motion to stay, JA308, and on May 12, 2026, the Fifth Circuit denied RIH's motion to stay. *See United States v. Rhode Island Hospital*, No. 26-10431 (5th Cir. May 12, 2026).

E. The Child Advocate's Motion to Quash

On May 4, 2026, the Child Advocate for the State of Rhode Island ("Child Advocate") filed an Emergency Motion to Quash the subpoena in the District of Rhode Island to protect the rights of the children in her care. JA13–57. The Office of the Child Advocate was established by the Rhode Island General Assembly to serve as an independent voice for children in the care or custody of the Rhode Island Department of Children, Youth & Families. R.I. Gen. Laws § 42-73-1 *et seq*. 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 Rhode Island's protective care, custody, or receiving treatment services. R.I. Gen. Laws § 42-73-7(6). On May 11, 2026, RIH filed its own Emergency Motion to Quash in Rhode Island. JA126–55.

The District of Rhode Island held a hearing on May 12, 2026, and granted both motions to quash on May 13. Addendum to Brief for Appellant ("Add.") at 29–52. The court held 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." Add.51–52 (identifying "independent grounds for quashal of the subpoena"). The court enjoined DOJ "from seeking, receiving, using, retaining, or disseminating any patient identifying information or protected health information produced by RIH." Add.52. The next day, DOJ filed a notice of appeal. JA321–22.

On May 18, the Northern District of Texas held a status conference. *Matter of Admin. Subpoena 25-1431-032,* No. CV 4:26-mc-00006-O, 2026 WL 1408263 (N.D. Tex. May 18, 2026). After the hearing, the Texas court ordered that "RIH submit to this Court all materials that it would have turned over to the Government in compliance with [the] Court's Enforcement Order to be secured and held *in camera,* inaccessible to the Government for the pendency of the appeals" by the next day. *Id.* at *3 According to the Texas court, the Rhode Island court's order prohibited DOJ from accessing the documents at issue, "but left the Enforcement Order [of the Texas court] otherwise in effect." *Id.* at *2. On May 19, this Court denied the Child Advocate's emergency motion for an injunction pending appeal, finding no irreparable harm where submitted anonymized materials would remain *in camera* and unavailable to DOJ during the appeals. *In re Motion to Quash Admin. Subpoena to R.I. Hosp.*, 177 F.4th 21, 22 (1st Cir. 2026). The panel expressly set aside the procedural and merits questions now presented. *Id.*

SUMMARY OF ARGUMENT

The Child Advocate's motion to quash is not precluded by the Texas enforcement proceeding that DOJ abruptly initiated to avoid the quashal that seven other courts ordered after reviewing identical subpoenas. The Child Advocate was not a party to that enforcement proceeding, and its interests were not represented in that proceeding. Given the lack of identity in both actions and DOJ's blatant forum shopping, the Child Advocate was not bound by that earlier proceeding.

On the merits, the District Court did not abuse its discretion in quashing a subpoena that clearly evinced an abuse of the court's process. DOJ's subpoena could be used only to investigate violations of the FDCA, which regulates the introduction, labeling, and distribution of drugs in interstate commerce. None of DOJ's stated justifications fall within the FDCA's scope. Investigating providers for FCA or billing fraud violations is irrelevant to the FDCA. Nor can DOJ investigate providers' off-label prescribing or their communications to patients; the FDCA explicitly prohibits any interference with the practice of medicine—the regulation of which belongs to the States. That DOJ chose to request sensitive health information about adolescent patients to conduct an open-ended inquiry into potential claims against manufacturers and distributors and to investigate a potential conspiracy between providers and manufacturers, without any specific theory of liability as to either, indicates just how far DOJ is willing to speculate in its efforts to obtain information to which it has no statutory right.

The gender-affirming care subpoenas that DOJ issued were instead designed to intimidate gender-affirming care providers and end that care altogether. As courts around the country evaluating the subpoenas have uniformly found, DOJ's bad faith in this regard is clear from the administration's own public, disparaging attacks on gender-affirming providers and its promises to end gender-affirming care.

As the District Court also correctly found, any compliance with the subpoena would violate the privacy interests of children. The subpoena seeks documents that

identify minors and their families, as well as the minors' diagnoses and treatments. The sensitivity of this information, which on its own may expose children to stigma and harassment, is compounded by the administration's mission to end gender-affirming care at any cost, and DOJ's own concession that it will use the information to "locate and question both children and their caregivers." Add.50 n.12. The District Court's decision to quash the subpoena on this ground is supported by both Federal Rule of Civil Procedure 45, which permits quashal where a subpoena burdens the privacy interests of non-party patients, and the Due Process Clause of the Fifth Amendment, which protects against the disclosure of intimate information like transgender status where, like here, the government's inquiry is not reasonable.

Given the impropriety of DOJ's subpoena, the District Court correctly exercised its discretion to quash the subpoena in full. DOJ's argument that quashal should have been limited to the children whose rights the Child Advocate represents is unsupported and impractical. In any event, narrowing the quashal order is not warranted here, where the subpoena exceeds statutory authority, lacks a proper purpose, and violates privacy protections. And neither redaction nor anonymization will remediate the harm from any disclosure given the risks of hostility against patients of transgender care and the chilling effect such disclosure would have on the receipt of that care.

There was no abuse of the court's discretion to enjoin DOJ from accessing any of the subpoenaed materials. The Texas enforcement action was a blatant

exercise of forum shopping to secure a favorable outcome from a court with no connection to either RIH or its patients, including those the Child Advocate represents. And because DOJ will continue to use any and all tools to try to obtain sensitive patient information about minors, only an injunction can protect their interests.

STANDARD OF REVIEW

A district court's decision to exercise jurisdiction in instances of multiple federal court filings is reviewed for abuse of discretion. *Curtis v. Citibank, N.A.*, 226 F.3d 133, 138 (2d Cir. 2000); *see Maldonado-Cabrera v. Anglero-Alfaro*, 26 F.4th 523, 526 (1st Cir. 2022) (citing *Curtis*, 226 F.3d at 133).

The Court also reviews a district court's order quashing a subpoena for abuse of discretion and any legal analyses therein de novo. *In re Grand Jury Subpoena (Roach),* 138 F.3d 442, 444 (1st Cir. 1998). "[A]bsent a mistake of law, an appellate tribunal should disturb the district court's determination [that the government had an improper purpose in issuing a subpoena] only if it is clearly erroneous." *United States v. Gertner*, 65 F.3d 963, 970 (1st Cir. 1995). On appeal from the grant of a permanent injunction, the scope of the injunction is reviewed for an abuse of discretion, and legal issues are reviewed de novo. *Esso Standard Oil Co. v. Lopez-Freytes*, 522 F.3d 136, 142 (1st Cir. 2008). The District Court's decision may be affirmed on any ground supported by the record, even if the court did not rely on that ground. *Doe v. Anrig*, 728 F.2d 30, 32 (1st Cir. 1984).

ARGUMENT

I. THE CHILD ADVOCATE'S REQUEST FOR QUASHAL WAS NOT A COLLATERAL ATTACK ON THE TEXAS COURT'S ORDER

DOJ's lead argument is that the Child Advocate's motion to quash was a collateral attack on the Northern District of Texas proceedings and that the District Court's quashal order disrespected "[b]asic principles of comity." Gov't Br. 18–19, 20. In making this argument, DOJ ignores the fundamental principle that a court in a later-filed proceeding must yield to the court where a related action was first filed only where the "actions involve[] the same parties and similar subject matter." *TPM Holdings, Inc. v. Intra-Gold Indus., Inc.*, 91 F.3d 1, 4 (1st Cir. 1996). The Child Advocate and affected children were not parties in Texas, which DOJ acknowledges, Gov't Br. 24, and received no notice before judgment. *See also Taylor v. Sturgell*, 553 U.S. 880, 884 (2008) ("[O]ne is not bound by a judgment in personam in a litigation in which he is not designated as a party or to which he has not been made a party by service of process." (quoting *Hansberry v. Lee*, 311 U.S. 32, 40 (1940))).

Contrary to DOJ's argument, the Child Advocate's interests were not represented in the Texas proceedings. Gov't Br. 24–25. The Child Advocate, which represents the children in Rhode Island protective care, has statutorily defined interests in protecting those children's privacy and sensitive personal information. R.I. Gen. Laws §§ 42-73-1, 42-73-7. As the Northern District of Texas acknowledged, RIH's interests are distinct from those of the patients it treats—

patients that the Texas court acknowledged "would be harmed." JA316. Unlike the Child Advocate, RIH does not serve as a fiduciary for those patients. Given that difference, neither the Child Advocate nor the children whose interests she represents were "adequately represented by someone with the same interests" in the Texas proceeding. *Taylor*, 553 U.S. at 894 (citation omitted). Nonparty-preclusion principles therefore do not bind the Child Advocate to the Texas judgment.

The cases that DOJ relies on are inapposite because there, unlike here, the parties in the distinct lawsuits were treated as legally identical. *Kohn L. Grp., Inc. v. Auto Parts Mfg. Mississippi, Inc.*, 787 F.3d 1237, 1241 (9th Cir. 2015) (plaintiff in later action "stands in the shoes" of plaintiff in the earlier action); *Save Power Ltd. v. Syntek Fin. Corp.*, 121 F.3d 947, 949 (5th Cir. 1997) (plaintiff in later action was "a shell corporation affiliated with one of the owners of" plaintiff in the earlier action and case was transferred to another judge of the same court, not to a distant court where plaintiff had no connection). In the third case that DOJ cites, *TPM Holdings*, the same parties appeared in both the first and later cases, 91 F.3d at 4, and even still, this Court held that the overlap between the two cases was not sufficient for the first-filed rule to apply. *Id*.

The first-filed rule is especially inapt here where DOJ ceased negotiations about RIH's production and abruptly turned to the Northern District of Texas—a venue 1500 miles away from RIH and its patients that had no prior connection to anything regarding the subpoena—for an enforcement order. *Supra* pp. 8–9. Neither

the Child Advocate nor the children she represents received notice of the enforcement action, nor did RIH. The principles of comity underlying the first-filed rule, which are intended to promote judicial economy and respect for the legal system, do not require acquiescence to such maneuvers. Accordingly, this Court and courts in this circuit have recognized several exceptions to the first-filed rule, such as where, as here, a party has engaged in a bad-faith negotiation, *Veryfine Prods., Inc. v. Phlo Corp.*, 124 F. Supp. 2d 16, 22 (D. Mass. 2000) (first-filed rule may be inappropriate "where a party has won the race to the courthouse by misleading his opponent into staying his hand in anticipation of negotiation"), or where, as here, a party engages in forum-shopping. *EMC Corp. v. Parallel Iron*, LLC, 914 F. Supp. 2d 125, 128 (D. Mass. 2012) (first-filed rule is inappropriate "when a litigant selects a forum with only a slight connection to the factual circumstances of his action, or where forum shopping alone motivated the choice." (citation omitted)); *see also Codex Corp. v. Milgo Elec. Corp.*, 553 F.2d 735, 737 (1st Cir. 1977) (reversing stay of later proceeding where, among other factors, first proceeding was filed in "an unnatural and inconvenient forum").

Nor is there merit to DOJ's argument that HIPAA precludes a challenge from parties, like the Child Advocate, who are not the direct recipients of the subpoena. Gov't Br. 26. A subpoena under Section 3486(a)(5) specifies who may invoke that statute's procedural mechanism to quash a subpoena; it does not strip other individuals of the ability to seek equitable relief when their own rights or interests

are threatened, as they are here. Indeed, Section 3486 expressly incorporates the standards applicable to judicial subpoenas. *See* 18 U.S.C. § 3486(a)(7). Those standards include Federal Rule of Civil Procedure 45, which mandates the quashal or modification of subpoenas that require disclosure of protected matter or impose undue burdens "on any 'person,' not just the recipient of the subpoena," including burdens such as "invading privacy or confidentiality interests." *Va. Dep't of Corr. v. Jordan*, 921 F.3d 180, 189–190 (4th Cir. 2019) (citing Fed. R. Civ. P. 45(d)(3)(A)(iv)). Rule 45 also makes clear that the proper venue for quashing a subpoena is "the court for the district where compliance is required," and defines the place of compliance as "where the [subpoena recipient] resides, is employed, or regularly transacts business in person." Fed. R. Civ. P. 45(c)(2)(A), (d)(3). The proper venue for the Child Advocate's quashal motion, therefore, was the one below, not a distant Texas court where neither RIH nor the Child Advocate had any connection.

On DOJ's account, *see* Gov't Br. 26, Congress designed a system in which patients may never learn that their most intimate records have been seized and, even if they do, may never be heard in any forum. But Congress does not strip the federal courts of equitable jurisdiction over constitutional claims by implication; any such intent must be clear. *Webster v. Doe*, 486 U.S. 592, 603 (1988). Nothing in Section 3486 clearly forecloses a constitutional challenge by the persons whose records are

targeted, and this Court should not read the statute to create a class of constitutional injuries that no court may ever redress.

The District Court also correctly concluded that the collateral attack doctrine did not prevent quashal of the subpoena for the independent reason that its order operates on the subpoena and on DOJ, not on the Texas court's judgment. Add.40. Contrary to DOJ's argument, Gov't Br. 27–28, the District Court's order did not vacate or overrule the order of the Texas court. As the Texas court itself recognized, the District Court's order here simply "prohibited the DOJ from taking the specified actions related to obtaining documents from RIH but left the Enforcement Order otherwise in effect." *Matter of Admin. Subpoena 25-1431-032,* 2026 WL 1408263 at *2.

In two cases where DOJ similarly has targeted other hospitals located outside Texas via grand jury subpoenas issued from Texas, both courts have rejected DOJ's "protestations about comity." *See Z.A. v. Blanche*, No. 26-CV-04998-PCP, 2026 WL 1907181, at *17 (N.D. Cal. July 2, 2026), *appeal docketed*, No. 26-4388 (9th Cir. July 10, 2026) ; *Coe By & Through Coe v. Blanche*, No. 26 CIV. 4641 (KPF), 2026 WL 1815507, at *2 (S.D.N.Y. June 24, 2026), *appeal docketed*, No. 26-1886 (2d Cir. July 13, 2026); *see also Z.A. v. Lucile*, No. 26-cv-04998 (N.D. Cal. May 27, 2026) Dkt. No 89, Ex. A (attaching Transcript of Teleconference Decision in *Coe* ("*Coe* Transcript")) at 8. As the Northern District of California recently held, "[a]ny risk of conflicting court orders … has been manufactured by DOJ itself." *Z.A.*, 2026 WL

1907181, at *17. Similarly, in *Coe v. Blanche*, the Southern District of New York held that it would "not blind itself to [the] reality ... of DOJ's efforts ... to recast discredited civil administrative subpoenas as grand jury subpoenas from a hand-picked faraway jurisdiction in order to minimize judicial review of constitutional infirmities." *Coe* Transcript, *supra* p. 19, at 11. The same forum shopping is at issue here, and the District Court's decision to "not blind itself," *id*., was not an abuse of discretion.

II. THE DISTRICT COURT DID NOT ABUSE ITS DISCRETION IN QUASHING THE SUBPOENA

A. A District Court May Quash a Subpoena Where, As Here, the Government Has Exceeded Its Investigatory Power and Acted in Bad Faith

The government must have a "legitimate purpose" for issuing an administrative subpoena. *United States v. Powell*, 379 U.S. 48, 57 (1964). In arguing that the role of courts is limited to superficial scrutiny of its purpose, DOJ invokes its power to "investigate merely on suspicion that the law is being violated, or even just because it wants assurance that it is not." Gov't Br. 28 (quoting *United States v. Morton Salt Co.*, 338 U.S. 632, 642–43 (1950)). But the Supreme Court in *Morton Salt* expressly contemplated "judicial review" of administrative subpoenas to guard against "harsh and overzealous [Executive] action" and made clear that an "investigation may be … so unrelated to the matter properly under inquiry as to exceed the investigatory power." 338 U.S. at 640, 652.

DOJ tries to limit judicial scrutiny of its subpoena by arguing that under this Court's decision in *Sturm, Ruger & Co.*, it need only show that the "agency's assertion of investigative 'authority is not obviously apocryphal.'" Gov't Br. 29 (citing 84 F.3d at 5). But DOJ overreads that language, given that, "if followed, [that reasoning] would preclude any form of judicial review as the Government's self-proclaimed say-so would always be sufficient to defeat a motion to quash." *Boston Children's*, 800 F. Supp. 3d at 237. Instead, "a court asked to enforce a subpoena has a broad power of inquiry to ensure that its process is not abused should, for example, the Government appear to be acting in bad faith." *SEC v. Howatt*, 525 F.2d 226, 229 (1st Cir. 1975). When a subpoena is challenged, it is "only after judicial process is afforded" that the government "can command the production of documents." *In re Subpoena Duces Tecum*, 228 F.3d 341, 348 (4th Cir. 2000) (citing *United States v. Miller*, 425 U.S. 435, 446 & n.8 (1976)).

Courts thus maintain an "independent role" in "subpoena enforcement proceedings." *CFPB v. Accrediting Council for Indep. Colleges & Schs.*, 854 F.3d 683, 689 (D.C. Cir. 2017) (citation omitted). That role "is to ensure that the [investigating agency] is using its broad authority in good faith and in compliance with the law." *Gertner*, 65 F.3d at 966. In reviewing the subpoena, the District Court thus correctly scrutinized an investigation that was both "plainly spurious" from the start and has since "wander[ed] unconscionably far afield." *FTC v. Swanson*, 560

F.2d 1, 2 (1st Cir. 1977) (per curiam)).[7] In any event, for the reasons discussed below (*infra* pp. 23–31), DOJ's assertion of subpoena authority in this case is obviously apocryphal.

When a subpoena is challenged, the government must first make a prima facie showing "[1] that the investigation will be conducted pursuant to a legitimate purpose, [2] that the inquiry may be relevant to the purpose, [3] that the information sought is not already within the [agency's] possession, and [4] that the administrative steps required by the [relevant statute] have been followed." *Powell*, 379 U.S. at 56–58. As to the second element, "the standard for relevancy may be a bit higher where the summons is directed at a third-party custodian of the records." *United States v. Freedom Church*, 613 F.2d 316, 321 (1st Cir. 1979).

If the government makes that showing, the burden shifts to the subpoenaed party "to disprove one or more of the *Powell* requirements, or to show that enforcement would be 'an abuse of process, e.g., that the summons was issued in bad faith for an improper purpose.'" *Sugarloaf Funding, LLC v. United States Dep't of the Treasury*, 584 F.3d 340, 346 (1st Cir. 2009) (citations omitted). These improper

[7] To that end, the *Sturm* court derived the "obviously apocryphal" language from this Court's earlier decision in *Swanson*. But *Swanson* did not purport to create a new, higher, standard which recipients of a subpoena must meet to obtain quashal; instead, this Court there relied on the Supreme Court's explanation that a subpoena is improper if it seeks information "irrelevant to any lawful purpose or . . . [because] unauthorized by law." *Swanson*, 560 F.2d at 2 (citing *Ok. Press Pub. Co. v. Walling*, 327 U.S. 186, 213 (1946)).

purposes include "to harass the [subpoenaed party] or put pressure on him to settle a collateral dispute, or for any other purpose reflecting on the good faith of the particular investigation." *Powell*, 379 U.S. at 58. The *Powell* Court thus expressly directed courts to "inquire into the underlying reasons" motivating an administrative subpoena to ensure its "process" is not "abused." *Id.*

DOJ faults the District Court for failing to "cite, much less apply" the obviously-apocryphal formulation. Gov't Br. 34. The criticism is empty. Whether DOJ's FDCA theory is legally cognizable is a question of law that this Court reviews de novo, and this Court may affirm on any ground the record supports. *See supra* p. 14. The question is therefore not whether the District Court recited the phrase; it is whether DOJ's assertion of authority survives it. It does not.

B. DOJ Did Not Meet Its Prima Facie Burden

DOJ has not demonstrated any valid statutory purpose.[8] DOJ's justifications for its investigation into RIH have shifted over time, but it has never identified any legal theory that permits its investigation into RIH under the FDCA. Additionally, the documents that DOJ seeks are unrelated to the purposes it asserts. For these

[8] This Court can affirm the District Court's ruling on the independent ground that DOJ's subpoena was issued pursuant to an improper purpose, under the second step of *Powell*, *infra* pp. 37–41. It need not also find that DOJ lacked a legitimate statutory purpose under *Powell* step one. *See QueerDoc*, 807 F. Supp. 3d at 1302 (focusing analysis on government's improper purpose).

reasons, the District Court's determination to quash the subpoena was not an abuse of discretion.

1. DOJ's Subpoena Was Not Issued for a Congressionally Authorized Purpose

The subpoena here was issued as part of an investigation in search of a justification. Early on, DOJ defended its subpoena—an expansive intrusion into the private medical information of children—on the theories of investigating providers for their treatment of patients under the FDCA, as well as FCA violations. JA22 n.18. But Section 3486 does not authorize DOJ to issue an administrative subpoena for those purposes. *See* supra p. 7. So, DOJ's theories had to evolve. More recently, DOJ has invoked other theories: (1) the hospital's physicians may have engaged in misbranding or off-label promotion of medications in treating their patients, with fraudulent intent, and/or somehow failed to supply adequate warnings to their patients; (2) the hospital's physicians may have engaged in miscoding and/or false billing which, according to DOJ, show their intent to violate the FDCA under 21 U.S.C. § 333(a)(2); and (3) the hospital's physicians may have information as witnesses to the crimes of manufacturers, and that such information can help DOJ "generate future investigative leads." Gov't Br. 30–32, 36. These theories of liability, however, do not supply any authorized purpose for the subpoena. And as the District Court correctly found, DOJ seeks to restrict activity—the practice of medicine—that falls outside the scope of the FDCA.

a) A subpoena under 18 U.S.C. § 3486 cannot be used to investigate alleged violations under the False Claims Act or for billing fraud

When DOJ first explained its investigation, it stated that it was investigating "health care providers" for alleged violations of the FCA. *See supra* n.1 & n.2 (Bondi and Shumate Memos). But a Section 3486 subpoena may issue only to investigate the specific "Federal health care offense[s]" enumerated in 18 U.S.C. § 24(a)—which do not include the FCA. *See* 18 U.S.C. § 3486(a)(1)(A)(i)(I); *id.* § 24(a)(1)–(2), (b). Moreover, DOJ has limited its authority to use Section 3486 subpoenas to investigate violations under the FDCA. JA88 (Hsiao Decl.) ¶ 5. Thus, DOJ cannot utilize such subpoenas for investigating violations of the FCA. *See also United States v. Cancer Treatment Ctrs. of Am.*, 350 F. Supp. 2d 765, 771 n.1 (N.D. Ill. 2004) (explaining that a subpoena under Section 3486 is distinct from one under "31 U.S.C. § 3733, which provides for civil investigative demands tailored for FCA investigations.").

Similarly, DOJ's more recent theory—that it seeks to investigate RIH for billing fraud and the submission of false claims—does not implicate the FDCA, which prohibits misbranding of drugs in interstate commerce. *Supra* p. 7. DOJ thus cannot use a Section 3486 subpoena to investigate billing practices.

b) The FDCA does not authorize a subpoena to investigate the practice of medicine

In its evolving articulations, DOJ has stated that it seeks to investigate providers' acts of off-label prescribing and/or labeling. Gov't Br. 30–32. As the District Court correctly determined, such an inquiry is outside the scope of the FDCA. While "drug manufacturers are prohibited from promoting off-label uses in marketing a drug," the FDCA "does not prohibit doctors from prescribing drugs for off-label uses." *Children's Hosp. Colo.*, 2026 WL 33398, at *1 (quoting *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121, 127 (2d Cir. 2010) and *In re Celexa & Lexapro Mktg. & Sales Pracs. Litig.*, 915 F.3d 1, 5 (1st Cir. 2019)).

DOJ does not accuse either RIH or its providers of manufacturing a drug, changing a package insert, repackaging the drug for commercial resale, distributing the drug to other prescribing physicians, or disseminating product labeling on behalf of a manufacturer. It instead seeks to investigate the provision of medical care by RIH providers, including by examining how providers treated individual children and those children's private medical records. But as this Court has explained, the FDCA "preserv[es] health care professionals' discretion to prescribe and administer [treatments] as they deem appropriate," including "to prescribe or administer any legally marketed [treatment] to a patient for any condition or disease." *United States v. Facteau*, 89 F.4th 1, 15 (1st Cir. 2023) (quoting 21 U.S.C. § 396); *see also Judge Rotenberg Educ. Ctr., Inc. v. U.S. Food and Drug Admin.*, 3 F.4th 390, 399 (D.C.

Cir. 2021) ("Choosing what treatments are or are not appropriate for a particular condition is at the heart of the practice of medicine."); *CHOP*, 810 F. Supp. 3d at 579 ("Congress, through 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 them.").

DOJ's inquiry into the medical practices of physicians improperly interferes with the States' sovereign authority to "protect the health and safety of their citizens" as they see fit. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996). The "regulation of health and safety matters is primarily, and historically, a matter of local concern." *Hillsborough Cnty. v. Automated Med. Lab'ys, Inc.*, 471 U.S. 707, 719 (1985). As the Supreme Court just made clear, it is within the states' authority to "pass legislation in areas where there is medical and scientific uncertainty." *Skrmetti*, 605 U.S. at 524 (recognizing the core State authority). Rhode Island has passed such legislation via the Healthcare Provider Shield Law, which specifically protects gender-affirming healthcare, Rhode Island patients receiving that care, and their providers. R.I. Gen. Laws §§ 23-101-1 *et seq*. If Congress had intended to upset the federal-state balance so drastically as DOJ suggests, it would have done so clearly. *See Gonzales v. Oregon*, 546 U.S. 243, 273–75 (2006); *United States v. Bass*, 404 U.S. 336 (1971). The clearest statement that Congress made in the FDCA about federalism was the opposite—the statutory bar on the federal government's

regulation of the practice of medicine, which is reserved to the States. 21 U.S.C. § 396 (FDCA "shall not 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").

The Hsiao declaration that DOJ filed to justify its subpoena only reinforces that DOJ's main aim was not to investigate FDCA violations but to probe into the treatment practices of RIH providers. Indeed, in the forty-six paragraphs of her declaration, Hsiao's only specific references to RIH are to the number of RIH patients treated for gender dysphoria, RIH's submission of fourteen insurance claims with an "endocrine disorder" diagnosis code, and the fact that four patients were treated based on what DOJ believes is an atypical diagnosis. JA101 ¶¶ 36–38. All of those facts, even if true, would not establish an FDCA violation and only underscore that DOJ is conducting an unauthorized inquiry into the practice of medicine.

DOJ tests another theory, arguing that "RIH or its employees could have engaged in misbranding by altering a drug's labeling, such as by providing false or misleading 'written, printed, or graphic matter … accompanying' the drug." Gov't Br. 36–37 (quoting 21 U.S.C. §§ 321(m), 352(a)); *see also* JA100 ¶¶ 34–35. But such a theory stretches the concept of "labeling" beyond all recognition. "Labeling" in 21 U.S.C. § 321(m) refers to written or graphic materials accompanying a drug—

i.e., materials disseminated by manufacturers or distributors in the chain of commerce, not by physicians themselves. *CHOP*, 810 F. Supp. 3d at 585. A physician's provision of information to patients regarding the off-label use of a drug neither creates the drug's labeling nor defines its intended use under the FDCA. *Id.* at 586. Thus, physicians' clinical assessments, consent discussions, and other patient-specific counseling that accompany medical care are not "labeling." *See id.*; *see also United States v. Evers*, 643 F.2d 1043, 1051–53 (5th Cir. 1981) ("information provided by [defendant doctor] to his patients is irrelevant" to issue of misbranding). And the FDCA does not prohibit providers from accurately describing a clinically appropriate off-label use. *Facteau*, 89 F.4th at 15; *see also Evers*, 643 F.2d at 1053 n.16 (FDCA "was intended to regulate the distribution of drugs in interstate commerce, not to restrain physicians from public advocacy of medical opinions not shared by the FDA.").[9]

[9] DOJ's argument that prescription drugs dispensed by practitioners are not exempt from the labeling requirements in Section 352(a) misses the mark. Gov't Br. 37–38. The District Court invoked the prescription drug exemption in 21 U.S.C. § 353(b)(2) in response to the misbranding theory DOJ articulated below: that off-label prescribing changes a drug's "intended use," rendering its labeling devoid of "adequate directions for use" under § 352(f)(1). Add.45; JA100 ¶ 34. That is exactly the provision that § 353(b)(2) exempts from § 352. DOJ, for the first time on appeal, argues that there is no exemption under § 352(a) for labeling that is "false or misleading in any particular." Even if the Court were to consider this argument for the first time on appeal, "labeling" under the FDCA does not pertain to materials from providers themselves. *See supra* pp. 28–29.

In a last-ditch effort, DOJ claims that individual patients' charts would be relevant to "identify patients' adverse health outcomes." Gov't Br. 32. But any adverse outcomes to patients are not related to "Federal health care offense[s]," as required by Section 3486. This justification, like all of the others relating to RIH's gender-affirming care, "concern[s] lawful medical practice governed by [Rhode Island] law." *CHOP*, 810 F. Supp. 3d at 580.

If DOJ's interpretation of FDCA liability as to health care providers for off-label prescribing were correct, it would upend the practice of medicine, for between 20 and 50 percent of all prescriptions are for off-label indications. James M. Beck, Off-Label Use in the Twenty-First Century: Most Myths and Misconceptions Mitigated, 54 UIC J. Marshall L. Rev. 1, 25–26 & n.112, n.113 (2021). That number includes situations where the off-label use of drugs is the standard of care, in particular for many cancer treatments. *Id.*

Given that "[n]o court has extended FDCA misbranding liability to a hospital or physician" on the basis that DOJ proffered, the District Court correctly determined that the subpoena lacked a congressionally authorized purpose. Add.44, 46. Courts considering similar subpoenas to other hospitals and providers have quashed or enjoined the subpoenas on the same basis. *Z.A.*, 2026 WL 1907181, at *3–4, n.8; *CHOP*, 810 F. Supp. 3d at 579.

2. The Information that DOJ Seeks Is Not Relevant to Any Congressionally Authorized Purpose

An independent basis exists for affirmance: DOJ failed to demonstrate that its requests were relevant to any of its theories, regardless of whether those theories might be legally permissible. *See Powell*, 379 U.S. at 57 (Government "must show that the investigation will be conducted pursuant to a legitimate purpose" *and* "that the inquiry may be relevant to the purpose"). The relevance element from the *Powell* standard requires DOJ to show "a realistic expectation rather than an idle hope that something may be discovered." *United States v. Harrington*, 388 F.2d 520, 524 (2d Cir. 1968). Insofar as the government is investigating the actions of third parties such as manufacturers, pharmaceutical companies, and distributors, and not RIH, none of that information will be found in the patient records that DOJ seeks. DOJ's use of a wide-ranging and extremely intrusive subpoena into the lives of children for this purpose does not meet the "higher" standard for relevancy that applies "where the summons is directed at a third-party custodian of the records." *Freedom Church*, 613 F.2d at 321 (citing *Harrington*, 388 F.2d 520). Nor is such a fishing expedition authorized by the FDCA.

a) The subpoena's requests are unrelated to claims of fraudulent billing or miscoding

DOJ claims that RIH's billing records, as well as the private medical records of the adolescents the hospital treats, are needed to "identify patterns of misbranding

or false billing" and to evaluate "instance[s] of false coding" and "the presence of an 'intent to defraud or mislead.'" Gov't Br. 31 (quoting 21 U.S.C. § 333(a)(2)). But this evidence could be relevant only if DOJ had a plausible theory of an FDCA violation, which it does not. *Supra* pp. 25–30. For the same reason, DOJ cannot obtain this information to "assess fraudulent intent" where there is no underlying FDCA violation. Gov't Br. 31; *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*.").

Evidence regarding false or fraudulent billing might be relevant to an FCA investigation, but as already discussed, an FCA investigation cannot be the basis for a subpoena under Section 3486. *See supra* p. 25. The evidence DOJ seeks could not support a false or fraudulent billing claim in any event. DOJ's stated purpose for an investigation of false or fraudulent billing relied on the theory that providers "attempt[ed] to evade state bans on gender dysphoria treatments by knowingly submitting claims to Medicaid with false diagnosis codes." *Supra* n.2 at *3 (Shumate memo). But because Rhode Island explicitly protects gender-affirming care, providers could not be evading a state ban in Rhode Island, and thus there is no basis for an investigation into fraudulent billing. To the contrary, Medicare and many state Medicaid programs explicitly cover this care. *See* JA19 (citing Rhode Island Gender

Dysphoria/Gender Nonconformity Coverage Guidelines); JA340 (gender-affirming care is "eligible for Medicaid reimbursement in the State of Rhode Island").

Here, as in other cases, DOJ seeks a vast amount of information "while not offering an iota of suspicion that [RIH] is actually engaging in fraudulent billing practices or off-label promotion in the first instance." *Boston Children's*, 800 F. Supp. 3d at 238.

b) The subpoena's requests for information from the hospital as a "co-conspirator" or "witness" to the potential bad acts of manufacturers and other third parties are nothing more than a fishing expedition

Through Section 3486, Congress authorized DOJ to subpoena documents that are relevant to an investigation, not to conduct an open-ended fishing expedition.

DOJ incorrectly claims that "RIH or its employees may be liable if they conspired with manufacturers and distributors who were misbranding drugs." Gov't Br. 36. But DOJ does not muster any support for its claim that RIH or its employees could be liable for conspiracy beyond its unfounded theories of the physicians' wrongdoing. *Supra* pp. 26–30. As the District Court correctly concluded, "it is … logically impossible to construct an aiding-and-abetting, facilitation, or conspiracy theory predicated on nothing more than the physician[s'] own lawful prescribing act[s]." Add.44.

DOJ also fails to find any legal support for its theory. DOJ cites an indictment it brought in a different court in an unrelated case. Gov't Br. 36 (citing Indictment,

United States v. Gleason, No. 1:06-cr-229 (E.D.N.Y. Apr. 5, 2006), Dkt. No. 8). That citation is a strange choice. There, the government indicted a psychiatrist and a pharmaceutical sales representative for conspiracy to introduce a misbranded drug into interstate commerce. *United States v. Caronia*, 576 F. Supp. 2d 385, 390 (E.D.N.Y. 2008), *vacated and remanded*, 703 F.3d 149 (2d Cir. 2012). The psychiatrist pled guilty, and the sales representative was later convicted in the Eastern District of New York. 576 F. Supp. 2d at 390; 703 F.3d at 159. But the Second Circuit later vacated the sales representative's conviction, which was premised on the same facts that led to the physician's guilty plea. 703 F.3d at 155–56, 169.

DOJ hedges by claiming that "RIH or its employees may simply be witnesses to misconduct by others, such as manufacturers or distributors engaged in misbranding." Gov't Br. 36. Notably absent, however, is any evidence that DOJ has subpoenaed or investigated pharmaceutical *manufacturers* or *distributors* for their practices in marketing drugs used by providers to treat gender dysphoria—strongly suggesting that DOJ's objective here is to coerce providers into abandoning treatment, not to pursue its tenuous theory of misbranding. Any such investigation into manufacturers and distributors would support, at most, subpoenas for manufacturer communications, contracts, promotional materials, or other non-patient-specific commercial materials. It would not permit the harmful intrusion into children's identities, diagnoses, Social Security numbers, and medical histories. DOJ

fails to provide any explanation tying the details about adolescent patients' care to the actions of manufacturers and distributors.

DOJ's reliance on children's private information to serve as "investigative leads," Gov't Br. 32, "underscores the speculative nature of" the patient data requests. *CHOP*, 810 F. Supp. 3d at 580; *see also Children's Hosp. Colo.*, 2026 WL 33398, at *4 (DOJ merely "surmis[ing] that the minors' patient information could aid them in finding potential witnesses" was too speculative). The speculative possibility that a child or parent may know something does not make every patient identifier reasonably relevant. *CHOP*, 810 F. Supp. 3d at 580. And "the government's demand for deeply private and personal patient information carries more than a whiff of ill-intent." *UPMC*, 2025 WL 3724705, at *2.

The only cases that DOJ cites, Gov't Br. 32–33, to support its need for patient records are inapt. "This is not," as in the Fourth Circuit case that DOJ cites, "a subpoena directed to an investigative target itself suspected of submitting fraudulent medical reimbursement claims." *Children's Hosp. Colo.*, 2026 WL 33398, at *4 (distinguishing *In re Subpoena Duces Tecum*, 228 F.3d at 350). DOJ cites one case where it asked a subpoena recipient to review 2,500 patient files. *In re Grand Jury Subpoenas Duces Tecum Dated Jan. 30, 1986*, 638 F. Supp. 794, 795 (D. Me. 1986). But that case did not involve a challenge by the patients to the disclosure of information, and the claim of overbreadth failed because the "movant previously

caused many of the requested documents to be culled from his records in response to state grand jury subpoenas seeking similar records." *Id.* Here, there is no doubt that the disclosures would be both harmful and overly burdensome to the children whose interests the Child Advocate represents.

Nor is the *Doe* case from the Sixth Circuit that DOJ cites on point; there, the subpoena recipient did not dispute the reasonableness of the government's request for patient documents. *Doe v. United States*, 253 F.3d 256, 265 (6th Cir. 2001). Here, the Child Advocate vigorously contests the reasonableness of DOJ's requests for myriad reasons. The requests seek sensitive medical records and personal information that are not tethered to the government's legal theories (which are ill-founded in any event). And DOJ cannot use a Section 3486 subpoena to "conduct open-ended discovery in search of witnesses or narratives to support a theory." *CHOP*, 810 F. Supp. 3d at 580.

DOJ's insistence that it can subpoena patient files so that it may find "investigative leads" lacks any reasonable bounds. DOJ seeks to transform its confined subpoena authority in Section 3486 into a tool that would allow it to collect patient files at will. As other courts considering virtually identical subpoenas have concluded, DOJ does not have that authority. *See, e.g.*, *Children's Hosp. Colo.*, 2026 WL 33398, at *4; *CHOP*, 810 F. Supp. 3d at 580–81 ("The Department of Justice

lacks statutory authority for a rambling exploration of the Hospital's files to learn the names and medical treatment of children.").

C. The District Court's Improper-Purpose Finding Was Not Clearly Erroneous

The District Court did not clearly err when it found in its "predominantly factbound" analysis that the subpoena also should be quashed because the Child Advocate had demonstrated DOJ's bad faith. *Gertner*, 65 F.3d at 970. Under the *Powell* standard, a court may quash a subpoena if the government had an improper purpose, including "to harass the [subpoenaed party] or to put pressure on him to settle a collateral dispute, or for any other purpose reflecting on the good faith of the particular investigation." *Powell*, 379 U.S. at 58. As the District Court determined, the record and timeline of DOJ's actions make clear that DOJ's purpose in issuing the subpoena was to intimidate providers into ceasing their gender-affirming care services, rather than legitimately investigate any FDCA violations.

DOJ seeks to invert the Supreme Court's standard in *Powell* by arguing that it can issue a subpoena for an improper purpose as long as it has some other proper purpose. Gov't Br. 39. The Child Advocate need not show that the "sole purpose" of the investigation is improper. If that were the case, DOJ could use subpoenas to harass and intimidate, so long as it also asserts other plausible proper purposes. *See also* Add.22 ("To hold otherwise would allow the DOJ to immunize any coercive investigation from the improper purpose doctrine simply by appending an untenable

legal theory to it."). The standard from this Court's decision in *Gertner* avoids such an absurd result, requiring only that a movant "articulate specific allegations of bad faith," 65 F.3d at 967, which the Child Advocate has done. In any event, as the District Court found, Add.22, and for the reasons discussed *supra* pp. 25–33, there was no legitimate purpose for the subpoenas, which means that DOJ issued the subpoena to RIH solely for an improper purpose.

From this administration's first day in office, it has made publicly clear that its mission is to end gender-affirming care, full stop, by pressuring providers into ceasing its gender-affirming care services. JA21 n.11. Between the President's executive orders vilifying transgender people, and DOJ's memoranda on "hold[ing] accountable those who mutilate [children] under the guise of care," the administration's use of subpoenas to accomplish those goals is more than just "strong opposition" to gender-affirming care as DOJ claims. Gov't Br. 41; JA15 n.1; JA21 n.11; *supra* n.1 & n.2. As in *Gertner*, public statements and the structure of the investigation were relevant evidence that the asserted statutory rationale was pretextual. 65 F.3d at 969. DOJ's evolving justifications are themselves evidence of pretext. *Cf. Dep't of Com. v. New York*, 588 U.S. 752, 785 (2019) (when an agency's proffered explanations are "incongruent with what the record reveals about the agency's priorities and decisionmaking process," a court need not accept the "contrived reasons" at face value).

Again, strikingly absent is any indication that DOJ is actually pursuing FDCA violations by focusing on the conduct of drug manufacturers and distributors. Instead, DOJ boasted in a press release that *hospitals* had curtailed their gender-affirming care as a result of its efforts. JA24 n.26. The administration's contemporaneous issuance of press releases with its issuance of the subpoenas is compelling evidence of its bad faith; "[t]he timeline tells the story here." *QueerDoc*, 807 F. Supp. 3d at 1302. Seven other federal courts that have considered materially identical subpoenas and the same public statements have concluded that they evinced improper purpose.[10]

Nor can DOJ insulate itself from improper purpose by calling these statements "policy" preferences. Gov't Br. 41. Certainly, presidential administrations can prefer and promote their own policy choices. What they cannot do, however, is utilize DOJ's investigative power to intimidate providers and patients of a medical practice they do not agree with but have no power to regulate, much less suppress, into ceasing their gender-affirming medical care. DOJ clearly lacks authority to regulate gender-affirming care in a state where it is legal, like Rhode Island. *Supra* p. 3. And because the "[g]overnment may not use threats of prosecution to coerce people into

[10] *See QueerDoc*, 807 F. Supp. 3d at 1303–04; *Boston Children's*, 800 F. Supp. 3d at 239; *In re Subpoena Duces Tecum No. 25-1431-016*, No. 25-mc-41, 2025 WL 3562151, at *11–13 (W.D. Wash. Sept. 3, 2025), *appeal pending*, 26-4009 (9th Cir.); *Children's Hosp. Colo.*, 2026 WL 33398, at *11; *Children's Nat'l*, 2026 WL 160792, at *8; *CHOP*, 810 F. Supp. 3d at 606; *UPMC*, 2026 WL 3724705, *2.

doing what it cannot directly order them to," *In re Grand Jury Subpoenas*, 823 F. Supp. 3d 1, 9 (D.D.C. 2026) (citation omitted), *reconsideration denied*, No. MC 26-12 (JEB), 2026 WL 1224046 (D.D.C. Apr. 3, 2026), DOJ's actions can only be understood as a means to "pressure," "harass," and "to settle a collateral dispute." *Powell*, 379 U.S. at 58. So far, this tactic to intimidate hospitals into settling has been successful in at least two cases where providers of gender-affirming care have settled with DOJ and agreed to completely cease their gender-affirming care services. *Supra* p. 6 & n.3 & n.4. Neither of these settlements allows for any gender-affirming care services that may be *consistent* with the FDCA, *supra* n.3 & n.4, reflecting DOJ's goal to end gender-affirming care through intimidation rather than prosecute legitimate FDCA violations.

DOJ's bad faith is particularly egregious in this case given the litigation tactics it has used to secure an enforcement order from an unrelated court. After DOJ issued its subpoena to RIH, RIH engaged in ongoing negotiations until February 2026, when "DOJ appear[ed] to have inexplicably ceased communicating with RIH." Add.31. When DOJ reinitiated contact at the end of April 2026, it requested a conference with RIH that same week. Add.32. But, instead of meeting with RIH, DOJ rushed to the Northern District of Texas, a venue with no connection to RIH or its patients, to file an enforcement petition without notice to either. *Id.* DOJ turned to this jurisdiction just after losing for the *seventh* time in *every* jurisdiction where

gender-affirming care subpoenas had been challenged.[11] In other words, the only way DOJ was able to succeed was by dragging RIH away (without notice) from the venue in which it is located and where all of the relevant evidence can be found. This Court is not required to ignore such tactics in determining that DOJ's purpose here was improper.

III. THE PRIVACY INTERESTS OF CHILDREN FAR OUTWEIGH DOJ'S INVESTIGATORY INTEREST

The District Court also correctly found another independent basis for quashal: Compelled disclosure of the patient records covered by the subpoena would violate the privacy interests of the children at issue. Add.47–48.

DOJ seeks patient records identifying individual children and detailing their private health care information, including their diagnoses and treatment. The requests also seek personally identifying information about minor patients, including names, dates of birth, and social security numbers. DOJ insists that aggregate information is not sufficient because it wants to analyze individuals' "actual diagnosis" and "health outcomes." Gov't Br. 31–32. These records unquestionably implicate children's substantial right to privacy, and the Government identifies no countervailing need sufficient to justify that intrusion. *See Borucki v. Ryan*, 827 F.2d 836, 848 (1st Cir. 1987) (privacy interests must be balanced against the government's

[11] See *supra* n.6.

interest in obtaining records). As another court recently said, "[s]uch detailed medical information is all the more sensitive because it identifies [minors] as having received care that is subject to intense political controversy, that the federal government has professed a desire to 'end,' and that state authorities in Texas have suggested could [form] the basis for child-abuse prosecutions against patients' parents." *Z.A.*, 2026 WL 1907181, at *18.

Federal Rule of Civil Procedure 45(d)(3)(A)(iv) provides that a court may quash a subpoena that imposes an undue burden. That standard, which Section 3486(a)(7) incorporates, applies in the context of an administrative subpoena. *See, e.g.*, *EEOC v. Maryland Cup Corp.*, 785 F.2d 471, 477 (4th Cir. 1986) ("[s]ome courts have referred by analogy to Rule 45 to determine the appropriate standards for enforcing administrative subpoenas"); *see also EEOC v. Kronos Inc.*, 694 F.3d 351, 371 (3d Cir. 2012), *as amended* (Nov. 15, 2012) ("[T]he text of [Rule 45], when coupled with Congress's decision to entrust courts with the enforcement of administrative subpoenas [is] a useful indicator of 'a broad congressional judgment with respect to fairness in subpoena enforcement proceedings.'" (citation omitted)).

Applying that standard, courts have quashed or limited subpoenas calling for disclosure of personal and intrusive information. *See, e.g.*, *Northwestern Mem. Hosp. v. Ashcroft*, 362 F.3d 923, 927–29 (7th Cir. 2004); *In re New England Compounding Pharm., Inc. Products Liability Lit.*, No. 13-2419, 2013 WL 6058483,

at *10 (D. Mass. Nov. 13, 2013) (quashing "subpoenas to the extent that they seek to obtain patient medical records or other patient information as to individuals who are not parties to any action presently pending"). To that end, the First Circuit has recognized that, as is relevant here, "concern for the unwanted burden thrust upon non-parties is a factor entitled to special weight in evaluating the balance of competing needs." *Cusumano v. Microsoft Corp.*, 162 F.3d 708, 717 (1st Cir. 1998). The District Court's quashal order is thus independently supported by Rule 45 and the cases that have applied it to block the disclosure of private information.

The privacy interests here also have a constitutional dimension, protected from unjustified intrusion by the Due Process Clause of the Fifth Amendment. *See Whalen v. Roe*, 429 U.S. 589, 599, 602 (1977) (recognizing privacy interest in "avoiding disclosure of personal matters," including "to representatives of the State"); *Nixon v. General Servs. Admin.*, 433 U.S. 425, 457 (1977) (similar); *Harper v. Werfel*, 118 F.4th 100, 113 (1st Cir. 2024) (reaffirming that "the substantive component of the Due Process Clause protects a limited liberty interest in the confidentiality of certain intimate information"); *Vega-Rodriguez v. Puerto Rico Tel. Co.*, 110 F.3d 174, 183 (1st Cir. 1997) (similar).[12]

[12] Although the District Court referred to the right to privacy as arising under the Fourteenth Amendment rather than the Fifth Amendment, that distinction is at most harmless error given the First Circuit has treated the privacy interests under either constitutional provision as largely indistinguishable. *Werfel*, 118 F.4th at 112 n.15.

"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) (citation omitted). Accordingly, "forced disclosure of a transgender person's most private information is not justified by any legitimate government interest." *Id.*; *see also CHOP*, 810 F. Supp. 3d at 597 ("The records sought here fall at the highest end of the intimate and personal spectrum" and contain a "level of detail [that] places the information among the most personal and sensitive a medical provider can hold and squarely within the class of intimate material [the Third Circuit] has long regarded as warranting the strongest constitutional protection.").

Nor is the harm alleviated merely because the disclosure may be only to the Government. Gov't Br. 47 (citing 18 U.S.C. § 3486(e)(1)). Instead, nonconsensual disclosure is harmful where it may expose a child to "stigma and harassment." *Doe v. Borough of Barrington*, 729 F. Supp. 376, 384 (D.N.J. 1990); *see also Planned Parenthood of S. Ariz. v. Lawall*, 307 F.3d 783, 789–90 (9th Cir. 2002) (the "right to 'informational privacy'" applies "when an individual chooses not to disclose highly sensitive information to the government" (citation omitted)); *CHOP*, 810 F. Supp. 3d at 599 (explaining that a court should consider the harm "if nonconsensual disclosure occurs," rather than just the mere "likelihood of disclosure"). DOJ's

requests seek information about diagnoses and treatments of individuals with gender dysphoria, "a medical condition characterized by persistent, clinically significant distress." *Skrmetti*, 605 U.S. at 502. The exposure of adolescents with this diagnosis to the stigma associated with it merits full protection, "particularly in political climates where those charged with protecting the public's welfare have taken an adversarial view of certain medical care based on ideology rather than deferring to [the state's] police power to regulate medical care." *CHOP*, 810 F. Supp. 3d at 599. And, as the District Court found, patients receiving gender-affirming care will suffer harm from disclosure of their personal information to DOJ, which conceded that its "investigative efforts would include attempting to locate and question both children and their caregivers." Add.50 n.12; JA449:10–12; JA451:13–16; *see also CHOP*, 810 F. Supp. 3d at 599 ("This is not a distant privacy concern.").

This is doubly so because the information the Government seeks comes in the form of health records, which the First Circuit has explained are of a "presumptively private nature." *United States v. Kravetz*, 706 F.3d 47, 63 (1st Cir. 2013). And "[p]rivacy interests are further exacerbated when, as here, the private medical information belongs to a minor. Federal law and the caselaw . . . unequivocally recognize the enhanced privacy rights of minors." *United States v. Hodges*, No. 23-cr-0048, 2025 WL 894936, at *4 (D. Me. March 24, 2025). Citing the Fourth Circuit's decision in *In re Subpoena Duces Tecum*, DOJ argues that patients have no

privacy interest in their health records, Gov't Br. 45–46, but the subpoena in that case concerned fraudulent reimbursement claims for the prescribing and distribution of controlled substances (as opposed to the practice of adolescent medicine), and was not facially targeted at *children's* health records. 228 F.3d at 344, 350. That the fact-intensive inquiry there produced a different result than the one that the District Court reached here should thus be no surprise. And, before *In re Subpoena Duces Tecum* reached the Fourth Circuit, the district court quashed that portion of the subpoena that sought "personal financial records." *Id*. at 345. The sensitive and private medical records of children warrant at least the same protection as financial records.

DOJ argues, Gov't Br. 45, that the children's interests here are "minimal" and that DOJ was authorized to collect the records at issue. But DOJ fails to acknowledge the weighty privacy interests of transgender children specifically. *Supra* pp. 44–46. It also fails to articulate an authorized basis for the subpoena. And it makes no persuasive argument that the medical records relating to the children are required for its investigation into violations of the FDCA. *See supra* pp. 31–37; *see also NASA v. Nelson*, 562 U.S. 134, 147–48 (2011) (government's inquiry must be "reasonable" to overcome privacy interest).

DOJ also argues that any privacy interest is lessened because patients are given notice that RIH may disclose their information in response to a lawful

subpoena, Gov't Br. 45–46, but any such notice does not eliminate patients' reasonable expectation that such disclosure will occur only when legally authorized and under applicable standards. *See Z.A.*, 2026 WL 1907181, at *19 ("A reasonable patient reading this language could very well maintain an expectation of privacy where their personal health information is minimally relevant to DOJ's professed law-enforcement purpose."). DOJ also ignores that the regulations implementing HIPAA provide that, while protected health information may be disclosed for a law enforcement purpose, identifiable information may be produced in response to an administrative subpoena only if "[t]he information sought is relevant and material to a legitimate law enforcement inquiry," and "[d]e-identified information could not reasonably be used." 45 C.F.R. § 164.512(f)(1)(ii)(C)(1)–(3). Children, and their guardians, thus had a reasonable expectation their privacy would be protected absent a compelling need to the contrary (which DOJ has failed to establish).

The Government argues that even if a privacy interest existed, such an interest would warrant anonymization, rather than quashal. Gov't Br. 47 n.7. But that argument does not explain why the Government believed it needed the identifiable records in the first instance, particularly in light of HIPAA's preference for the production of deidentified information. It was DOJ that chose to seek highly intrusive and sensitive personally identifiable information, and it has failed to explain why it is needed.

Nor will redaction or anonymization remove the serious risk that identifying information could be strung together to identify the youth (particularly in a small state like Rhode Island where the number of patients seeking gender-affirming care at the State's leading hospital is likely quite small), which would lead both to a risk of hostility against them and their families and a chilling effect on their care. *See generally Northwestern Mem'l Hosp.*, 362 F.3d at 929 ("Even if all the [patients] whose records the government seeks know what 'redacted' means, they are bound to be skeptical that redaction will conceal their identity from the world … and doubtless they are also aware that hostility" surrounds their care). And in any event, the task of redacting the patient records to remove all personally identifying information would itself be so arduous as to be unduly burdensome. *See Hodges*, 2025 WL 894936, at *4 ("While redaction of personally identifiable information may be an adequate remedy in some circumstances, nearly every page of the attached medical records at issue here is replete with not only the children's names, but detailed medical histories, treatment plans, and doctors' notes … such that redaction is not practical.").

Because of the specific harm that comes from disclosure to the government itself, DOJ's related suggestion that the District Court "could have issued a protective order rather than quash," Gov't Br. 47, fares no better. *Supra* pp. 44–45.

Moreover, a protective order presupposes a lawful subpoena; it is no answer to a subpoena that lacks statutory authorization and was issued in bad faith.

In sum, children's privacy interests in their most sensitive health and personal information are weighty. Against that, the Government's platitudes about investigative need do not outweigh those interests.

IV. THE DISTRICT COURT CORRECTLY EXERCISED ITS DISCRETION TO QUASH THE ENTIRE SUBPOENA AND IT PROPERLY ISSUED AN INJUNCTION

DOJ argues as a fallback that the District Court improperly issued an injunction and quashed the subpoena in full. Gov't Br. 47–50. As to the Child Advocate, DOJ argues that quashal of the subpoena in full is unwarranted because its subpoena seeks more than just the medical records of patients.[13] Gov't Br. 49–50. These arguments fail.

Courts may quash or modify subpoenas that are unlawful, unreasonable, or unconstitutional, whether or not every affected individual is formally before the court. *In re Admin. Subpoenas to Children's Hosps.*, No. 8:26-cv-01834-JRR, 2026 WL 1660098, at *10 (D. Md. June 9, 2026) ("where a movant has standing to challenge the subpoena, the quashal scope is not necessarily tied to the particular

[13] DOJ has not argued in this Court that the Child Advocate lacks Article III standing. DOJ also conceded below that it did not "dispute injury in fact here as to the Child Advocate's ability to raise the interests of [children in state care or custody]." Add.3.

movant, but rather to the lawfulness of the challenged subpoena"); *In re Grand Jury Subpoena: Subpoena Duces Tecum*, 829 F.2d 1291, 1297 (4th Cir. 1987) ("The subpoena duces tecum 'remains at all times under the control and supervision of a court.'" (quoting *United States v. Doe*, 457 F.2d 895, 898 (2d Cir. 1972))). Limiting relief to named challengers would harm the privacy interests of similarly situated patients based solely on their inability to file a lawsuit and to retain counsel. The District Court correctly exercised its discretion to quash the entirety of the plainly unlawful subpoena, even though not every affected child was a party. *UPMC*, 2025 WL 3724705, at *3 (granting motion to quash subpoena as to all patients).

Nor has DOJ articulated any reason for tailoring relief to just the individual patient records. Tailoring of the quashal order may be appropriate where a subpoena is overbroad but otherwise lawful. But a quashal in full is required where, as here, a subpoena exceeds statutory authority, lacks a proper purpose, and violates privacy protections. *In re Subpoena Duces Tecum*, 228 F.3d at 349.

Additionally, as the District Court found, any limiting of the subpoena to records pertaining exclusively to children whose rights the Child Advocate represents is unsupported. Add.50. Reviewing each responsive record and segregating the records of patients in state custody would be highly burdensome and impractical, *Hodges*, 2025 WL 894936, at *4, and the "process would itself expose

precisely the sensitive intersection of information" relating to gender-affirming care patients that "are vulnerable wards of the state." Add.50.

The court was also well within its discretion to issue the injunction. As discussed at length above, *supra* pp. 16–17, DOJ's enforcement action in Texas was a blatant forum-shopping maneuver that dragged RIH to a distant, unrelated court. DOJ has turned to the same Texas court in two other instances, seeking and obtaining grand jury subpoenas in that court against hospitals located in California and New York. The patients who received care at those hospitals and their parents have sought injunctions in federal courts in their home states, and those courts also have issued injunctions to prevent the receipt of records in Texas. *Z.A.*, 2026 WL 1907181, at *15, 25; *Coe*, 2026 WL 1815507, at *2; *see also Coe* Transcript, *supra* p. 19, at 17–18, 30. As the District Court for the Northern District of California determined, "[g]iven DOJ's persistence in pursuing transgender minors' patient data, there is little reason to think that the grand jury subpoena will be DOJ's last such effort." *Z.A.*, 2026 WL 1907181, at *15. It therefore granted an injunction because "[a] motion to quash could not enjoin those new efforts; equitable relief can." *Id.*; *see also Coe* Transcript, *supra* p. 19, at 18 ("Only an order enjoining the government from seeking plaintiffs' identifying and sensitive personal information is sufficiently protective of plaintiffs' privacy interests and enough to afford complete relief to plaintiffs in this case.").

DOJ argues that the District Court's injunction is deficient because it did not directly reference the four-factor test for injunctions. Gov't Br. 48–49. DOJ puts form over substance. The District Court found an injunction necessary to enforce its quashal order in a well-reasoned opinion that considers factors that plainly overlap with the four-factor test for an injunction. *See A.W. Chesterton Co., Inc. v. Chesterton*, 128 F.3d 1, 5 (1st Cir. 1997) ("(1) plaintiffs prevail on the merits; (2) plaintiffs would suffer irreparable injury in the absence of injunctive relief; (3) the harm to plaintiffs would outweigh the harm the defendant would suffer from the imposition of an injunction; and (4) the public interest would not be adversely affected by an injunction"). The District Court made extensive findings about the merits of the plaintiffs' claims (factor 1), the "very real—and likely irreparable—harm to the children,"[14] Add.49 (factor 2), and the lack of harm to DOJ given its failure to show "*how* this information is related to its legitimate authority to conduct its investigation" (factors 3 and 4). *Id*; *see also Nken v. Holder*, 556 U.S. 418, 435 (2009) ("The third and fourth factors . . . merge when the Government is the opposing party"). The fact that the District Court did not make explicit reference to these four factors does not defeat the validity of its underlying reasoning. *See*

[14] DOJ quotes this statement out of context to suggest that the District Court conflated the standards for permanent or preliminary injunctions. Gov't Br. 49. But the context reveals that the District Court was identifying likely harm if "unfettered, compelled disclosure" were to occur, not the likelihood of *finding* irreparable harm after a consideration of the merits. Add.49–50.

Conservation L. Found., Inc. v. Busey, 79 F.3d 1250, 1271 (1st Cir. 1996) ("Although the district court did not discuss its factual or legal reasons for concluding that the plaintiffs did not suffer irreparable harm, its lengthy opinion provides a detailed discussion of the factual and legal bases for its substantive conclusions.").

The District Court acted well within its discretion, and on the basis of well-supported factual and legal determinations, in quashing the subpoena and entering the injunction against DOJ.

CONCLUSION

The Court should affirm the District Court's judgment.

July 17, 2026

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that the forgoing brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B)(i) because, excluding the parts of the document exempted by FRAP 32(f), it contains 12,966 words. The brief complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5) and (6); it has been prepared using Microsoft Word in proportionally spaced 14-point Times New Roman typeface.

/s/ Paul R.Q. Wolfson
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ADDENDUM

18 U.S.C. § 24. Definitions relating to Federal health care offense (a) As used in this title, the term "Federal health care offense" means a violation of, or a criminal conspiracy to violate-- A2

18 U.S.C. § 3486(a)(1)(A)(i)(I). Administrative subpoenas (a) Authorization. A3

21 U.S.C. § 331. Prohibited acts A5

21 U.S.C. § 333(a)(2). Penalties A8

21 U.S.C. § 352. Misbranded drugs and devices A9

21 U.S.C. § 353. Exemptions and consideration for certain drugs, devices, and biological products A11

21 U.S.C. § 396. Practice of medicine A13

31 U.S.C. § 3729. False claims A14

R.I. Gen. Laws § 23-101-2. Definitions As used in this chapter, the followings words shall have the following meanings unless the context clearly indicates otherwise: A15

R.I. Gen. Laws 23-101-5. Testimony, documents, and subpoenas. A16

R.I. Gen. Laws § 42-73-1. Establishment. There is created the child advocate office. A17

R.I. Gen. Laws § 42-73-7. Duties of advocate. The child advocate shall perform the following duties: A17

45 C.F.R. § 164.512. Uses and disclosures for which an authorization or opportunity to agree or object is not required. A18

Fed. R. Civ. P. 45. Subpoena A20

18 U.S.C. § 24. Definitions relating to Federal health care offense

(a) As used in this title, the term "Federal health care offense" means a violation of, or a criminal conspiracy to violate--

(1) section 669, 1035, 1347, or 1518 of this title or section 1128B of the Social Security Act (42 U.S.C. 1320a-7b);

(2) section 287, 371, 664, 666, 1001, 1027, 1341, 1343, 1349, or 1954 of this title section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331), or section 501 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1131), or section 411, 518, or 511 of the Employee Retirement Income Security Act of 1974,, [sic] if the violation or conspiracy relates to a health care benefit program.

(b) As used in this title, the term "health care benefit program" means 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. § 3486(a)(1)(A)(i)(I). Administrative subpoenas

(a) Authorization.

(1)

(A) In any investigation of--

(i)(I) a Federal health care offense; or (II) a Federal offense involving the sexual exploitation or abuse of children, the Attorney General;

* * * * *

may issue in writing and cause to be served a subpoena requiring the production and testimony described in subparagraph (B).

* * * * *

(5) At any time before the return date specified in the summons, the person or entity summoned may, in the United States district court for the district in which that person or entity does business or resides, petition for an order modifying or setting aside the summons, or a prohibition of disclosure ordered by a court under paragraph (6).

* * * * *

(7) A summons issued under this section shall not require the production of anything that would be protected from production under the standards applicable to a subpoena duces tecum issued by a court of the United States.

* * * * *

(c) Enforcement. In the case of contumacy by or refusal to obey a subpoena issued to any person, the Attorney General may invoke the aid of 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, to compel compliance with the subpoena. The court may issue an order

requiring the subpoenaed person to appear before the Attorney General to produce records, if so ordered, or to give testimony concerning the production and authentication of such records. Any failure to obey the order of the court may be punished by the court as a contempt thereof. All process in any such case may be served in any judicial district in which such person may be found.

21 U.S.C. § 331. Prohibited acts

The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce.

(c) The receipt in interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

(d) The introduction or delivery for introduction into interstate commerce of any article in violation of section 404, 415, 505, 564, or 607 [21 USCS § 344, 350d, 355, 360bbb-3, or 364c].

(e) The refusal to permit access to or copying of any record as required by section 412, 414, 417(j), 416, 504, 564, 605, 703, 704(a), 760, or 761 [21 USCS § 350a, 350c, 350f(j), 350e, 354, 360bbb-3, 364a, 373, 374(a), 379aa, or 379aa-1]; or the failure to establish or maintain any record, or make any report, required under section 412, 414(b), 417, 416, 504, 505(i) or (k), 512(a)(4)(C), 512 (j), (l) or (m), 572(i), 515(f), 519, 564, 605, 611, 760, 761, 909, or 920 [21 USCS § 350a, 350c(b), 350f, 350e, 354, 355(i) or (k), 360b(a)(4)(C), 360b(j), (l), or (m), 360ccc-1(i), 360e(f), 360i, 360bbb-3, 364a, 364g, 379aa, 379aa-1, 387i, or 387t] or the refusal to permit access to or verification or copying of any such required record; or the violation of any recordkeeping requirement under section 204 of the FDA Food Safety Modernization Act [21 USCS § 2223] (except when such violation is committed by a farm).

(f) The refusal to permit entry or inspection as authorized by section 704 [21 USCS § 374].

(g) The manufacture, within any Territory of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

(h) The giving of a guaranty or undertaking referred to in section 303(c)(2) [21 USCS § 333(c)(2)], which guaranty or undertaking is false, except by a person who relied upon a guaranty or undertaking to the same effect signed by, containing the

name and address of, the person residing in the United States from whom he received in good faith the food, drug, device, tobacco product, or cosmetic; or the giving of a guaranty or undertaking referred to in section 303(c)(3) [21 USCS § 333(c)(3)], which guaranty or undertaking is false.

(i)

(1) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated under the provisions of section 404 or 721 [21 USCS § 344 or 379e].

(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render such drug a counterfeit drug.

(3) The doing of any act which causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug.

(j) The using by any person to his own advantage or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this Act [21 USCS §§ 301 et seq.], any information acquired under authority of section 404, 409, 412, 414, 505, 510, 512, 513, 514, 515, 516, 518, 519, 520, 571, 572, 573, 704, 708, 721, 904, 905, 906, 907, 908, 909, or 920(b) [21 USCS § 344, 348, 350a, 350c, 355, 360, 360b, 360c, 360d, 360e, 360f, 360h, 360i, 360j, 360eee, 360eee-1, 360eee-2, 374, 379, 379e, 387d, 387e, 387f, 387g, 387h, 387i, or 387t(b)], concerning any method or process which as a trade secret is entitled to protection; or the violating of section 408(i)(2) [21 USCS § 346a(i)(2)] or any regulation issued under that section.[.] This paragraph does not authorize the withholding of information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee or subcommittee of such committee or any joint committee of Congress or any subcommittee of such joint committee.

(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, tobacco product, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

* * * * *

21 U.S.C. § 333(a)(2). Penalties

(a) Violation of section 331 of this title; second violation; intent to defraud or mislead

(1) Any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than $1,000, or both.

(2) Notwithstanding the provisions of paragraph (1) of this section, if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $10,000, or both.

* * * * *

21 U.S.C. § 352. Misbranded drugs and devices

A drug or device shall be deemed to be misbranded—

(a) False or misleading label.

> (1) If its labeling is false or misleading in any particular. Health care economic information provided to a payor, formulary committee, or other similar entity with knowledge and expertise in the area of health care economic analysis, carrying out its responsibilities for the selection of drugs or devices for coverage or reimbursement, shall not be considered to be false or misleading under this paragraph if the health care economic information relates to an indication approved under section 505, 510(k), 513(f)(2), or 515 of this Act [21 USCS §§ 355, 360(k), 360c(f)(2), or 360e] or section 351 of the Public Health Service Act [21 USCS § 360aaa] for such drug or device, is based on competent and reliable scientific evidence, and includes, where applicable, a conspicuous and prominent statement describing any material differences between the health care economic information and the labeling approved for the drug or device under section 505, 510(k), 513(f)(2), or 515 of this Act [21 USCS §§ 355, 360(k), 360c(f)(2), or 360e] or section 351 of the Public Health Service Act [21 USCS § 360aaa]. The requirements set forth in section 505, 510(k), 513(f)(2), or 515 of this Act [21 USCS §§ 355, 360(k), 360c(f)(2), or 360e] or section 351 of the Public Health Service Act [21 USCS § 360aaa] shall not apply to health care economic information provided to such a payor, committee, or entity in accordance with this paragraph. Information that is relevant to the substantiation of the health care economic information presented pursuant to this paragraph shall be made available to the Secretary upon request.

* * * * *

(b) Package form; Contents of label. If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: Provided, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

* * * * *

(f) Directions for use and warnings on label. Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, except that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement. Required labeling for prescription devices intended for use in health care facilities or by a health care professional and required labeling for in vitro diagnostic devices intended for use by health care professionals or in blood establishments may be made available solely by electronic means, provided that the labeling complies with all applicable requirements of law, and that the manufacturer affords such users the opportunity to request the labeling in paper form, and after such request, promptly provides the requested information without additional cost.

* * * * *

21 U.S.C. § 353. Exemptions and consideration for certain drugs, devices, and biological products

(a) Regulations for goods to be processed, labeled, or repacked elsewhere. The Secretary is hereby directed to promulgate regulations exempting from any labeling or packaging requirement of this Act [21 USCS §§ 301 et seq.] drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such drugs and devices are not adulterated or misbranded under the provisions of this Act [21 USCS §§ 301 et seq.] upon removal from such processing, labeling, or repacking establishment.

(b) Prescription by physician; exemption from labeling and prescription requirements; misbranded drugs; compliance with narcotic and marihuana laws.

(1) A drug intended for use by man which—

(A) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or

(B) is limited by an approved application under section 505 [21 USCS § 355] to use under the professional supervision of a practitioner licensed by law to administer such drug,

shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

(2) 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 502 [21 USCS § 352], except paragraphs (a), (i)(2) and (3), (k), and (l) [21 USCS § 352(a), (i)(2), (3), (k), (l)], and the packaging requirements of paragraphs (g), (h) and (p) [21 USCS § 352(g), (h), (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. This exemption shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail, or to a drug dispensed in violation of paragraph (1) of this subsection.

21 U.S.C. § 396. Practice of medicine

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. This section shall not limit any existing authority of the Secretary to establish and enforce restrictions on the sale or distribution, or in the labeling, of a device that are part of a determination of substantial equivalence, established as a condition of approval, or promulgated through regulations. Further, this section shall not change any existing prohibition on the promotion of unapproved uses of legally marketed devices.

* * * * *

31 U.S.C. § 3729. False claims

(a) Liability for certain acts.

(1) In general. Subject to paragraph (2), any person who—

(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

(C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G);

(D) has possession, custody, or control of property or money used, or to be used, by the Government and knowingly delivers, or causes to be delivered, less than all of that money or property;

(E) is authorized to make or deliver a document certifying receipt of property used, or to be used, by the Government and, intending to defraud the Government, makes or delivers the receipt without completely knowing that the information on the receipt is true;

(F) knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the Government, or a member of the Armed Forces, who lawfully may not sell or pledge property; or

(G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government,

is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-410), plus 3 times the amount of damages which the Government sustains because of the act of that person.

* * * * *

R.I. Gen. Laws § 23-101-2. Definitions

As used in this chapter, the followings words shall have the following meanings unless the context clearly indicates otherwise:

* * * * *

(4) "Gender-affirming healthcare services" means all supplies, care, and services of a medical, behavioral health, mental health, surgical, psychiatric, therapeutic, diagnostic, preventive, rehabilitative, or supportive nature, including medication, relating to the treatment of gender dysphoria and gender incongruence in accordance with the accepted standard of care as defined by major medical professional organizations and agencies with expertise in the field of gender-affirming health care, including the Standards of Care for the Health of Transgender and Gender Diverse People, Version 8, or subsequent version, published by the World Professional Association for Transgender Health. "Gender-affirming healthcare services" does not include conversion therapy as defined by § 23-94-2.

* * * * *

(8) "Legally protected healthcare activity" means:

> **(iii)** "Legally protected healthcare activity" does not include any conduct that could form the basis of a civil, criminal, or administrative action under the laws of this state had the course of conduct that forms the basis for liability occurred entirely within this state and/or in violation of Rhode Island law.

* * * * *

R.I. Gen. Laws 23-101-5. Testimony, documents, and subpoenas.

(a) Notwithstanding any other provision in this chapter or court rule to the contrary, except as required by federal law, a court may not order a person who is domiciled or found within this state to give testimony or a statement or produce documents or other things with any proceeding in a tribunal outside this state concerning hostile litigation.

(b) Any person in this state upon whom a subpoena seeking information concerning legally protected healthcare activity is served by any state or federal court in connection with hostile litigation, may move to modify or quash such subpoena on any grounds provided by court rule, statute, or on the grounds that the subpoena is inconsistent with the public policy as set out in this act.

(c) Except as required by federal law, a judicial officer may not issue a summons in a case where prosecution is pending concerning legally protected healthcare activity, or aiding and assisting legally protected healthcare activity, or where a grand jury investigation concerning legally protected healthcare activity or aiding and assisting legally protected healthcare activity has commenced or is about to commence for a criminal violation of a law of such other state unless the acts forming the basis of the prosecution or investigation would also constitute an offense if occurring entirely in this state.

* * * * *

R.I. Gen. Laws § 42-73-1. Establishment.
There is created the child advocate office.

R.I. Gen. Laws § 42-73-7. Duties of advocate.
The child advocate shall perform the following duties:

* * * * *

(6) Take all possible action including, but not limited to, programs of public education, legislative advocacy, and formal legal action, to secure and ensure the legal, civil, and special rights of children subject to the provisions of § 42-73-9.1 and chapter 72 of this title;

* * * * *

45 C.F.R. § 164.512. Uses and disclosures for which an authorization or opportunity to agree or object is not required.

Except as provided by § 164.502(a)(5)(iii), a covered entity may use or disclose protected health information without the written authorization of the individual, as described in § 164.508, or the opportunity for the individual to agree or object as described in § 164.510, in the situations covered by this section, subject to the applicable requirements of this section and § 164.509. When the covered entity is required by this section to inform the individual of, or when the individual may agree to, a use or disclosure permitted by this section, the covered entity's information and the individual's agreement may be given verbally.

* * * * *

(f) Standard: Disclosures for law enforcement purposes. A covered entity may disclose protected health information for a law enforcement purpose to a law enforcement official if the conditions in paragraphs (f)(1) through (f)(6) of this section are met, as applicable.

(1) Permitted disclosures: Pursuant to process and as otherwise required by law. A covered entity may disclose protected health information:

* * * * *

(ii) In compliance with and as limited by the relevant requirements of:

* * * * *

(C) An administrative request for which response is required by law, including an administrative subpoena or summons, a civil or an authorized investigative demand, or similar process authorized under law, provided that:

(1) The information sought is relevant and material to a legitimate law enforcement inquiry;

(2) The request is specific and limited in scope to the extent reasonably practicable in light of the purpose for which the information is sought; and

(3) De-identified information could not reasonably be used.

* * * * *

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* * * * *

(c) Place of Compliance.

* * * * *

(2) *For Other Discovery***.** A subpoena may command:

(A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and

* * * * *

(d) Protecting a Person Subject to a Subpoena; Enforcement.

* * * * *

(3) *Quashing or Modifying a Subpoena*.

(A) *When Required*. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:

* * * * *

(iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
(iv) subjects a person to undue burden.

* * * *

CERTIFICATE OF SERVICE

I certify that on July 17, 2026, the foregoing was filed using the Court's CM/ECF system. All participants in the case are registered CM/ECF users and will be served electronically via that system.

/s/ Paul R.Q. Wolfson
Paul R.Q. Wolfson