

No. 26-1568

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

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

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CHILD ADVOCATE FOR RHODE ISLAND, et al.,

Petitioners-Appellees,

v.

UNITED STATES OF AMERICA,

Respondent-Appellant.

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

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**BRIEF FOR APPELLANT**

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### **REASONS WHY ORAL ARGUMENT SHOULD BE HEARD**

Oral argument is necessary in this case. The district court quashed a facially valid subpoena that another district court had already enforced and enjoined the government from, among things, seeking and receiving documents responsive to that subpoena. Both the litigants in this case and the Court would benefit from a thorough vetting of the issues at oral argument.

## INTRODUCTION

This case involves a district court's remarkable departure from basic principles of comity and respect for the judgments of coordinate federal courts. As part of an investigation into potential violations of the Federal Food, Drug, and Cosmetic Act (FDCA), the Department of Justice issued an administrative subpoena to Rhode Island Hospital (RIH). About ten months after the subpoena's issuance, RIH had produced only one document, so the Department moved to enforce the subpoena in the Northern District of Texas, a district in which the investigation is being conducted. *See* 18 U.S.C. § 3486(c). A judge in the Northern District of Texas quickly entered an enforcement order and directed RIH to comply within fourteen days.

What followed in the District of Rhode Island was a remarkable effort to nullify the Northern District of Texas's judgment. First, the Child Advocate for the State of Rhode Island filed a motion to quash the same subpoena the Texas court had already enforced. The district court then permitted RIH to intervene and file its own motion to quash. In the meantime, the Texas court, and later the Fifth Circuit, denied RIH's motions to stay the Texas court's enforcement order pending appeal. Rather than defer to the first-filed action in Texas, the district court granted both motions to quash and further enjoined the government from receiving or reviewing certain documents the Texas court had ordered RIH to produce in response to the subpoena.

This disregard for basic principles of judicial comity and respect for the judgment of coordinate courts is reason enough for reversal. But on its merits, the district court's

reasoning fares no better. Under this administration, the Department of Justice (Department) has made it a priority to investigate potential violations of the FDCA and other federal health care offenses in connection with pediatric gender medicine. The Department has a substantial basis to believe that various actors in the industry, from hospitals to pharmaceutical companies, have violated federal law. Given that the practices at issue are “associated with harmful—and sometimes irreversible—risks,” *United States v. Skremetti*, 605 U.S. 495, 517 (2025), the Department has made ensuring compliance with federal law in this area a particular focus.

The district court, however, held that the Department could not investigate potential FDCA violations in this space based on its view that no FDCA liability could arise under one particular legal theory. The court did not grapple with precedent from this Court explaining that such pre-adjudication of theories of liability is improper in considering the validity of a subpoena, did not acknowledge that the Department has disclaimed the particular theory on which the court focused, and ignored both that RIH could be a witness to misconduct by others and additional theories of potential FDCA liability the Department did, in fact, articulate. Based on those fundamental errors, the district court went on to conclude that the government’s only purpose for the subpoena was an improper one and that the subpoena trenched on the constitutional rights of patients. Those holdings fall with the court’s erroneous view of the validity of the underlying subpoena. They are also erroneous on their own terms—and threaten to

immunize an entire industry from federal investigation while laying the groundwork for delaying or thwarting future FDCA investigations.

The safety and propriety of gender-related interventions for minors is a topic of “fierce scientific and policy debates.” *Skermetti*, 605 U.S. at 525. But that political backdrop does not excuse federal judges from complying with time-honored constraints on their authority. Nor does it excuse participants in this industry from complying with the same federal health care laws as everyone else. And it certainly should not shield them from ordinary criminal investigations or duly authorized subpoenas. This Court should reverse the order below.

### **STATEMENT OF JURISDICTION**

The district court denied the government’s motion to transfer on May 7, 2026, and then denied the renewed motion on May 12, 2026. The district court quashed the subpoena, enjoined the government, and entered judgment on May 13, 2026. The government filed a timely notice of appeal on May 14, 2026. *See* Fed. R. App. P. 4(a)(1)(B) (60-day time limit). On the same day the government noticed its appeal, the district court amended its order and slightly expanded its injunction. The government therefore filed a second timely notice of appeal on May 14, 2026. *See id.* This Court docketed this second notice as an amended notice of appeal. This Court has appellate jurisdiction under 28 U.S.C. § 1291.

## STATEMENT OF THE ISSUE

Whether the district court erred in quashing a subpoena to RIH expressly authorized by 18 U.S.C. § 3486, that another district court had already enforced, on the bases that the Department failed to show a proper purpose, issued the subpoena for an improper purpose, and sought records that, if produced, would violate patients' Fourteenth Amendment right to informational privacy.

## STATEMENT OF THE CASE

### A. Statutory Background

#### 1. The Federal Food, Drug, and Cosmetic Act

In 1938, Congress passed, and President Franklin D. Roosevelt signed into law, the FDCA. The FDCA's "overriding purpose [is] to protect the public health." *United States v. Bacto-Unidisk*, 394 U.S. 784, 798 (1969). Because the FDCA's purpose should "infuse construction of the" FDCA, *United States v. Dotterweich*, 320 U.S. 277, 280 (1943), courts give the FDCA a "liberal construction" that furthers protection of the public health, including criminal enforcement, *Bacto-Unidisk*, 394 U.S. at 798.

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

A drug manufacturer obtains FDA approval for a new drug through a new drug application (NDA) that demonstrates its drug is safe and effective for each of its intended uses. 21 U.S.C. § 355(a). When FDA approves a drug, it approves it as safe and effective for particular use(s) in the NDA. *See id.* § 352(f); 21 C.F.R. § 201.5. In addition, for prescription drugs, FDA must also approve elements of the drug’s labeling, such as the prescribing information, which specifies, among other things, the essential scientific information needed for the safe and effective use of the drug for its FDA-approved uses and adequate directions for those uses. 21 U.S.C. §§ 352(f)(1), 355; *see* 21 C.F.R. §§ 201.5, 201.55-201.57, 201.100. Because a drug that is safe and effective for one use may be neither safe nor effective for others, FDA approval extends only to the uses specified in a drug’s approved application and labeling. 21 U.S.C. § 355(d).

The FDCA generally prohibits “misbranding” a drug. *See* 21 U.S.C. § 352; *id.* § 331(a)-(c), (k). A drug may be misbranded if, among other things, its labeling is false or misleading, *id.* § 352(a), or if its labeling does not bear adequate directions for its intended use, *id.* § 352(f)(1). “Intended use” means the “objective intent of the persons legally responsible for the labeling of an article (or their representatives).” 21 C.F.R. § 201.128. Such intent “may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives.” *Id.* And the “intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer.” *Id.* If, for example, a seller “intends an article for different uses than those intended by the person from whom he or she received the

article,” then the “seller is required to supply adequate labeling in accordance with the new intended uses.” *Id.*

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

Given the FDCA’s protective purpose, misdemeanor violations of the FDCA are punishable on a strict liability basis, without any proof of criminal intent. *See* 21 U.S.C. §§ 331, 333(a)(1); *United States v. Park*, 421 U.S. 658, 672-73 (1975); *United States v. Wiesenfeld Warehouse Co.*, 376 U.S. 86, 91 (1964). For example, if a drug manufacturer or other person causes the distribution of an approved drug for an unapproved use, the manufacturer or other person could be charged with misbranding the drug or distributing a drug with labeling that lacks adequate directions for its intended uses. 21 U.S.C. §§ 331(a)-(c), (k), 352(f)(1). Where a violator has an intent to defraud or mislead, an FDCA violation may be punishable as a felony. *Id.* § 333(a)(2).

Misbranding, via false or misleading “written, printed, or graphic matter” on a drug, container, or wrapper or that supplements, explains, or is designed for use with a

drug, is a classic FDCA violation. *See, e.g., United States v. Marschall*, 82 F.4th 774, 779 (9th Cir. 2023) (quotation omitted) (upholding misbranding conviction of the defendant who shipped drugs with false informational sheets). Drug manufacturers and distributors also can be convicted of FDCA violations, for example, for shipping drugs in interstate commerce intending that they be used off-label, with that intent frequently shown through evidence of promoting the drugs for such uses. *See* 21 C.F.R. § 201.128 (intent may “be shown by labeling claims, advertising matter,” “oral or written statements,” and “circumstances in which the [drug] is, with the knowledge of” certain persons, “offered or used for a purpose for which it is neither labeled nor advertised”); *see, e.g., Judgment, United States v. Cephalon, Inc.*, No. 2:08-cr-598 (E.D. Pa. Oct. 10, 2008), Dkt. 11 (conviction of manufacturer for promoting three drugs for off-label uses). Thus, in such prosecutions, the government may rely on evidence of communications between pharmaceutical sales representatives and prescribing physicians and recommendations to doctors of diagnostic codes to mask off-label prescriptions to ensure payment for unapproved uses. *See, e.g., Information at 4-5, ¶¶ 12-18, United States v. Cephalon, Inc.*, No. 2:08-cr-598 (E.D. Pa. Sep. 29, 2008), Dkt. No. 1; Press Release, U.S. Dep’t of Just., *Eli Lilly and Company to Pay U.S. \$36 Million Relating to Off-Label Promotion* (Dec. 21, 2005), <https://perma.cc/2Y64-FUK5> (announcing guilty plea of drug manufacturer involving illegal off-label promotion and highlighting evidence that

the defendant “[e]ncourag[ed] sales representatives . . . to send unsolicited medical letters to promote the drug for an unapproved use to doctors”).<sup>1</sup>

## 2. The Health Insurance Portability and Accountability Act of 1996 and HIPAA Subpoenas

In 1996, Congress passed, and President Clinton signed into law, the Health Insurance Portability and Accountability Act (HIPAA). As relevant here, the statute permits the Attorney General to issue a subpoena—often referred to as a “HIPAA subpoena”—to investigate federal health care offenses. 18 U.S.C. § 3486(a)(1)(A)(i)(I). A federal health care offense includes a “violation of, or a criminal conspiracy to violate” 21 U.S.C. § 331, “if the violation or conspiracy relates to a health care benefit program,” 18 U.S.C. § 24(a)(2). And a “health care benefit program” is “any public or private plan or contract, affecting commerce, under which any medical benefit, item, or service is provided to any individual, and includes any individual or entity who is providing a medical benefit, item, or service for which payment may be made under the plan or contract.” *Id.* § 24(b). The Department is therefore expressly empowered to use

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<sup>1</sup> There are many similar examples. *See, e.g.*, Press Release, U.S. Dep’t of Just., *Genzyme Corporation to Pay \$32.5 Million to Resolve Criminal Liability Relating to Septrafilm* (Sep. 3, 2015), <https://perma.cc/P7AT-MUVT> (highlighting evidence that manufacturer encouraged off-label uses by distributing promotional materials citing a misleading scientific study); *United States v. Endo Pharms., Inc.*, No. 1:14-CR-66 (N.D.N.Y. Feb. 21, 2014), Dkt. 2 (deferred prosecution agreement regarding drug manufacturer’s off-label promotion of drug, highlighting evidence that manufacturer distributed a misleading scientific study and promoted off-label uses at educational presentations for physicians).

a HIPAA subpoena to investigate violations of the FDCA and related conspiracies, if the violation or conspiracy relates to products or services that might ultimately be paid for by a private or public health insurance program.

**B. Factual Background**

**1. Off-Label Provision of Puberty Blockers and Cross-Sex Hormones to Treat Gender Dysphoria**

This case involves a HIPAA subpoena that the Department issued in connection with an investigation into the provision of certain prescription drugs to minors with gender dysphoria. *See* JA60-86. These include prescription drugs that suppress the production of sex hormones to delay puberty (commonly referred to as “puberty blockers”) and cross-sex hormones meant to induce physical changes to alter the child’s secondary sexual characteristics to resemble those typically seen in the opposite sex and less like the individual’s biological sex. *See United States v. Skermetti*, 605 U.S. 495, 503-04 (2025) (describing use of these drugs). Although these drugs are approved by FDA for some uses, FDA has not determined that any of these drugs are safe or effective for the treatment of gender dysphoria, nor has FDA approved any of these prescription drugs for the treatment of gender dysphoria or any other psychiatric disorder.

The use of these drugs in the treatment of gender dysphoria in minors is highly controversial—the subject of “fierce scientific and policy debates.” *Skermetti*, 605 U.S. at 525. As the Supreme Court recently explained, “health authorities in a number of European countries have raised significant concerns regarding the potential harms

associated with using puberty blockers and hormones to treat transgender minors,” and “more than 20 States have enacted laws banning the provision of sex transition treatments to minors.” *Id.* at 504-05.

Shortly after entering office, President Trump issued Executive Orders weighing in on these and related issues. Executive Order 14168 establishes a policy “to recognize two sexes, male and female,” and states that a contrary “gender ideology” is harmful and that the two “sexes are not changeable and are grounded in fundamental and incontrovertible reality.” Exec. Order No. 14,168, § 2, 90 Fed. Reg. 8615, 8615 (Jan. 30, 2025). Executive Order 14187 establishes a federal policy not to “fund, sponsor, promote, assist, or support the so called ‘transition’ of a child from one sex to another.” Exec. Order No. 14,187, § 1, 90 Fed. Reg. 8771, 8771 (Feb. 3, 2025).

Since issuing those orders, the White House has praised hospitals’ decisions to “downsize or eliminate their so-called ‘gender-affirming care’ programs,” explaining that the latter executive order was “already having its intended effect — preventing children from being maimed and sterilized by adults perpetuating a radical, false claim that they can somehow change a child’s sex.” Press Release, The White House, *President Trump Is Delivering on His Commitment to Protect Our Kids* (Feb. 3, 2025), <https://perma.cc/K7DT-J428>.

## **2. The Department’s FDCA Investigation**

The Department has taken steps to investigate potential violations of the FDCA in connection with the provision of puberty blockers and cross-sex hormones to

minors. In April, Attorney General Bondi directed the Department “to investigate and hold accountable medical providers and pharmaceutical companies that mislead the public about the long-term side effects of chemical and surgical mutilations.” Memorandum from the Att’y Gen., Off. of the Att’y Gen., to Select Component Heads 4 (Apr. 22, 2025), <https://perma.cc/N345-R8QL> (Bondi Memo). The Bondi Memo directed the Department to “undertake appropriate investigations of any violations of the [FDCA] by manufacturers and distributors engaged in misbranding by making” purported “false claims about the on- or off-label use of puberty blockers, sex hormones,” and similar drugs. *Id.*

In June, Assistant Attorney General for the Civil Division Brett Shumate issued a memorandum stating that “[t]he Civil Division will use all available resources to prioritize investigations of doctors, hospitals, pharmaceutical companies, and other appropriate entities . . . [including] possible violations of the [FDCA] and other laws by (1) pharmaceutical companies that manufacture drugs used in connection with so-called gender transition and (2) dealers such as online pharmacies suspected of illegally selling such drugs.” Memorandum from Brett A. Shumate, Assistant Att’y Gen., U.S. Dep’t of Just., to Civ. Div. Emps. 2-3 (June 11, 2025), <https://perma.cc/AMR2-U7W3> (Shumate Memo). This memo also expressed an intention to investigate potential violations of existing federal statutes.

Based on information from whistleblowers and experts, there may be violations of federal law associated with gender-related treatments for minors. For example, the

marketing or promotion of puberty blockers and cross-sex hormones (the drugs at the center of the investigation) for treating gender dysphoria in minors—an unapproved use—could constitute illegal misbranding under the FDCA. Misleading or deceiving minors and their parents about the risks of gender-related treatments could similarly violate the FDCA.

These are not mere technical violations. Bypassing the drug approval process carries real health consequences for children. After surveying the evidence, the United States Department of Health and Human Services (HHS) has identified harms associated with these drugs—including infertility and sterility, impaired bone density development, cardiovascular and metabolic disease, and psychiatric conditions—and determined that “[a]vailable evidence cannot support determinations regarding the effectiveness of these medical interventions for improving mental health or alleviating gender dysphoria symptoms in children and adolescents.” Admiral Brian Christine, Assistant Sec’y for Health, U.S. HHS, *Evidence-Based Care for Children and Adolescents with Gender Dysphoria* 1 (Dec. 18, 2025), <https://perma.cc/ZH22-R5GH> (HHS Statement).

### **3. The Subpoena to RIH**

Through the “Gender and Sexuality Program at Hasbro’s Children’s Hospital,” RIH’s physicians and providers “administer comprehensive, multi-disciplinary gender-affirming care.” JA132. These services for minors include “hormone therapy.” *Id.* Thus, it is undisputed that RIH is involved in the provision of puberty blockers and cross-sex hormones for unapproved uses.

The Civil Division issued a HIPAA subpoena to RIH in July 2025 seeking information relevant to its investigation into potential violations of the FDCA in connection with the provision of puberty blockers and cross-sex hormones to minors. JA60-86. The subpoena explained that it seeks information to investigate “Federal health care offenses as defined in 18 U.S.C. § 24(a),” JA60, and included 15 different requests for documents. The subpoena seeks documents and data relating to RIH’s provision of gender-related medical treatment, including medical records for patients prescribed puberty blockers or hormone therapy and documents relating to billing or coding practices, or insurance claims, for gender-related care. JA66-68. It also seeks communications with pharmaceutical manufacturers regarding the use of puberty blockers or hormones in connection with gender affirming care for minor patients. JA67.

At a minimum, given RIH’s self-described history of prescribing the drugs at the center of the Department’s investigation, RIH could be a witness to federal misconduct by other actors in the distribution chain, like pharmaceutical companies. And in a declaration filed in the Texas action, JA87-105, the Department also outlined information specific to RIH’s transgender health program that raised concerns related to the investigation. For example, between 2020 and 2025, RIH provided a first diagnosis of central precocious puberty to at least four minors age 12 or older—much older than children who are typically diagnosed with precocious puberty. JA100-01. Over that same period, the number of claims bearing a “endocrine disorder” diagnosis

code “experienced similar growth” as claims bearing a gender dysphoria code. JA101. And the director of RIH’s pediatric “Gender and Sexuality Program . . . was responsible for at least 14 insurance claims for RIH patients bearing an ‘endocrine disorder’ diagnosis code over the last decade—indeed more than his claims bearing a ‘gender dysphoria’ diagnosis code over the same period.” JA101. This data raises, at the least, a question as to the legitimacy of RIH’s billing practices and the presence of fraudulent intent. Also supporting the Department’s investigation is the fact that medical records obtained from similarly situated pediatric hospitals demonstrate a disparity between the disorder treated and the diagnosis code. JA101-02.

The subpoena’s return date was August 7, 2025. JA60. In early conversations with counsel for RIH, the Department “communicated that it would be willing to receive documents responsive to the subpoena past the return date but that it did not expect to extend that grace period beyond reason.” JA105. In turn, counsel for RIH communicated “several times that [RIH] intends to and would be producing responsive documents.” *Id.* On February 4, 2026, RIH provided a “list of search terms Brown Health has used in its efforts to identify records that are responsive to document requests 7-10 and 14 of the subpoena.” Add.52.<sup>2</sup>

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<sup>2</sup> As explained further below, the court did not order the Department to respond to RIH’s motion to quash. The Department thus did not file a response addressing RIH’s factual assertions about discussions between RIH and the Department. The quotation here is from a letter RIH sent to the Department by email on February 4. Although the letter is discussed in both RIH’s motion to quash (JA135) and the district

*Continued on next page.*

As of April 30, 2026, RIH had produced to the Department just one six-page document consisting of a list of names of hospital employees and certain drugs. JA105.

### **C. Prior Proceedings**

On April 30, more than eight months after the subpoena's response date, the Department moved to enforce the subpoena in the Northern District of Texas, where the Department is carrying on its investigation into FDCA violations in the gender medicine industry. *See* JA156-68. The Northern District of Texas signed an order enforcing the subpoena the same day, directing compliance by May 14. *In the Matter of Administrative Subpoena 25-1431-032*, No. 4:26-mc-6 (N.D. Tex. 2026 Apr. 30, 2026), Dkt. 2 at 1. RIH appealed and unsuccessfully moved for a stay pending appeal of the enforcement order in both the district court and the Fifth Circuit. *In the Matter of Administrative Subpoena 25-1431-032*, 4:26-mc-6 (N.D. Tex. May 10, 2026), Dkt. 12 (order denying stay pending appeal); *United States v. Rhode Island Hosp.*, 26-10431 (5th Cir. May 12, 2026), Dkt. 34 (same).

After the Northern District of Texas ordered the subpoena enforced, on May 4, the Child Advocate for Rhode Island—who represents children in the care, custody, or treatment of the Rhode Island Department of Children, Youth & Families (DCYF), JA30—moved to quash the same subpoena in the District of Rhode Island, citing the

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court's opinion, Add.32, and RIH filed as an exhibit the email conveying the letter, JA201, the letter itself was not included as an exhibit. We have attached the letter here for the Court's reference. *See* Add.53-56.

Northern District of Texas’s order as the cause for the district court’s immediate intervention. JA13-59. The District of Rhode Island ordered the Department to respond to the Advocate’s motion by May 7. Dkt. Text Order (May 4, 2026). The Department filed a response and separately moved to stay the case or transfer it to the Northern District of Texas. JA106-10. The district court denied that motion because the Child Advocate “was not a party to the Texas proceeding,” and “Rhode Island Hospital, the only party before the Texas court,” was not a party in the Rhode Island litigation, and the court further believed “the issues [were] not similar: the Texas court adjudicated the enforceability of the subpoena as between the government and Rhode Island Hospital,” whereas the Rhode Island litigation at that time concerned “the independent constitutional privacy rights of minor patients who were never before any court.” Add.1.

On May 10, RIH moved to intervene and file its own motion to quash in the Rhode Island action. *See* JA126-55. Unlike with the Advocate’s motion, the district court did not order a response to either RIH’s motion to intervene or motion to quash. The court granted intervention the following day, Dkt. Text Order (May 11, 2026), and at a hearing the next day—May 12—the court heard both motions to quash. The government thus did not respond to RIH’s motion before the hearing.

At the hearing, the district court denied the Department’s renewal of its motion to transfer. Add.3. The next day, the court issued an order purporting to grant both motions to quash. Add.51-52. Applying *res judicata* principles, the district concluded

that the collateral attack doctrine did not apply because (1) the Advocate represented interests that “are distinct from those that either were or could have been litigated in the Texas court”; (2) quashal would not be “a collateral attack on the Texas court’s Order”; and (3) RIH “was not provided notice and an opportunity to be heard before the Texas court ordered the administrative subpoena enforced.” Add.39-40 On the merits, the district court concluded that “the DOJ’s FDCA theory does not constitute a legally cognizable basis for this investigation as applied to a prescribing hospital,” and thus that the subpoena lacked a legitimate purpose. Add.42-46. Based on that conclusion, the district court further held that the sole purpose for the subpoena was to pursue policy goals the court regarded as illegitimate, and thus that the subpoena was issued for an improper purpose, and concluded that enforcement of the subpoena would “violate the right to informational privacy of the children” the Advocate represents. Add.46-50. The district court also enjoined the government from receiving or retaining documents responsive to the subpoena. Add.52.<sup>3</sup>

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<sup>3</sup> The district court’s opinion made a series of statements asserting that the Department misled the court (or the Texas court) as to the content and extent of its communications with RIH before April 30. Add.31-34. The district court also referred this matter “for further proceedings under R.I. Dist. Ct. Local Rule 210(b).” Dkt. Text Order (June 5, 2026). Those statements are not relevant to the questions on appeal, and the Department will respond as appropriate to the district court’s assertions in the necessary forum. But for now, we note that the Department disagrees in the strongest terms with the district court’s statements, which were based on an incomplete record of the Department’s discussions with RIH.

On May 18, the Northern District of Texas entered an order recognizing that its enforcement order remained binding and also that the government is presently unable to receive the documents due to the Rhode Island court's injunction. *In the Matter of Administrative Subpoena 25-1431-032*, No. 4:26-mc-6 (N.D. Tex. May 18, 2026), Dkt. 26. The court concluded that RIH's "flagrant attempts to avoid compliance with lawful orders leads the Court to conclude that it is necessary to hold the materials responsive to the subpoena *in camera* pending outcome of the appeals" to "ensure the preservation of the materials subject to the subpoena." *Id.* at 5. The court thus ordered production of the documents to the court, where they will remain "inaccessible to the Government for the pendency of the appeals" in this Court and the Fifth Circuit. *Id.* at 5-6.

The Advocate asked this Court for an injunction against RIH pending appeal barring compliance with the Northern District of Texas's order, which a panel of this Court unanimously denied. Order, *In re: Motion to Quash Admin. Subpoena to RI Hosp.*, 26-1568 (1st Cir. May 19, 2026). RIH has since started producing documents in camera to the Texas court. *In the Matter of Administrative Subpoena 25-1431-032*, No. 4:26-mc-6 (N.D. Tex. May 19, 2026), Dkt. 30.

### **SUMMARY OF ARGUMENT**

This Court should reverse the district court's order quashing the subpoena and permanently enjoining the government from, among other things, seeking and receiving documents responsive to the subpoena. At the outset, the district court should not have adjudicated a challenge to a subpoena already subject to litigation between the

Department and RIH in the Northern District of Texas, particularly where that litigation had produced a final judgment enforcing the subpoena—a judgment currently on appeal to the Fifth Circuit. Basic principles of comity and respect for the judgments of coordinate federal courts dictated that the district court here should have dismissed these actions or transferred them to the Northern District of Texas.

Even aside from those errors, the district court erred on the merits. The court concluded that the Department’s subpoena was invalid based on its view that a particular theory of liability under the FDCA would be invalid. Even aside from the fact that the Department never stated that the documents were needed for that theory of liability, the district court ignored this Court’s precedent making clear that in assessing the validity of a subpoena courts do not resolve questions about the agency’s “substantive authority to regulate,” which are instead to be resolved in any future action that results from the investigation. *United States v. Sturm, Ruger & Co.*, 84 F.3d 1, 5 (1st Cir. 1996). Nor did the district court address the multiple explanations for the relevance of the subpoenaed materials that the Department *did* advance. And the court’s erroneous conclusion that the Department had no statutory authority to investigate undergirded its subsequent conclusions that the subpoena was issued solely for an improper purpose and that the informational privacy rights of patients would be unduly burdened by RIH’s compliance with the subpoena.

The district court’s relief was also erroneous. The district court erred in issuing a permanent injunction without applying the four-factor test the Supreme Court has

articulated for such relief. And even if the Advocate’s suit could proceed, the district court could not quash the subpoena in full based on alleged injuries from the disclosure of the medical records of particular patients.

### **STANDARD OF REVIEW**

An order quashing an administrative subpoena is reviewed for abuse of discretion. *McLane Co. v. EEOC*, 581 U.S. 72, 75 (2017). So is the district court’s decision not to yield in favor of a prior-filed federal action. *Maldonado-Cabrera v. Anglero-Alfaro*, 26 F.4th 523, 526 (1st Cir. 2022). As for a permanent injunction, “questions of law are reviewed *de novo*, the scope of the injunction is reviewed for abuse of discretion, and factual findings are reviewed for clear error.” *Doe v. Rhode Island Interscholastic League*, 137 F.4th 34, 39 (1st Cir. 2025) (quotation omitted and alteration adopted). A district court abuses its discretion “if it based its ruling on an erroneous view of the law or on a clearly erroneous assessment of the evidence.” *Nyer v. Winterthur Int’l*, 290 F.3d 456, 461 (1st Cir. 2002) (quoting *Cooter & Gell v. Hartmarx Corp.*, 496 U.S. 384, 405 (1990)).

### **ARGUMENT**

#### **I. Principles of comity and respect for the judgments of coordinate courts foreclose these petitions.**

At the threshold, the district court should not have adjudicated these motions to quash. Ordinary principles of comity and prohibitions on collateral attack preclude a suit asking a different district court to set aside the Northern District of Texas’s judgment.

A. The Department of Justice filed a subpoena enforcement petition in the Northern District of Texas to which RIH was the respondent. That petition resulted in a final and appealable judgment enforcing the subpoena on April 30. Indeed, RIH appealed from that judgment and sought a stay pending appeal from both the Northern District of Texas and the Fifth Circuit, both of which denied relief.

Under settled principles of comity between federal courts, the filing of the action in the Northern District of Texas and that court's issuance of a final judgment precluded efforts to relitigate the validity of the subpoena in a different federal district court. There was no colorable basis for the district court to permit RIH to intervene and bring a motion to quash the very subpoena at issue in the Northern District of Texas case to which RIH is a party. And those principles apply equally to the Advocate, which filed this action for the avowed purpose of undermining the effectiveness of the Northern District of Texas's judgment, rather than seeking to intervene in that case.

It has long been the "usual practice" in federal litigation "for the court that first had jurisdiction" over a case "to resolve the issues," and for a subsequent district court presented with a later-filed suit presenting the same issues "to defer." *Maldonado-Cabrera*, 26 F.4th at 526 (quotation omitted). This rule of deference avoids the "[o]bvious concerns" that arise in such circumstances, such as "wasted resources because of piecemeal litigation, the possibility of conflicting judgments, and a general concern that the courts may unduly interfere with each other's affairs." *TPM Holdings, Inc. v. Intra-Gold Indus., Inc.*, 91 F.3d 1, 4 (1st Cir. 1996) (per curiam). This rule—

commonly called the “first-filed” rule—is thus regularly applied to avoid this sort of conflict as to “actions involving the same parties and similar subject matter.” *Id.* In those circumstances, “[c]onsiderations of comity and orderly administration of justice dictate that two courts of equal authority should not hear the same case simultaneously.” *Washington Metro. Area Trans. Auth. v. Ragonese*, 617 F.2d 828, 830 (D.C. Cir. 1980).

Additional considerations arise because the Northern District of Texas entered a final judgment on the merits. The Supreme Court has recognized that a federal district court’s orders “are to be respected” until “reversed for error by orderly review, either by itself or by a higher court.” *Celotex Corp. v. Edwards*, 514 U.S. 300, 313 (1995). Accordingly, litigants may not attempt to circumvent one court’s ruling by filing a subsequent action in another court; this rule is often referred to as the “collateral attack” doctrine. *E.g.*, *Pratt v. Ventas, Inc.*, 365 F.3d 514, 519 (6th Cir. 2004); *see also Republic Bldg. Co., Inc. v. Charter Twp. of Clinton*, 81 F.4th 662, 666 (6th Cir. 2023) (“[C]ollateral attacks exist where the relief sought would, in some way, overrule another court’s ruling.”).

Those principles apply with full force here. The Department’s subpoena enforcement action in the Northern District of Texas was filed before any action—much less RIH’s motion to intervene—in the District of Rhode Island. And the subpoena enforcement action resulted in a final judgment enforcing the subpoena as to RIH. To seek relief from that order, RIH must either litigate in the Northern District of Texas or the Fifth Circuit—as it is presently doing, having filed an appeal to that

court. *See* 28 U.S.C. § 1294(1). RIH cannot file a separate action in a different court seeking to quash the very subpoena that has been enforced in the Northern District of Texas.

That is precisely what the district court permitted here. Although the Texas court had enforced the subpoena and ordered RIH to “provide all records responsive to each request in the subpoena” no later than May 14, 2026, JA169-70, RIH asked the district court to quash “in its entirety” the same subpoena, JA139. The district court obliged, granting intervention and then granting the motion to quash. The district court believed that it was “likely” that RIH could pursue an independent action because RIH “was not provided notice and an opportunity to be heard before the Texas court ordered the administrative subpoena enforced,” and thus could not be precluded by the judgment of the Northern District of Texas. Add.40. Even aside from the fact that the district court granted final judgment based only on an assessment of RIH’s “likely” success, that reasoning gets matters entirely backwards. RIH is free to pursue its arguments that the Northern District of Texas’s judgment is invalid in its appeal to the Fifth Circuit. Indeed, RIH’s stay motion to the Fifth Circuit argued that the Texas court “denied RIH due process” in the Northern District of Texas proceedings, among other objections. *United States v. Rhode Island Hosp.*, 26-10431 (5th Cir. May 12, 2026), Dkt. 15-1. If the Fifth Circuit ultimately rejects those arguments and affirms the Northern District of Texas’s enforcement order, that conclusion will *itself* be res judicata as to the due process argument the district court suggested might succeed. Add.39-40. This case thus

manifestly presents all of the concerns about “wasted resources,” “the possibility of conflicting judgments,” and the risk of undue interference in the affairs of other courts that undergird the first-to-file rule. *TPM Holdings*, 91 F.3d at 4. And the district court plainly had no power to overrule or reverse the Northern District of Texas’s order and enter a directly contrary order as to the very party before the Northern District of Texas (and now the Fifth Circuit). Instead, the Northern District of Texas’s order is “to be respected” unless and until “reversed for error by orderly review,” *Edwards*, 514 U.S. at 313, not based on a separate district court’s assessment of a party’s arguments in a pending appeal before another circuit.

**B.** The same principles apply to the suit by the Advocate. The Advocate’s suit presents the same risk of competing judgments about the validity of the subpoena as RIH’s action, as well as the same concerns about wasted resources and interference with the Northern District of Texas’s judgment that motivate the first-to-file rule. *TPM Holdings*, 91 F.3d at 4. And although the Advocate is not a party to the Northern District of Texas action, courts have recognized that “the first-to-file rule does not require exact identity of the parties”; “substantial similarity” is sufficient. *Kohn L. Grp., Inc. v. Auto Parts Mfg. Miss., Inc.*, 787 F.3d 1237, 1240 (9th Cir. 2015); see *Save Power Ltd. v. Syntek Fin. Corp.*, 121 F.3d 947, 951 (5th Cir. 1997) (“Complete identity of parties is not required for dismissal or transfer of a case filed subsequently to a substantially related action.”). Similarly, to the extent the Advocate advanced different arguments from those pressed by RIH, “[t]he issues in both cases also need not be identical, only substantially similar,”

such that there is “substantial overlap” between them. *Kohn*, 787 F.3d at 1240-41 (quotation omitted). That approach reflects the overarching purpose of the first-filed rule, under which “courts should be driven to maximize economy, consistency, and comity.” *Id.* at 1240 (quotation omitted).

The overlap between the two actions here is obvious. RIH’s stay motion in the Fifth Circuit, for example, advanced all but one of the arguments about the validity of the subpoena that the Advocate presented and the district court considered here. *United States v. Rhode Island Hosp.*, 26-10431 (5th Cir. May 12, 2026), Dkt. 15-1. Indeed, the similarity is so great that RIH sought to intervene in the Advocate’s suit rather than filing its own separate action seeking quashal. Although the district court did not specify on what ground it granted intervention, under either intervention as of right or permissive intervention, RIH would be required to show some interest affected by, or claim or defense in common with, the Advocate’s suit. *See* Fed. R. Civ. P. 24(a), (b).

It is thus plain that “the overlap between” this case and the action in Texas was “nearly complete,” *TPM Holdings*, 91 F.3d at 4, and most certainly was effectively complete by the time the district court allowed RIH to intervene. Given this overlap and the Texas court’s enforcement order, the district court’s intervention would necessarily “interfere with the Texas court’s authority [and] conduct of its case.” *Id.* Deference to the Texas court, accordingly, should have followed. *Cf. Save Power*, 121 F.3d at 951 (finding abuse of discretion when the issues “substantially overlap[ped]” and “inconsistent rulings have already resulted”).

The case for applying the first-filed rule, and ensuring a single adjudication of the validity of the subpoena, is especially strong here given unique features of the HIPAA subpoena process Congress created. Congress contemplated that disputes over the validity of a subpoena would be resolved in one proceeding, providing that “the person or entity summoned” may move to quash a HIPAA subpoena “before the return date specified in the summons,” 18 U.S.C. § 3486(a)(5), and omitting any provisions—present in other statutes—expressly authorizing suits by third parties to challenge the subpoena or requiring notice to third parties to effectuate such suits. *Cf.* 18 U.S.C. § 2704(a)(2), (b) (Electronic Communications Privacy Act). Moreover, HIPAA allows a district court to forbid a subpoena recipient from “disclos[ing] to any other person or entity” the “existence” of the subpoena, 18 U.S.C. § 3486(a)(6)(A), and further preempts state laws and displaces federal requirements that could otherwise require a subpoena recipient to notify patients that their medical records will be or have been produced in compliance with the subpoena, *id.* § 3486(d). Congress instead addressed patient health information by limiting the use of that information after it has been received in response to a subpoena. *Id.* § 3486(e)(1).

Thus, even assuming that the Advocate may challenge the subpoena on informational-privacy grounds, Congress’s considered choices in establishing the HIPAA subpoena process provide every reason to ensure that disputes over a subpoena are adjudicated in a single forum. Were it otherwise, a single subpoena could be subject to numerous individual challenges by patients in different districts around the country,

with the corresponding risks of wasted resources, conflicting judgments, and interference between courts—to say nothing of the risk of impeding investigations into federal healthcare offenses. One proceeding—with one answer about a subpoena’s enforceability—would thus be in the interest of comity and consistency, adding further reason the district court erred in declining to defer to the first-filed action and direct the Advocate to seek relief there.

The district court did not address the caselaw making clear that a substantial overlap of parties and issues is all that is necessary to apply the first-filed doctrine, much less explain why that would not be met here. The court instead analogized its consideration of the Advocate’s motion to an “APA claim[]” under which “a district court has the power to vacate challenged agency action even where vacatur may necessarily implicate other courts’ judgments regarding that same action.” Add.40. Thus, the court theorized, it could “effectively vacate (i.e., quash) the administrative subpoena at issue here despite the fact that doing so necessarily implicates the parties’ responsibilities under the Texas court’s Order.” *Id.*

That is wrong. The Northern District of Texas’s order enforcing the subpoena is valid and in force unless or until reversed, vacated, or suspended by that court or a superior court. The validity of the Texas court’s order—which commands RIIH’s compliance with the subpoena—does not turn on whether some other court views the underlying subpoena as separately valid. In other words, RIIH’s obligation to comply with the subpoena flows from the Texas court’s enforcement order, not solely from the

subpoena itself. Federal district courts cannot “vacate” the rulings of coordinate district courts in the manner the district court suggested.

Moreover, unlike APA actions in which multiple parties challenge a generally applicable rule, and in which APA-specific remedies are at play, both this case and the Northern District of Texas action ask whether RIH should be required to turn over a defined corpus of documents that the government seeks for its investigation. All the ordinary considerations of comity and conservation of judicial resources dictate that those questions should be resolved in a single forum. The Advocate would be free to seek to intervene in the Texas suit or otherwise move to protect its interests before that court. *See In re Rhode Island Hosp.*, No. 26-1568, 2026 WL 1407553, at \*3 (1st Cir. May 19, 2026) (Dunlap, J., concurring). But it would be startling to conclude that the district court could openly seek to nullify the Northern District of Texas’s order in the fashion employed here, whether at the invitation of RIH or another party dissatisfied with the Northern District of Texas’s ruling.

## **II. The subpoena is valid and lawfully issued.**

Even if this Court reaches the merits, the district court’s decision should be reversed. Congress has authorized the Department to investigate and prosecute federal healthcare offenses. Accordingly, the Department “may take steps to inform itself as to whether there is probable violation of the law.” *United States v. Morton Salt*, 338 U.S. 632, 643 (1950). Indeed, the Department “can investigate merely on suspicion that the law is being violated, or even just because it wants assurance that it is not.” *Id.* at 642-43.

And in its investigation, the Department is entitled to any evidence unless it is “plainly incompetent or irrelevant to any lawful purpose” in investigating federal healthcare offenses. *Endicott Johnson Corp. v. Perkins*, 317 U.S. 501, 509 (1943).

In accord with these principles, this Court has long provided that the “requirements for enforcement of an administrative subpoena are not onerous.” *United States v. Sturm, Ruger & Co.*, 84 F.3d 1, 4 (1st Cir. 1996). The agency must show that “(1) the subpoena is issued for a congressionally authorized purpose, the information sought is (2) relevant to the authorized purpose and (3) adequately described, and (4) proper procedures have been employed in issuing the subpoena.” *Id.* The subpoena at issue meets these minimal requirements and the district court’s contrary reasons do not withstand scrutiny.

**A. The subpoena satisfies the essential requisites for a valid administrative subpoena.**

Each of the requirements the First Circuit and the Supreme Court have identified are satisfied here. At the outset, the subpoena is plainly within the Department’s congressionally granted authority and seeks information relevant to that authorized investigation. An administrative subpoena meets these requirements if the agency’s assertion of investigative “authority is not obviously apocryphal,” *Sturm, Ruger & Co.*, 84 F.3d at 5; accord *U.S. Dep’t of Just. v. Ricco Jonas*, 24 F.4th 718, 726 (1st Cir. 2022); *FTC v. Swanson*, 560 F.2d 1, 2 (1st Cir. 1977) (per curiam), and the information sought is “reasonably relevant,” *Morton Salt*, 338 U.S. at 652, to the “general purposes of the

agency’s investigation,” *Dow Chem. Co. v. Allen*, 672 F.2d 1262, 1268 (7th Cir. 1982) (alteration adopted and quotation omitted); see *United States v. Trustees of Bos. Coll.*, 718 F.3d 13, 24 (1st Cir. 2013). And at the subpoena stage, courts do not resolve questions about the agency’s “substantive authority to regulate,” which are instead to be resolved in any future action that results from the investigation. *Sturm, Ruger & Co.*, 84 F.3d at 5; accord *Swanson*, 560 F.2d at 2.

Here, Congress has expressly authorized the Attorney General to issue subpoenas to investigate potential violations of “Federal health care offense[s],” including qualifying offenses in the FDCA. 18 U.S.C. § 3486(a)(1)(A)(i)(I). The subpoena to RIH was issued for that very purpose.

The Civil Division is investigating, among other things, potential violations of the FDCA related to puberty blockers and cross-sex hormones. RIH houses a “Gender and Sexuality Program” and prescribes the drugs at issue. JA101. The subpoena seeks information relevant to the Department’s investigation in two different ways. First, the Department seeks records to determine whether RIH itself may have engaged in conduct that implicates the FDCA. Second, the Department seeks records from RIH to determine whether manufacturers and distributors of the drugs at issue may have violated the FDCA.

There are four groups of Requests, all of which extend from January 1, 2020, to the present. Request 1 seeks personnel files to identify who had authority to direct prescribing, billing, or marketing practices and to determine which actors may have

liability. JA66. Requests 2 through 6—which seek documents related to billing, insurance claims, and diagnosis coding practices—are informative as to the existence of false billing and the presence of an “intent to defraud or mislead.” 21 U.S.C. § 333(a)(2); *see* JA66-67. Requests 7 through 10 seek documents related to the relationship between RIH and drug manufacturers, which can provide evidence of misbranding and fraudulent intent. JA67. For example, communications between pharmaceutical sales representatives and prescribing physicians can provide evidence of off-label promotion, which would be relevant to an FDCA prosecution for misbranding drugs.

Finally, Requests 11 through 15 seek patient records, which will allow the Department to assess the scope of the potential violations at issue, identify patterns of misbranding or false billing, and assess fraudulent intent. JA67-68. For example, identifying an instance of false coding typically requires evaluating a patient’s medical records to ascertain the patient’s actual diagnosis and the patient’s billing records to detect a mismatch between the patient’s diagnosis and the bill submitted to the patient’s insurer. *See* JA103-04. That is not a hypothetical: In this investigation, the Department has obtained medical records from other pediatric hospitals that have used pharmaceuticals for gender-related medical interventions, and review of those records has revealed evidence that treatments have been coded as treatment for disorders other than the actual diagnosis, suggesting concealment of off-label use of puberty blockers and hormones. JA101-02.

Patient records may also be necessary to identify patients' adverse health outcomes, which are often significant in FDCA and other health care offenses. *See* JA104.<sup>4</sup> Obtaining patient records also permits investigators to determine the scale of potential FDCA violations, to compare records to distinguish between one-off billing errors and institutionalized practices suggesting intentional miscoding of treatments, and to generate future investigative leads such as identifying relevant records to request from health benefit programs. JA103-04. Investigations of FDCA and other health care offenses thus regularly involve use of patient records. *See, e.g., In re Subpoena Duces Tecum*, 228 F.3d 341, 350 (4th Cir. 2000); *Doe v. United States*, 253 F.3d 256, 265 (6th Cir. 2001) (enforcing subpoena that included "requests for the files of patients").<sup>5</sup>

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<sup>4</sup> *See also, e.g.,* Dep't of Just., *Founder and Chief Executive Officer of Injectable Stem Cell Product Manufacturer Sentenced for Distributing Unapproved Drug* (Sep. 30, 2024), <https://perma.cc/JWH4-23UA> (highlighting evidence that defendant's conduct was linked to patients' hospitalization); Dep't of Just., *Owners and CEO of Wholesale Pharmaceutical Company Sentenced for Distributing More Than \$92M of Black-Market HIV Drugs* (Mar. 16, 2026), <https://perma.cc/X2TR-8JBJ> (highlighting trial testimony from patient who was harmed by defendants' conduct).

<sup>5</sup> In other circumstances, the DOJ has negotiated modifications to the subpoena demands, including agreeing in some cases to accept de-identified patient data—at least in the first instance—to avoid litigation and advance the investigation. Such compromises are commonplace in complex investigations. The Department's willingness to negotiate, however, does not mean that patient records lack investigative value or are unnecessary, particularly where, as here, the district court precluded access to *any* records, anonymized or otherwise.

For these reasons, the documents the Department seeks are far from “irrelevant to any lawful” FDCA investigation, *Endicott Johnson Corp.*, 317 U.S. at 509, and the relevance requirement is satisfied.

These requests are also “adequately described.” *Sturm, Ruger & Co.*, 84 F.3d at 4. There is no meaningful doubt about what records are sought. And though the requests are broad, that flows from the nature of the investigation itself: because the Department’s “inquiry” is “a relatively broad one,” “the permissible scope of materials that [can] reasonably be sought [is] necessarily equally broad.” *McPhaul v. United States*, 364 U.S. 372, 382 (1960); see *Securities & Exch. Comm’n v. McGoff*, 647 F.2d 185, 192-93 (D.C. Cir. 1981) (“We agree that the demands are broad. But the nature of the inquiry precludes a trim list of requests.” (footnote omitted)); cf. *Sugarloaf Funding, LLC v. U.S. Dep’t of the Treasury*, 584 F.3d 340, 348 (1st Cir. 2009) (“[T]here are no cases that universally proscribe the use of ‘all documents’ language.”). The Department’s requests are not atypical in this area. See, e.g., *In re Subpoena Duces Tecum*, 228 F.3d at 350; see also *In re Grand Jury Subpoenas Duces Tecum Dated Jan. 30, 1986*, 638 F. Supp. 794, 795-96 (D. Me. 1986) (concluding that grand jury subpoenas in health-care fraud investigation were not overbroad despite necessity that psychiatrist review all 2,500 patient files). Further, the “subpoena commands production of materials covering only a reasonable period of time,” currently a little over six years. *In re Grand Jury Matters*, 751 F.2d 13, 18 (1st Cir. 1984); cf. *In re Subpoena Duces Tecum*, 228 F.3d at 350.

Finally, there is no dispute that the “proper procedures have been employed in issuing the subpoena.” *Sturm, Ruger & Co.*, 84 F.3d at 4. The subpoena was signed by the Assistant Attorney General, properly served on RIH, and calls for the production of nonprivileged documents relevant to the investigation within 500 miles of RIH. *See* 18 U.S.C. § 3486(a)(3).

**B. The district court’s contrary conclusion is based on interrelated errors of law.**

The district court offered three reasons why quashal was warranted: (1) Congress did not authorize the issuance of this subpoena; (2) the Department issued the subpoena “for an improper purpose in bad faith”; and (3) RIH’s compliance with the subpoena would violate patients’ “Fourteenth Amendment right to informational privacy.” Add.42-50. None of these grounds provide reason for quashal.

**1. The subpoena has a congressionally authorized purpose.**

As discussed above, the first prerequisite for a valid subpoena is that the subpoena must be “issued for a congressionally authorized purpose.” *Sturm, Ruger & Co.*, 84 F.3d at 4. “A challenge to a subpoena” on the ground that it fails to meet that element “will fail [a]s long as the agency’s assertion of authority is not obviously apocryphal.” *Ricco Jonas*, 24 F.4th at 726 (alteration in the original) (quoting *Sturm, Ruger & Co.*, 84 F.3d at 5).

The district court did not cite, much less apply, this Court’s governing “obviously apocryphal” standard. It instead opined at length (Add.42-46) that particular conduct—

specifically a physician’s writing of a prescription for off-label use of a particular medication—cannot violate the FDCA. That reasoning was mistaken in both conception and execution. To begin, this Court, like others, has “repeatedly admonished that questions concerning the scope of an agency’s substantive authority to regulate are not to be resolved in subpoena enforcement proceedings.” *Sturm, Ruger & Co.*, 84 F.3d at 5; *Swanson*, 560 F.2d at 2. Were it otherwise, every subpoena recipient could seek to pre-litigate issues of potential liability or statutory coverage, which would “stop much if not all of investigation in the public interest at the threshold of inquiry.” *Oklahoma Press Pub. Co. v. Walling*, 327 U.S. 186, 213 (1946); see *Endicott Johnson Corp. v. Perkins*, 317 U.S. 501, 508-09 (1943). Other courts have repeatedly rejected the same maneuver just as emphatically. See, e.g., *EEOC v. Karuk Tribe Hous. Auth.*, 260 F.3d 1071, 1076-77 (9th Cir. 2001); *United States v. American Target Advert., Inc.*, 257 F.3d 348, 353 (4th Cir. 2001).

The district court’s extended disquisition on FDCA liability was thus entirely beside the point. But even on its own terms, that analysis misunderstood the FDCA, the Department’s investigation, and the scope of the subpoena. At the outset, the district court believed that the Department’s investigation rested on a theory “that off-label prescribing by licensed practitioners gives rise to FDCA criminal liability.” Add.43. But the Department explained “that the act of writing a prescription for an off-label” use does not “in and of itself, give rise to FDCA liability.” Dkt. 9 at 27. Instead, it is well-settled that FDCA liability may arise when a party—such as a manufacturer or

distributor—introduces a drug into interstate commerce with the intent that it be used in an off-label manner. *See, e.g., In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 915 F.3d 1, 5 (1st Cir. 2019) (“The FDCA creates both civil and criminal penalties for drug manufacturers that promote the use of approved drugs for unapproved uses (referred to here as ‘off-label’ uses).”); *supra* pp. 7-8 (collecting examples). And evidence of that intent may be found from a variety of sources, including marketing materials and communications between pharmaceutical sales representatives and prescribing physicians—which, unsurprisingly, are among the materials the subpoena seeks. *See* JA67.

As this point illustrates, RIH or its employees may simply be witnesses to misconduct by others, such as manufacturers or distributors engaged in misbranding. The district court did not explain why RIH would not be expected to have information relevant to the potential misconduct of others, and thus did not dispute that obtaining that information would be a perfectly valid basis for the subpoena. And the district court’s myopic focus on the irrelevant question of whether RIH could be held liable under the FDCA for the mere act of a physician’s prescribing of a drug for an off-label use also led it to ignore entirely the other explanations the Department offered. The Department explained that RIH or its employees may be liable if they conspired with manufacturers and distributors who were misbranding drugs. *See, e.g., Indictment, United States v. Gleason*, No. 1:06-cr-229 (E.D.N.Y. Apr. 5, 2006), Dkt. 8. Or 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. 21 U.S.C. § 321(m); *see id.* § 352(a).

The district court entirely “failed to analyze” these theories on their own terms. *In re Rhode Island Hosp.*, 2026 WL 1407553, at \*3 (Dunlap, J., concurring). But they need no deep analysis here. This Court’s precedents make clear that in the subpoena enforcement posture, it suffices that the Department’s assertion of authority is not “obviously apocryphal,” *Ricco Jonas*, 24 F.4th at 726 (quotation omitted), and the Department obviously has no burden to provide evidence of wrongdoing—by RIH or others—before using the very investigative tool Congress has conferred for gathering evidence to determine if wrongdoing has occurred. *See, e.g., Morton Salt*, 338 U.S. at 642-43; *Oklahoma Press*, 327 U.S. at 201. The district court’s demand that the Department produce evidence of misbranding by RIH, Add.44, was thus misplaced. But even if some evidence was needed, the Department offered evidence related to valid FDCA theories, both in general and specific to RIH. *See, e.g.*, JA99-102.

The district court’s other conclusions were equally misguided. The district court pointed to 21 U.S.C. § 353(b)(2), which exempts “[a]ny drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug” from some requirements of 21 U.S.C. § 352. This provision, to the district court, invalidates the Department’s “entire misbranding theory” because “RIH’s physicians prescribe medications to patients in the clinical setting pursuant to their medical judgment.” Add.45. But the district court failed to read the next clause in the

statute, which carves § 352(a) out of the exemption. *See* 21 U.S.C. § 353(b)(2) (“except paragraphs (a), (i)(2) and (3), (k), and (l)”). And § 352(a) provides that a drug is misbranded “[i]f its labeling is false or misleading in any particular.” Thus, even aside from the points above, § 353(b)(2) does not provide the complete immunity from misbranding liability that the district court contemplated.

The district court also invoked federalism concerns. Add.43. But the Department’s FDCA theories do not constitute a “displace[ment]” of Rhode Island’s “medical regulatory framework.” *Id.* The fact that Rhode Island may generally regulate the practice of medicine, and has provided that certain interventions for minors are lawful in the state, does not immunize providers in the state from complying with federal law. Likewise, it does not shield them from complying with valid investigations. *See Doe v. Dynamic Physical Therapy, LLC*, 607 U.S. 11, 11 (2025) (per curiam) (“[A] State has no power to confer immunity from federal causes of action.” (emphasis omitted)). Through the FDCA, the Federal Government has “enact[ed] a comprehensive, uniform regulatory scheme for the distribution of drugs,” *United States v. Regenerative Scis., LLC*, 741 F.3d 1314, 1319 (D.C. Cir. 2014), and states cannot displace that scheme through their own laws. And the district court’s assertion that the federal government intrudes on state authority by adopting “novel interpretations of federal statutes,” Add.43, simply repackages the district court’s erroneous view that it should hypothesize about the merits of a potential future FDCA enforcement action in the context of a subpoena proceeding.

**2. The Department did not issue the subpoena in bad faith and for an improper purpose.**

The district court also concluded that the Department's sole purpose behind the issuance of the subpoena was an improper one because of the administration's policy views. Add.46-47. This conclusion is largely derivative of the erroneous argument just discussed and is also unsustainable on its own terms.

The Supreme Court has explained that, when called upon to enforce an administrative subpoena, a district court has the ability to ensure that "its process" is not "abused." *United States v. Powell*, 379 U.S. 48, 58 (1964). "Such an abuse would take place if the summons had been issued for an improper purpose, such as to harass the [recipient] 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." *Id.* Even assuming an improper purpose (*but see infra* pp. 40-44), quashal on that theory is only warranted when the "sole purpose" is an improper one. *United States v. Gertner*, 65 F.3d 963, 970 (1st Cir. 1995); *see Donaldson v. United States*, 400 U.S. 517, 533 (1971) (inquiring whether "the sole objective of the investigation is to" impermissibly use a civil subpoena to "obtain evidence for use in a criminal prosecution"); *Lynn v. Biderman*, 536 F.2d 820, 826 (9th Cir. 1976) ("It is not . . . a ground to deny enforcement of a subpoena that it is being employed for a wrongful purpose if there is also a legitimate purpose for the subpoena."); *cf. Vahlsing v. Commercial Union Ins. Co.*, 928 F.2d 486, 490 (1st Cir. 1991) ("When process is employed for the purpose for which the law intends its use, no abuse

of process occurs even though the person using the process may have an improper motive in addition to his lawful intention.”).

The district court acknowledged that quashal would be appropriate only if an improper purpose were the “sole purpose” of the investigation, Add.46, but to conclude that the “sole purpose” standard was met, simply repeated its view that the Department’s “legal theory” for the investigation was “not legally cognizable,” Add.47. That argument is mistaken for the reasons already discussed. *See supra* pp. 34-38. Thus, “the district court’s improper purpose reasoning” simply “fall[s] away” when its errors about the absence of congressional authorization for the subpoena are corrected, *In re Rhode Island Hosp.*, 2026 WL 1407553, at \*3 (Dunlap, J., concurring), and the court’s “improper purpose” analysis adds nothing to its erroneous understanding of the investigation and its own authority.

But even beyond that mistake, the district court’s conclusion that an administration’s policy preferences can constitute an improper purpose was likewise erroneous. Add.46-47. Those preferences cannot immunize entire industries or practices from scrutiny to determine if they have complied with existing federal law. The district court here made no finding—and Appellees presented no evidence—that the government issued the subpoena to harass RIH, pressure RIH to settle a collateral dispute, or for any other reason specific to RIH that may constitute an improper purpose under *Powell* or this Court’s caselaw. Instead, the court inferred an improper purpose based largely on statements, executive orders, and memoranda expressing the

administration’s view on the propriety of “gender-affirming care.” Add.46. Those statements—which rest on a “rational basis,” *United States v. Skremetti*, 605 U.S. 495, 523 (2025)—cannot establish an improper purpose.

There is no dispute that the President and others in the administration have expressed strong opposition to the practice of irreversibly altering minors’ bodies to address diagnoses of gender dysphoria. The administration has concluded these interventions are unproven, unsafe, unnecessary, and unethical—concerns that are gaining traction within the medical community in the United States and abroad. *See* HHS Statement 1-3; HHS Secretary Declaration 1-9; Dep’t of Health & Hum. Servs., *Treatment for Pediatric Gender Dysphoria: Review of Evidence and Best Practices* (Nov. 19, 2025), <https://perma.cc/MUB7-2ETU>. At the same time, the administration’s actions do not purport to declare those interventions categorically unlawful or to change federal law in any respect. They merely direct investigations (and, if appropriate, enforcement actions) designed to enforce existing federal health care laws against entities in this industry. There is nothing bad-faith or pretextual about that.

The district court’s conflation of policy opposition with improper purpose is misguided. An administration’s policy statements on a particular topic have never amounted to an improper reason to issue a subpoena or to investigate whether a particular federal law has been violated. *Cf. Department of Com. v. New York*, 588 U.S. 752, 781 (2019) (“[A] court may not set aside an agency’s policymaking decision solely because it might have been influenced by political considerations or prompted by an

Administration’s priorities.”); *Trump v. Hawaii*, 585 U.S. 667, 706-07 (2018). But under the district court’s logic, the government would be precluded from investigating anything touching on gender-related treatment—from fraud on government insurance to drug adulteration—effectively immunizing illegal conduct in this space.

The district court’s approach would have startling consequences. Consider an administration that publicly advocated for a federal ban on sports gambling, while simultaneously seeking to ensure that the industry, where lawful, carried out its activities in a manner consistent with existing federal law. On the court’s logic, tax or other investigatory subpoenas to sports gambling operations and related businesses could be quashed based on the administration’s policy views. Similarly, an administration that pursued or supported new legislation that would ban or limit certain practices of large technology or social media companies could see subpoenas related to ensuring that those practices comply with existing law quashed on the same basis.

The list could go on. But the central point is that the government’s opposition to a particular industry or practice does not immunize that industry or practice from scrutiny to ensure that it is complying with existing law. Just as sports gambling companies would not be immunized from scrutiny if a future administration sought to ban them, actors engaged in the sorts of activities at issue here are not immunized from compliance with existing federal law—or from a response to an otherwise-lawful subpoena designed to ascertain if violations of existing federal law have occurred.

Indeed, at bottom, the district court’s rationale is simply an attack on the core executive power to exercise enforcement discretion in prioritizing what misconduct to investigate. Under Article II, the Executive Branch possesses the “exclusive authority and absolute discretion,” *Trump v. United States*, 603 U.S. 593, 620 (2024) (quotation omitted), to decide “how to prioritize and how aggressively to pursue legal actions against defendants who violate the law,” *TransUnion LLC v. Ramirez*, 594 U.S. 413, 429 (2021). “The power to decide when to investigate, and when to prosecute, lies at the core of the Executive’s duty to see to the faithful execution of the laws,” *Community for Creative Non-Violence v. Pierce*, 786 F.2d 1199, 1201 (D.C. Cir. 1986), and “the Government’s enforcement priorities” are a legitimate consideration in decisions about whether to prosecute, *Wayte v. United States*, 470 U.S. 598, 607 (1985).

Under those established principles, the Department is entitled to prioritize financial crimes, immigration offenses, or health care fraud—and it can also choose to prioritize the investigation and enforcement of those offenses in particular sectors or in relation to particular activities (such as gambling operations or cryptocurrency). It is axiomatic that government resources are limited, that different administrations have different priorities, and that administrations thus allocate resources differently to align with their policy priorities.

Here, at most, the district court’s logic could support an inference that the Department is focusing on misconduct by drug companies, insurers, and medical clinics engaged in providing “gender-affirming care” to minors because of the administration’s

broader policy concerns with that activity. Even if so, that is entirely permissible, and certainly not an “improper purpose” sufficient to quash a subpoena. Nothing in *Powell* or this Court’s cases suggests otherwise. There is simply no inconsistency between an administration’s desire for a disfavored practice to end and an administration’s desire to ensure that current federal law is enforced.

Finally, the district court’s rationale makes no sense on its own terms, since the subpoenas do not and cannot “end” the interventions the administration opposes. Add.46. The subpoenas merely seek information so the Department can investigate—and, if appropriate, prosecute—federal criminal offenses that nobody disputes may occur in connection with puberty blockers and cross-sex hormones. Ensuring that such violations have not occurred with respect to those drugs is plainly a legitimate purpose, and that is precisely what the Department is doing. The district court accordingly erred in quashing the subpoena and enjoining the Department from seeking and receiving responsive documents.

**3. Compliance with the subpoena would not result in a violation of any constitutional privacy interest.**

The district court separately erred in concluding that “the children who are the subject of the medical records” have a “right to informational privacy in these records and that RIIH’s compliance with the full scope of the requests contained within the subpoena would violate this right.” Add.47-48. This conclusion works a “substantial

enlargement” of this Court’s “prior rulings relating to informational privacy.” *In re Rhode Island Hosp.*, 2026 WL 1407553, at \*3 (Dunlap, J., concurring).<sup>6</sup>

The Supreme Court has never endorsed a constitutional right to “informational privacy,” instead assuming its existence while *upholding* the government’s access to personal information. *See NASA v. Nelson*, 562 U.S. 134, 138, 147-48 (2011). Even in making those assumptions, the Court has explained that in the medical context, “disclosures of private medical information to doctors, to hospital personnel, to insurance companies, and to public health agencies are often an essential part of modern medical practice even when the disclosure may reflect unfavorably on the character of the patient.” *Whalen v. Roe*, 429 U.S. 589, 602 (1977). And this Court, in contemplating the application of such a right, has recognized that any asserted right “must often give way to considerations of public interest.” *Daury v. Smith*, 842 F.2d 9, 13 (1st Cir. 1988).

Here, there is no basis to conclude that any right to informational privacy justified relief. At the outset, any expectation of privacy is minimal in this context. As the Fourth Circuit has explained, the possibility of disclosure “is not meaningfully distinguishable from a host of other unpleasant invasions of privacy that are associated with many facets of health care.” *In re Subpoena Duces Tecum*, 228 F.3d at 351 (quotation omitted). Nor can patients claim surprise: as required by federal law, *see* 45 C.F.R. § 164.520, RIH discloses to every one of its patients that it can and will share their

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<sup>6</sup> The district court did not explain why the Fourteenth Amendment, which applies to states, creates a right against the federal government.

information for law enforcement purposes, including in response to a subpoena. *See* JA118 (informing patients that it “may release” their “protected health information to a law enforcement official for a law enforcement purpose,” “in response to ... subpoenas”). This notice results in a “reduced expectation of privacy.” *In re Subpoena Duces Tecum*, 228 F.3d at 351. On the other hand, the Department has a “compelling interest in finding, convicting, and punishing those who violate the law,” *Samia v. United States*, 599 U.S. 635, 655 (2023), and here, Congress has specifically authorized the Department to collect records—including patient records—while investigating potential offenses. That interest outweighs any “privacy rights of those whose records were turned over to the government.” *In re Subpoena Duces Tecum*, 228 F.3d at 351.

Against this backdrop, it is no surprise that no court of appeals has embraced the premise that a HIPAA subpoena that obtains patient records in any respect violates any right to informational privacy, even though such records are regularly obtained through HIPAA subpoenas. *See, e.g., In re Subpoena Duces Tecum*, 228 F.3d at 351; *Doe*, 253 F.3d at 265 (enforcing subpoena that included “requests for the files of patients”).

Here, too, the district court’s contrary conclusion was largely downstream of its erroneous assessment of the merits of a potential FDCA enforcement action, referring back to its conclusion that “DOJ failed to specify how this information is related to its legitimate authority to conduct its investigation.” Add.49. Once again, the district court’s constitutional objection “fall[s] away” once its foundational error is corrected and the government’s interest in disclosure is properly weighed. *In re Rhode Island Hosp.*,

2026 WL 1407553, at \*3 (Dunlap, J., concurring). The district court separately suggested that there were “serious concerns for how DOJ would adequately protect and otherwise safeguard this information.” Add.49. The district court did not further explain the nature of those concerns, much less provide any substantiation for them. Any such concerns are particularly misplaced given the statutory restrictions on disclosure. 18 U.S.C. § 3486(e)(1); see *In re Subpoena Duces Tecum*, 228 F.3d at 351.<sup>7</sup> And even if the district court was worried about public disclosure, it could have issued a protective order rather than quash the subpoena.

**III. At a minimum, injunctive relief was improper, and quashal of the entire subpoena was overbroad.**

As the foregoing illustrates, the district court erred both in entertaining these quashal motions and in granting them, and its judgment should thus be vacated in full. But even if some relief were warranted, the district court erred in multiple respects in fashioning that relief. The district court entered permanent injunctive relief without considering or applying the relevant factors for such relief, and it did so based on conclusions premised on RIH’s “likely” success. Moreover, the Advocate lacks standing to seek quashal of the subpoena in full. Thus, even if the Advocate could bring a motion to quash and demonstrate an entitlement to relief, the relief granted would have to be

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<sup>7</sup> Even if the district court correctly found a privacy interest, that, at most, would have justified an order requiring anonymization rather than a full quashal and an injunction. See *C.N. v. Ridgewood Bd. of Educ.*, 430 F.3d 159, 180 (3d Cir. 2005).

narrowed to apply only to those portions of the subpoena as to which the Advocate has standing.

**A.** The district court permanently enjoined the Department “from seeking, receiving, using, retaining, or disseminating” responsive information. Add.52; *see* Add.30. That was error in multiple respects. At the outset, the fact that the district court believed injunctive relief against the government was necessary only underscores that “quashal” of the subpoena is in no sense sufficient to relieve RIH from the obligation to comply with the Northern District of Texas’s order. In other words, injunctive relief could have relevance only if “quashal” of the subpoena would be insufficient to thwart the Northern District of Texas’s judgment. Indeed, despite its occasional protestations to the contrary, the district court was correct in implicitly accepting that the Texas court’s order would compel RIH to comply with the subpoena even if the district court here purported to “quash” the subpoena. But the fact that the district court believed injunctive relief was in any sense needed encapsulates the inherent conflict between this action and the Northern District of Texas judgment, and thus the need to apply ordinary principles of comity between coordinate courts.

Even aside from improperly attempting to nullify the judgment of a coordinate court, the district court failed to heed the basic requirements for entry of a permanent injunction. The Supreme Court has made clear that injunctive relief “does not follow from success on the merits as a matter of course.” *Winter v. NRDC*, 555 U.S. 7, 32 (2008). Under “well-established principles of equity, a plaintiff seeking a permanent

injunction must satisfy a four-factor test before a court may grant such relief.” *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388, 391 (2006). Where a court does not “correctly appl[y] the traditional four-factor framework that governs the award of injunctive relief,” vacatur is warranted. *Id.* at 394; *see, e.g., e360 Insight, Inc. v. The Spambaus Project*, 500 F.3d 594, 604 (7th Cir. 2007); *Whitserve, LLC v. Computer Packages, Inc.*, 694 F.3d 10, 35-36, 36 n.19 (Fed. Cir. 2012).

Here, the district court did not acknowledge the four-factor test the Supreme Court has established for permanent injunctive relief, much less explain how that test was satisfied. The district court’s failure to engage with these factors is especially glaring because it couched several of its conclusions in terms of likelihood—the standard for *preliminary*, not permanent, injunctive relief. For example, the district court stated that the asserted injuries to the informational privacy rights of children were “likely irreparable,” Add.49, and that it was “unlikely that quashal—the primary relief sought by the Child Advocate here—constitutes a collateral attack on the Texas court’s Order,” Add.40.

Thus, at a minimum, the district court’s injunctive relief should be vacated considering its failure to apply the standards for such relief.

**B.** Finally, even if the Advocate could properly bring this action in Rhode Island and were able to succeed on the merits, that could not support quashal of the subpoena in full. The Advocate challenged the subpoena “on behalf of children in DCYF custody or care whose medical records are sought,” seeking “to protect the

constitutional privacy rights of identifiable children in the state of Rhode Island’s care.” JA32-33. Many of the subpoena’s requests for documents, however, have nothing to do with medical records of patients, much less the records of “identifiable children in the state of Rhode Island’s care.” Requests related to RIH’s personnel files, billing and insurance claims, diagnosis coding practices, and communications with drug manufacturers, for example, do not implicate the privacy interests the Advocate asserts. JA66-67. Indeed, the Advocate appeared to recognize as much, requesting—as an alternative to full quashal—relief only as to specific patient information. JA57.

Given that the Advocate can assert no injury from many aspects of the subpoena, the district court’s complete quashal of the subpoena could not be sustained based on the Advocate’s motion to quash. *See Gill v. Whitford*, 585 U.S. 48, 73 (2018) (“A plaintiff’s remedy must be tailored to redress the plaintiff’s particular injury.”). At a minimum, remand would be necessary to tailor the quashal order to address only those aspects of the subpoena the Advocate has standing to challenge. As part of that remand, this Court should direct the district court to reconsider whether other steps would be appropriate to tailor the relief to the Advocate.

## CONCLUSION

For the foregoing reasons, the judgment of the district court should be reversed.

Respectfully submitted,

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### **CERTIFICATE OF COMPLIANCE**

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 12,977 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Word for Microsoft 365 in Garamond 14-point font, a proportionally spaced typeface.

*/s/ Brantley T. Mayers*  
\_\_\_\_\_  
Brantley T. Mayers

**ADDENDUM**

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05/07/2026

TEXT ORDER. The Government's Motion to Stay or Transfer Venue (ECF No. 8) is DENIED. When deciding whether to apply the first-to-file rule, courts must consider: "(1) which action was filed first; (2) the similarity of the parties; and (3) the similarity of the issues." *Waithaka v. Amazon.com, Inc.*, 404 F. Supp. 3d 335, 350 (D. Mass. 2019), *aff'd*, 966 F.3d 10 (1st Cir. 2020). While the Texas enforcement action was filed first, the remaining factors are not satisfied. The parties are not similar: the Child Advocate was not a party to the Texas proceeding, had no notice of those proceedings, and had no opportunity to be heard there. Rhode Island Hospital, the only party before the Texas court, is not a party here. The issues are not similar: the Texas court adjudicated the enforceability of the subpoena as between the government and Rhode Island Hospital; this Court is asked to adjudicate the independent constitutional privacy rights of minor patients who were never before any court. Those claims were neither raised nor considered in Texas and could not have been, as the affected parties were absent. The first-to-file rule does not apply. So Ordered by District Judge Mary S. McElroy on 5/7/2026. (Potter, Carrie) (Entered: 05/07/2026)

1 THE COURT: Of course.

2 MR. OLSHAN: Thank you.

3 THE COURT: We are going to take a 10-minute  
4 recess to allow the stenographer to rest her fingers  
5 for a bit, so we'll be back in 10.

6 (Recess)

7 MR. MAYERS: Good afternoon, your Honor.

8 THE COURT: Good afternoon.

9 MR. MAYERS: I tend to speak fast, so let me  
10 know if there's a problem.

11 THE COURT: Yes, just take a deep breath in  
12 between.

13 MR. MAYERS: Yes.

14 THE COURT: You know, it is hard for her to get  
15 the record and I tend to interrupt, so, I also speak  
16 fast. So whenever you're ready.

17 MR. MAYERS: May it please the Court. The  
18 motion before the Court today, I'd like to briefly  
19 renew our motion to transfer. There a few factual  
20 developments that are relevant to the first-filed  
21 rule --

22 THE COURT: Uh'huh.

23 MR. MAYERS: -- that have taken place in the  
24 interim between your Honor's ruling and present.  
25 First, of course, the fact that Rhode Island intervened

1 and so there's --

2 THE COURT: I've denied that motion, --

3 MR. MAYERS: Okay.

4 THE COURT: -- and I've articulated the reason.

5 The first-filed rule doesn't apply when Rhode Island  
6 Hospital wasn't before the court in Texas. The fact  
7 that they've now been forced to intervene here and in  
8 Texas doesn't bootstrap you into the first-filed rule.

9 MR. MAYERS: Understood, your Honor.

10 So next I'll turn to two threshold arguments  
11 that we made that you discussed with the person on the  
12 other side; first, standing; and second, the collateral  
13 attack doctrine.

14 THE COURT: Okay.

15 MR. MAYERS: Both of those in the Government's  
16 opinion confirm that any relief --

17 (Court Reporter requests pause)

18 THE COURT: The Government submits that both of  
19 those doctrines confirm that any relief the parties  
20 seek should be in front of the Northern District of  
21 Texas and not this Court.

22 So first, standing. The Child Advocate talks  
23 about injury in fact. Your Honor, we don't dispute  
24 injury in fact here as to the Child Advocate's ability  
25 to raise the interests of DCYF.

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF RHODE ISLAND

_____	)	
	)	
	)	
In Re: Administrative Subpoena 25-1431-032	)	C.A. No. 1:26-mc-0007-MSM-AEM
to Rhode Island Hospital.	)	
	)	
_____	)	

**MEMORANDUM AND ORDER**

Mary S. McElroy, United States District Judge.

The United States Department of Justice (“DOJ”) possesses immense prosecutorial authority and discretion. As citizens, we trust that federal prosecutors, when wielding this awesome power against a state, a company, or certainly against vulnerable children, will play fair and be honest with its counterparts and the judiciary.

DOJ has proven unworthy of this trust at every point in this case. It has misrepresented and withheld information to both this Court and the United States District Court for the Northern District of Texas (the “Texas court”). It did so in an obvious effort to shield it’s recent investigative tactics—previously rejected by every other court to review them—from this Court’s review, in favor of a distant forum that DOJ deems friendly to its political positions.<sup>1</sup> Its representatives have, under oath,

<sup>1</sup> The presiding judge in the Texas court has branded “the Department of Justice, the world's largest law firm” a “frequent forum shopper.” Opening Remarks from Judge Reed O'Connor [2024 TX Chapters Conference], The Federalist Society (Oct. 22, 2024), <https://www.youtube.com/watch?v=HMTt9pxWBhA> [https://perma.cc/GR7A-H6N8]. It is clear that the DOJ has done so here.

misrepresented salient facts. It has misled the parties with whom it was negotiating in Rhode Island, who have now been placed in an untenable and unprecedented procedural position. And when its attorneys came to this Court to explain their conduct, the senior attorney—who was present at many of the events that took place in this case—sat silently by as his counterpart, a junior attorney who has been practicing law for approximately six months and had no relevant information, was forced to answer questions about DOJ’s blatant disregard for the proper course of negotiations.

Now before the Court is the petitioner, the Child Advocate for the State of Rhode Island’s (the “Child Advocate”) Emergency Motion to Quash a subpoena duces tecum issued by DOJ as well as Rhode Island Hospital’s (“RIH”) Motion to Quash the same subpoena. (ECF Nos. 1, 28.) For the following reasons, the Court GRANTS both Motions to Quash and enjoins the DOJ from seeking or receiving any documents related to this now invalid subpoena.

## I. BACKGROUND

This matter arises out of an ostensible nationwide healthcare fraud investigation that seeks to examine the manner in which children throughout the United States receive gender-affirming care. Because the issue decided here occurred during what appears to be the preliminary phase of one aspect of this wide-ranging investigation, the Court begins by laying the foundation that prompted the instant dispute.

Beginning in July 2025, the DOJ issued a broad and sweeping administrative subpoena—pursuant to 18 U.S.C. § 3486—to RIH seeking over half a decade of

sensitive medical information of *every* minor patient that had received gender affirming care at that hospital.<sup>2</sup> (ECF No. 1-2.) Specifically, this subpoena sought to sweep in information about these children including: (1) their names; (2) Social Security numbers; (3) addresses; (4) diagnoses; (5) clinical histories; and (6) familial information. *Id.* at 5–7. Upon its receipt of this HIPAA subpoena, RIH elected to negotiate with DOJ over the subpoena’s applicability and scope. No. 4:26-mc-00006-0 (N.D. Tex.), ECF No. 1-3. Following an initial production, the parties began to negotiate the more granular aspects of RIH’s compliance with this subpoena, including the proper search terms and parameters needed to make a more fulsome production to the DOJ. Notwithstanding the parties’ active engagement with one another, beginning in February 2026, the DOJ appears to have inexplicably ceased communicating with RIH.<sup>3</sup> (ECF No. 28-11.) The hearing before this Court on May 12, 2026, was the first time that this Court was made aware of the ongoing nature of these negotiations and of the fact that several conferences had been held since the issuance of the subpoena. Prior to this, the DOJ had represented to this Court that “[t]he Hospital chose not to move to quash the subpoena, and in fact engaged with

<sup>2</sup> The DOJ issued this subpoena as authorized by the Health Insurance Portability and Accountability Act, otherwise known as HIPAA. *See* 18 U.S.C. § 3486. Sometimes, individuals colloquially refer to these subpoenas as “HIPAA subpoenas.”

<sup>3</sup> With respect to the parties’ negotiation of RIH’s options to comply with the subpoena, Counsel Gunn for the DOJ stated that he cannot “specifically recall” whether the parties discussed accepting anonymized patient information. (ECF No. 32-1.) The attorney for RIH represented that the DOJ had not discussed that with them. The Court credits RIH’s representation.

the Government and led the Government to believe it would comply with the subpoena. However, the Hospital never complied and never moved to quash.” (ECF No. 9 at 2.) Notably, and misleadingly, the DOJ never acknowledged that it had failed to respond in any way to the February message from RIH where it suggested search terms for compliance with the subpoena.

Thereafter, on April 28, 2026, email correspondence between the DOJ and RIH reveals that DOJ reinitiated contact with RIH, explained that the responsible prosecutor had “been out for a few weeks[,]” and requested that the parties conference “this week” regarding Rhode Island Hospital’s next production. (ECF No. 28-11.) Notwithstanding this representation to RIH, and roughly forty-eight hours later, DOJ instead decided to file an unannounced Petition for Enforcement of this *same* administrative subpoena in the Northern District of Texas, Fort Worth Division. No. 4:26-mc-00006-O, ECF No. 1. At 6:10 PM on April 30, DOJ emailed RIH reversing its previous negotiating position and announcing that there was “[n]o immediate need to connect now.” (ECF No. 28-11 at 2.) This omission leads the Court to conclude this request was a subterfuge to prevent RIH from realizing that DOJ had decided to go to Texas for an order compelling production of the very records that they had been discussing for months.<sup>4</sup>

<sup>4</sup> It is well established that counsel are responsible for working in a cooperative, rather than an adversarial manner, and to confer in good faith when negotiating the parameters of a subpoena. *In re Risner*, 338 F.R.D. 380, 383 (S.D. Ohio 2021). The parties had done so up until DOJ’s about face on April 30, when it repaired to the Texas court and presented RIH with a *fait-accomplie* motion to enforce (after it had submitted it), followed a few hours later by an order granting that motion. The Child

Alongside their Petition for Enforcement, the DOJ attached: (1) the subpoena itself; (2) preliminary email correspondence between the DOJ and Rhode Island Hospital; (3) and, of particular relevance here, a declaration from the Acting Director of the Enforcement & Affirmative Litigation Branch within the Civil Division of the DOJ, Lisa K. Hsiao. (ECF No. 1-1-3.) With respect to Ms. Hsiao's declaration itself, she represented that RIH had failed to comply with the subpoena and provided the following factual summary to the Texas court:

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

(ECF 1-3 ¶ 46.)

This representation that the communication with RIH had ceased as of February 4, 2026, was clearly misleading, if not utterly false. At the hearing on this Motion, DOJ's attorney attempted to justify the glaring omission by saying that the February 4, 2026 email was the last "such" communication. This is patently untrue because, just the day before filing the declaration containing this representation the attorneys for RIH had sent an email in response to DOJ's request for a conference to

Advocate learned of the subpoena and motion that targeted its children's private information by a DOJ press release the next day.

discuss the terms provided in the February 4th email. This reckless disregard for the duty of candor owed to a federal court is appalling.<sup>5</sup>

Ms. Hsiao also represented that requests regarding “patient-level clinical practices and drug safety” (Requests 11–15) were necessary because “without this information, DOJ cannot fully determine the scope of the violations, identify patterns of misbranding or fraudulent billing, or assess whether the conduct was undertaken with intent to defraud or mislead, as required for felony liability under 21 U.S.C. § 333(a)(2).”<sup>6</sup> But Ms. Hsiao neglected to inform the Texas court that DOJ had agreed to anonymized data in several other jurisdictions. Her assertion that DOJ *needed* this information was therefore, at best, deceptive, if not intentionally and knowingly false.

With respect to this case’s purported nexus to Texas, the DOJ claims that its investigation is taking place in the Northern District of Texas. Notwithstanding the DOJ’s belated disclosure, this update came as a surprise to RIH and the Child Advocate. Ms. Hsiao as well as all other attorneys, save one Assistant U.S. Attorney,

<sup>5</sup> This is not the first time Ms. Hsiao and her subordinates have, in their crusade to obtain transgender children’s medical records, acted in ways that appear to deviate from the norms of professional conduct expected of attorneys representing the United States. *See, e.g., In re Subp. No. 25-1431-014*, 810 F. Supp. 3d 555, 582 (E.D. Pa. 2025) (taking note of an “inconsistency” in Ms. Hsiao’s sworn declaration there and reminding counsel “sworn declarations filed in federal court must reflect verified facts, not speculation recast as fact”); *QueerDoc, PLLC v. U.S. Dept. of J.*, 807 F. Supp. 3d 1295, 1303 n.2 (W.D. Wash. 2025) (describing a filing reflecting “a fundamental misunderstanding—or deliberate misuse—of court procedure”).

<sup>6</sup> During the Court’s hearing on this matter, RIH’s counsel represented that the parties had not yet conferred at any time regarding production of Requests 11–15.

who appear to be assigned to this nationwide investigation, and to this matter itself, are based in Washington D.C., where the DOJ's Civil Division/Enforcement and Affirmative Litigation Branch is located. *See* No. 4:26-mc-00006-O (N.D. Tex.). At all times, RIH conferred with counsel based in Washington D.C. or Rhode Island. The records sought were in Rhode Island, from a Rhode Island corporation, and of Rhode Island citizens. Additionally, during the hearing before this Court, counsel for DOJ represented that the investigation began in Washington D.C. but could not specify when it transferred this investigation to the Northern District of Texas.

Following its receipt of DOJ's motion, the Texas court summarily granted it, without any notice to or response from RIH. No. 4:26-MC-0006-O (N.D. Tex. Apr. 30, 2026), ECF No. 2. That order commanded RIH to "provide all records responsive to each request in the subpoena" by May 14, 2026, and warned that "failure to fully comply with the subpoena or show just cause for continued noncompliance" could result in sanctions, up to and including contempt. *Id.*

RIH moved to stay the Texas court's order pending their appeal in the Fifth Circuit. The Texas court denied RIH's motion to stay and refused to "exercise [its] judicial discretion" to "grant extraordinary relief" because it determined that RIH had not demonstrated a likelihood of success on any of its claims. No. 4:26-MC-0006-O (N.D. Tex. Apr. 30, 2026), ECF No. 12 at 2, 8. In reaching this decision, the Texas court relied on the "Government's representation in the initial Hsiao Declaration" and the facts as presented to it at that time. *Id.* at 8. RIH simultaneously moved to stay pending its appeal to the Fifth Circuit, which promptly denied its motion in a

one sentence order. *See United States v. Rhode Island Hospital*, No. 26-10431 (5th Cir. May 12, 2026).

This Court held a hearing on the Child Advocate’s and RIH’s Emergency Motion to Quash on May 12, 2026. Further facts are set forth, as necessary, below.

## II. DISCUSSION

### A. The Child Advocate Has Standing to Challenge the Administrative Subpoena

DOJ contests the Child Advocate’s standing to challenge the administrative subpoena. (ECF No. 9 at 3–5.) To have standing, a plaintiff must demonstrate “(1) an injury in fact, (2) a causal connection between the injury and the conduct complained of, and (3) a likelihood that the injury will be redressed by a favorable decision.” *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560–61 (1992). An injury sufficient to establish standing “does not arise only when a defendant causes a tangible harm to a plaintiff, like a physical injury or monetary loss. It can also arise when a defendant burdens a plaintiff’s constitutional rights.” *First Choice Women’s Res. Ctrs., Inc. v. Davenport*, No. 24-781, 2026 WL 1153029, at \*8 (U.S. Apr. 29, 2026).

The Child Advocate meets the requirements to have standing here. First, as addressed below, the children represented by the Child Advocate have individual rights to informational privacy that will surely be injured by the disclosure of their extremely personal medical information under these circumstances. *See In re Children’s Nat’l Hosp.*, No. 1:25-CV-03780-JRR, 2026 WL 160792, at \*4–6 (D. Md. Jan. 21, 2026); *In re: 2025 UPMC Subpoena*, 2025 WL 3724705, at \*1 (W.D. Pa. Dec. 24, 2025). Second, this imminent injury is causally connected to the administrative

subpoena they challenge here. Third, as the following discussion explains, the injury is redressable by this Court notwithstanding the Texas court's Order.

**B. The Collateral Attack Doctrine Does Not Bar the Child Advocate or RIH's Requested Relief**

"A 'collateral attack' is a tactic whereby a party seeks to circumvent an earlier ruling of one court by filing a subsequent action in another court." *Pratt v. Ventas, Inc.*, 365 F.3d 514, 519 (6th Cir. 2004). This tactic is generally prohibited by the "collateral attack doctrine," under which a district court "lacks authority to hear an appeal of the rulings made by another federal judge." *Verogna v. Johnstone*, 583 F. Supp. 3d 331, 337 (D.N.H. 2022) (collecting cases), *aff'd*, No. 22-1364, 2022 WL 19795808 (1st Cir. Nov. 14, 2022). Instead, the proper avenue for challenging a district court's order is typically through a motion with that court or through appeal.

The DOJ contests the ability of both the Child Advocate and RIH to seek quashal here given the Texas court's Order. (ECF No. 9 at 5–6.) According to DOJ, the parties seek an order here that would effectively circumvent the Texas court's Order. *Id.* at 6. Were the circumstances of this case akin to those that typically implicate the collateral attack doctrine (for example, where a party seeks to invalidate one court's pecuniary or penal judgment by petitioning another court for injunctive relief) the DOJ would likely be correct. But the peculiar facts of this case—including RIH's lack of notice prior to the Texas court's Order, the Child Advocate's nonparty status with respect to that case, and the underlying challenge here being to

an agency’s administrative subpoena rather than to a court’s judgment—appear to be distinguishable from the typical case.<sup>7</sup>

The collateral attack doctrine is based on the principles underpinning *res judicata*, i.e., claim preclusion. *Cf. Baella-Silva*, 454 F.3d 5, 9 (1st Cir. 2006) (“A district court’s express or implicit determination that it has jurisdiction is open to direct review, but it is *res judicata* when collaterally attacked.”) (italics in original). The elements of *res judicata* are “(1) a final judgment on the merits in an earlier suit, (2) sufficient identity between the causes of action asserted in the earlier and later suits, and (3) sufficient identity between the parties in the two suits.” *In re Iannochino*, 242 F.3d 36, 43 (1st Cir. 2001) (quoting *Mass. School of Law v. American Bar Assoc.*, 142 F.3d 26, 37 (1st Cir.1998)). For the Child Advocate, the third element is most at issue here because it was not itself party to the Texas court proceedings.

In *Martin v. Wilks*, the Supreme Court evaluated what it termed the “impermissible collateral attack doctrine.” 490 U.S. 755, 765 (1989). The plaintiffs there were white employees challenging alleged race-conscious employment decisions that were made pursuant to consent decrees entered in collateral litigation between the defendants and the NAACP. *Id.* at 759–60. The Supreme Court found that the plaintiffs were not precluded from challenging the employment decisions because they were not parties to the litigation from which the consent decrees stemmed. *Id.* at 761–62. As the Court explained, “[a]ll agree that ‘it is a principle of general

<sup>7</sup> The Court is unaware of any similar case where a party has petitioned a court to quash an administrative subpoena that another court ordered enforced without prior notice or opportunity to be heard.

application in Anglo-American jurisprudence that one 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.” *Id.* at 761 (quoting *Hansberry v. Lee*, 311 U.S. 32, 40 (1940)). Thus, “[a] judgment or decree among parties to a lawsuit resolves issues as among them, but it does not conclude the rights of strangers to those proceedings.” *Id.* at 762.<sup>8</sup>

Here, the Child Advocate alleges injuries that flow from another court’s decision to which it was not a party. And, similarly to how the white firefighters in *Wilks* had distinct interests from those litigated in the consent decree to which they were not parties, the interests of the children that the Child Advocate represents (the “legal, civil, and special rights of children” under protective care, *see* R.I. Gen. Laws § 42-73-7) are distinct from those that either were or could have been litigated in the Texas court—a fact that was acknowledged by the Texas court itself. *See In Re: Administrative Subpoena 25-1431-032*, No. 4-26MC-006-0 (N.D. Tex.) ECF No. 9 at 9 (“Thus, RIH has not shown how it would be harmed rather than its patients, who are third parties.”). And while *Wilks* recognized an exception to the general rule against nonparty preclusion in “limited circumstances” where a nonparty “has his interests adequately represented by someone with the same interests who is a party,” 490 U.S. at 762 n.2, this exception typically applies to class actions and suits involving

<sup>8</sup> The Supreme Court has since found *Wilks* to have been superseded by statute, insofar as it allows collateral attacks on consent decrees. *See Landgraf v. USI Film Products*, 511 U.S. 244, 251 (1994). But *Landgraf* did not repudiate *Wilks*’s reasoning.

fiduciaries, and is inapplicable here, particularly given that the record reflects that the Child Advocate's interests were *not* adequately represented in the Texas court. *See Taylor v. Sturgell*, 553 U.S. 880, 894 (2008) ("Representative suits with preclusive effect on nonparties include properly conducted class actions, and suits brought by trustees, guardians, and other fiduciaries.") (internal citations omitted).

It also appears unlikely that quashal—the primary relief sought by the Child Advocate here—constitutes a collateral attack on the Texas court's Order, notwithstanding the fact that quashal necessarily implicates that Order. Unlike a traditional judicial subpoena issued under the authority of a court, such as one issued under Federal Rule of Civil Procedure 45, the administrative subpoena here is the product of the DOJ's own statutory authority, *see* 18 U.S.C. § 3846. It was not issued by the Texas court, whose order is premised on that subpoena's legal force. It seems to follow that, as with APA claims—where a district court has the power to vacate challenged agency action even where vacatur may necessarily implicate other courts' judgments regarding that same action—the Court has the power to effectively vacate (i.e., quash) the administrative subpoena at issue here despite the fact that doing so necessarily implicates the parties' responsibilities under the Texas court's Order.

As such, the collateral attack doctrine poses no barrier to the Child Advocate's Petition. It also seems likely that, based on the underlying principles of *res judicata*, the collateral attack doctrine does not bar RIH's intervention here because it was not provided notice and an opportunity to be heard before the Texas court ordered the administrative subpoena enforced. As the Supreme Court has explained:

The doctrine of res judicata rests at bottom upon the ground that the party to be affected, or some other with whom he is in privity, has litigated or had an opportunity to litigate the same matter in a former action in a court of competent jurisdiction. The opportunity to be heard is an essential requisite of due process of law in judicial proceedings.

*Postal Telegraph Cable Co. v. City of Newport, Ky.*, 247 U.S. 464, 476 (1918). Thus, this Court “may not, consistently with the Fourteenth Amendment, enforce a judgment against a party named in the proceedings without a hearing or an opportunity to be heard.” *Id.*; see also *Blonder-Tongue Laboratories, Inc. v. U. of Illinois Found.*, 402 U.S. 313, 329 (1971) (“Some litigants—those who never appeared in a prior action—may not be collaterally estopped without litigating the issue.”).

While RIH may have subsequently had an opportunity to seek reconsideration of the Texas court’s Order, the preclusive effect of that order seems questionable given that it was granted *before* RIH had any notice or opportunity to be heard as due process requires. Further, “[r]econsideration of a judgment after its entry is an extraordinary remedy that should be used sparingly.” *Templet v. HydroChem Inc.*, 367 F.3d 473, 479 (5th Cir. 2004). Thus, RIH (and, by extension, the Child Advocate) was deprived of any opportunity to argue the propriety of the subpoena in a posture that did not demand “extraordinary relief” or was not summary in nature, and should not be precluded from litigating that issue here.

### C. The Merits

Given that the collateral attack doctrine does not preclude consideration of the Petitioners’ Motions to Quash, the Court proceeds to the merits of those Motions.

### 1. The Subpoena Lacks A Congressionally Authorized Purpose

To enforce an administrative subpoena issued under 18 U.S.C. § 3486, the DOJ must show that “(1) the subpoena is issued for a congressionally authorized purpose, the information sought is (2) relevant to the authorized purpose and (3) adequately described, and (4) proper procedures have been employed in issuing the subpoena.” *U.S. Dep’t of Just. v. Ricco Jonas*, 24 F.4th 718, 726 (1st Cir. 2022) (quoting *United States v. Sturm, Ruger & Co.*, 84 F.3d 1, 4 (1st Cir. 1996)). Here, the DOJ fails to meet the first element, and that failure is fatal to their subpoena.

The DOJ asserts that it issued this subpoena to investigate potential violations of the Food, Drug, and Cosmetic Act (“FDCA”), specifically the FDCA’s prohibition on misbranding. Their argument proceeds as follows: when a physician prescribes a drug for an off-label use, the drug’s “intended use” within the meaning of 21 C.F.R. § 201.128 changes. This changed intended use then renders the drug’s labeling inadequate under 21 U.S.C. § 352(f)(1), and then any party in the distribution chain who helped place that drug in commerce—including a hospital whose physicians wrote the prescriptions—faces criminal liability under 21 U.S.C. §§ 331, 333(a)(1), which also potentially includes individual administrators under the responsible corporate officer doctrine of *United States v. Park*, 421 U.S. 658 (1975).

But the First Circuit has held that “medical professionals may lawfully prescribe and administer a device for an off-label use as long as that device has received [FDA] clearance for any intended use.” *United States v. Facticeau*, 89 F.4th 1, 15 (1st Cir. 2023), *cert. denied*, 145 S. Ct. 137 (2024). The drugs at issue—puberty

blockers and cross-sex hormones—are FDA-approved for various uses, and RIH’s physicians prescribe and administer them in clinical care. The DOJ’s theory that off-label prescribing by licensed practitioners gives rise to FDCA criminal liability cannot be squared with *Facteau*. See also *In re Celexa & Lexapro Mktg. & Sales Pracs. Litig.*, 915 F.3d 1, 5 (1st Cir. 2019) (“The FDCA . . . does not prohibit doctors from prescribing drugs for off-label uses.”).

Congress did not merely leave off-label prescribing unregulated: it affirmatively protected it. Section 396 of the FDCA provides that “[n]othing 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.” 21 U.S.C. § 396. Further, the regulation of the practice of medicine has long been understood to remain within the states’ prerogative, and the Executive may not adopt novel interpretations of federal statutes to displace a state’s medical regulatory framework without clear congressional authorization to do so. See *Gonzales v. Oregon*, 546 U.S. 243, 269-70 (2006). Rhode Island has expressly protected gender-affirming care as lawful medical practice. R.I. Gen. Laws §§ 5-37.8-1, 23-101-2. The DOJ acknowledges that merely writing off-label prescriptions is not an FDCA offense but attempts to reach prescribing hospitals indirectly by characterizing their participation in a supply chain as causing the distribution of misbranded drugs. That reframing does not save the theory.

Because off-label prescribing by physicians is lawful, which the DOJ does not dispute, it is therefore logically impossible to construct an aiding-and-abetting, facilitation, or conspiracy theory predicated on nothing more than the physician's own lawful prescribing act.<sup>9</sup> No court has extended FDCA misbranding liability to a hospital or physician on this basis. As one court considering a similar subpoena observed, the DOJ "seeks all this while not offering one iota of suspicion" that RIH engaged in the off-label promotion that the FDCA does actually prohibit. *In re Admin. Subpoena No. 25-1431-019*, 800 F. Supp. 3d 229, 238 (D. Mass. 2025).

The DOJ's current litigation position is also in direct conflict with its own prior legal interpretations of the same statutory scheme. The FDA has stated publicly that once a drug is approved, healthcare providers may generally prescribe it for unapproved uses when they determine that doing so is medically appropriate. FDA, *Understanding Unapproved Use of Approved Drugs "Off Label"* (Feb. 5, 2018), <https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label>. The FDA, in guidance that is final but pending before the Office of Management and Budget, restated that position in guidance issued as recently as January 2025. *See FDA, Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products; Questions and Answers; Guidance for Industry* 8–9 (Jan. 2025), <https://www.fda.gov/media/184871/download>.

<sup>9</sup> The DOJ has also made references, in the Hsiao Declaration and at oral argument, to theories based on conspiracy, billing fraud, and healthcare fraud. But these theories are also tethered to off-label use and fail for the same reasons.

More significantly, the DOJ's own Office of Legal Counsel ("OLC") has concluded that the "FDA does not regulate the practice of medicine, which includes 'off-label' prescribing," and that "[w]hile the FDCA bars a manufacturer or distributor from selling any drug or device for an unapproved use, physicians may, with limited exceptions, prescribe and administer FDA-approved drugs and devices for unapproved uses." Steven A. Engel, *Whether the Food & Drug Administration Has Jurisdiction Over Articles Intended for Use in Lawful Executions*, 43 Op. O.L.C. 81, 85 (2019).

There also is a separate and independently sufficient basis on which the DOJ's misbranding claim fails as applied to RIH. Section 353(b)(2) exempts from the requirements of § 352 any drug "dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug." 21 U.S.C. § 353(b)(2). Thus, § 352(f) (the adequate-directions-for-use requirement on which the DOJ's entire misbranding theory rests) does not apply to prescription drugs dispensed pursuant to a licensed practitioner's prescription. RIH's physicians prescribe medications to patients in the clinical setting pursuant to their medical judgment. That conduct falls squarely within § 353(b)(2)'s exemption.

In sum, the DOJ's FDCA theory does not constitute a legally cognizable basis for this investigation as applied to a prescribing hospital. *See Facteau*, 89 F.4th at 15. The off-label prescribing conduct at the core of the DOJ's theory is not illegal under the FDCA. Section 353(b)(2) exempts the specific misbranding provision the DOJ invokes. The DOJ's own OLC has interpreted the same statutory scheme in a

manner that directly contradicts their current litigation position. The subpoena therefore lacks a congressionally authorized purpose and must be quashed. *See Ricco Jonas*, 24 F.4th at 726.

## 2. Improper Purpose

The Court additionally concludes that the subpoena should be quashed because it was issued for an improper purpose in bad faith. A subpoena “issued for an improper purpose, such as to harass” a recipient or “to put pressure on him” or “for any other purpose reflecting on the good faith of the particular investigation” cannot be enforced. *United States v. Powell*, 379 U.S. 48, 58 (1964); *United States v. Comley*, 890 F.2d 539, 542 (1st Cir. 1989) (recognizing that courts have “adequate justification to deny enforcement of [a] subpoena” when there is evidence of bad faith). Where the DOJ issues a subpoena for an improper purpose, quashal is warranted when that improper purpose is the sole purpose of the investigation. *United States v. Gertner*, 65 F.3d 963, 970 (1st Cir. 1995).

The evidence of improper purpose here is in the DOJ’s own public record and detailed in the decisions of the seven other federal courts that have considered identical subpoenas. The Administration has publicly characterized gender-affirming care for minors as abuse, directed the DOJ to bring its practice to an end, and celebrated when hospitals curtailed such programs as a result of this subpoena campaign. (ECF No. 20-1 at 22, 23 n.8.)

The DOJ, however, contends that even if a policy purpose exists, a legitimate FDCA investigation runs alongside it and the *Gertner* sole-purpose standard

therefore cannot be satisfied. *See* 65 F.3d at 970. But this would require a genuine legitimate investigative purpose, not merely a legal theory, which, as described above, is not legally cognizable as applied to a prescribing hospital. 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.

Seven other federal courts have found these subpoenas to have been issued for an improper purpose, and this Court finds their reasoning persuasive and applies it her. *See QueerDoc, PLLC v. U.S. Dep't of Just.*, 807 F. Supp. 3d 1295, 1303–04 (W.D. Wash. 2025); *In re Admin. Subpoena No. 25-1431-019*, 800 F. Supp. 3d 229, 239 (D. Mass. 2025); *In re Subpoena Duces Tecum No. 25-1431-016*, No. 25-mc-41, 2025 WL 3562151, at \*12–13 (W.D. Wash. Sept. 3, 2025); *In re Dep't of Just. Admin. Subpoena No. 25-1431-030*, No. 25-mc-63, 2026 WL 33398, at \*11 (D. Colo. Jan. 5, 2026); *In re Children's Nat'l Hosp.*, No. 1:25-cv-03780-JRR, 2026 WL 160792, at \*8 (D. Md. Jan. 21, 2026); *In re Subpoena No. 25-1431-014*, 810 F. Supp. 3d 555, 580 (E.D. Pa. 2025); *In re 2025 UPMC Subpoena*, No. 2:25-MC-01069-CB, 2026 WL 570419 (W.D. Pa. Mar. 2, 2026).

### **3. The Fourteenth Amendment Right to Informational Privacy**

But there is another ground warranting quashal. The Child Advocate contends that the children who are the subject of the medical records themselves possess a Fourteenth Amendment right to informational privacy in these records and that

RIH's compliance with the full scope of the requests contained within the subpoena would violate this right. (ECF No. 1 at 39–41.) The Court agrees.<sup>10</sup>

Nearly half a century ago, the Supreme Court recognized a right to informational privacy, which prevents the compelled disclosure of personal matters. *See Whalen v. Roe*, 429 U.S. 589, 599 (1977) (describing the “individual interest in avoiding disclosure of personal matters[.]”). Following its initial acknowledgement of this right, the Supreme Court has repeatedly acknowledged its existence in the decades that followed. *See Nat’l Aeronautics & Space Admin. v. Nelson*, 562 U.S. 134, 138 (2011) (Alito, J.) (“We assume, without deciding, that the Constitution protects a privacy interest of the sort mentioned in *Whalen* and *Nixon*.”); *Dobbs v. Jackson Women’s Health Organization*, 597 U.S. 215, 219 (2022) (Alito, J.) (“But *Roe* conflated the right to shield information from disclosure and the right to make and implement personal decisions without governmental interference.”) (citing *Whalen*, 429 U.S. at 599–600).

Throughout its history, the First Circuit has also acknowledged the existence of an individual’s constitutional right to informational privacy. *See Borucki v. Ryan*, 827 F.2d 836, 845–49 (1st Cir. 1987) (grappling with *Whalen*’s “paucity of concrete guidance”); *see also Vega-Rodriguez v. Puerto Rico Telephone Co.*, 110 F.3d 174 (1st Cir. 1997) (Selya, J.) (“Even if the right of confidentiality has a range broader than that associated with the right of autonomy, that range has not extended beyond

<sup>10</sup> In doing so, the Court provides no view on whether, as asserted by the Child Advocate, the Fourth Amendment provides a separate, independent source of constitutional protection in this context.

prohibiting profligate disclosure of *medical*, financial, and other intimately personal data.”) (emphasis added).

Finally, at least one court within the First Circuit has also: (1) concluded that the constitutional right to informational privacy exists; and (2) applied it to litigants appearing before it in that matter. *See Arroyo Gonzelez v. Rossello Nevares*, 305 F. Supp. 3d 327, 333 (D.P.R. 2018) (determining that Puerto Rico’s ban on changing the gender markers in the plaintiffs’ birth certificates violates their right to informational privacy).<sup>11</sup>

Here, the Child Advocate has successfully demonstrated that the subpoena’s enforcement in full would violate the right to informational privacy of the children that it represents. Specifically, the Court determines that DOJ’s request for intimate medical details from one of this country’s most vulnerable populations constitutes a drastic overreach of its investigative authority. As discussed elsewhere, not only has the DOJ failed to specify *how* this information is related to its legitimate authority to conduct its investigation, but it has also failed to assuage the Court of its serious concerns for how DOJ would adequately protect and otherwise safeguard this information. When faced with the very real — and likely irreparable — harm to the children in the State’s current or former care that unfettered, compelled disclosure

<sup>11</sup> Notwithstanding the legal developments that have taken place within the First Circuit, courts across the country have had a myriad of opportunities to address, and develop, the constitutional right to informational privacy. *See Carmel Shachar & Carleen Zubrzycki, Informational Privacy After Dobbs*, 75 ALA. L. REV. 1, 19 (2023). Separately, the Court thanks the amici for their helpful and speedy submissions in this matter.

that compliance with this subpoena would create, this Court concludes that RIH's compliance would violate affected children's rights to informational privacy.<sup>12</sup> As a result, the Court determines that the application of this right constitutes a separate basis for quashal of the subpoena.

The Court turns to the scope of relief this separate finding would require. The DOJ argued that any remedy grounded in the children's constitutional right should be limited to records pertaining to children in DCYF custody or care—those whose rights the Child Advocate represents. The Court rejects this proposed limitation on practical grounds.

To implement a carveout limited to DCYF children, RIH would first have to identify which among its minor patients are DCYF wards: reviewing each responsive record to determine which patients are in state custody or care before segregating those records from the rest. That identification process would itself expose precisely the sensitive intersection of information the constitutional right is designed to protect: which gender-affirming care patients are vulnerable wards of the state. When asked at oral argument how the DOJ envisioned this segregation process working in practice, the DOJ offered no adequate answer. The Court is left with no basis to conclude that a DCYF-only carveout is operationally feasible, and every reason to conclude it is not.

<sup>12</sup> To provide a more concrete example of the potential harm at issue here, the DOJ conceded during the Court's hearing that their investigative efforts would include attempting to locate and question both children and their caregivers in its search for criminal conduct.

There is no way to protect the informational privacy rights of DCYF children without first doing what the constitutional right forbids: identifying them as DCYF wards in the process of separating their records from those of other minor patients. The relief this Court grants therefore necessarily extends to the records of all minors. This extension flows not from any expansion of the Child Advocate’s standing, but from the practical impossibility of implementing a narrower remedy without violating the very right the remedy is designed to vindicate.

### III. CONCLUSION

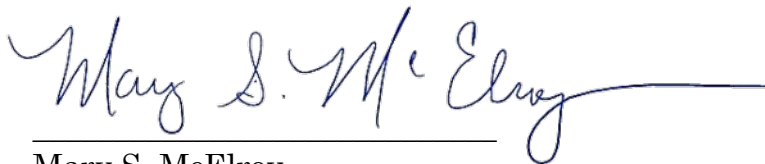
Ultimately, the Court’s decision is based solely on its application of the law to the administrative subpoena at issue here. But the discrepancy between the honorable conduct expected of federal prosecutors and DOJ’s tactics in this case is unsettling. The Court cannot help but share the sentiment that “[t]he presumption of regularity that has previously been extended to [DOJ] that it could be taken at its word—with little doubt about its intentions and stated purposes—no longer holds.” *United States v. Oregon*, No. 6:25-CV-01666-MTK, 2026 WL 318402, at \*11 (D. Or. Feb. 5, 2026). It is regrettable that this is now the case.

The Emergency Motions to Quash (ECF Nos. 1 & 28) are GRANTED. In granting these Motions, this Court quashes the administrative subpoena—the instrument issued by the DOJ—not the enforcement order entered by the Texas court. What this Court holds is that the subpoena itself lacks a congressionally authorized purpose, was issued for an improper purpose, and demands the production of records that cannot be obtained consistent with the constitutional privacy rights of

Rhode Island children. Those are independent grounds for quashal of the subpoena that this Court has authority to adjudicate.

In addition, the DOJ is hereby ENJOINED from receiving, using, retaining, or disseminating any patient-identifying information or protected health information produced by RIH in response to Administrative Subpoena No. 25-1431-032, including all materials responsive to Requests 11 through 15 and any other materials that identify, or reasonably permit the identification of, Rhode Island's children.

IT IS SO ORDERED.



Mary S. McElroy  
United States District Judge

May 13, 2026

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF RHODE ISLAND

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In Re: Administrative Subpoena 25-1431-032 )  
to Rhode Island Hospital. )  
)  
\_\_\_\_\_ )

C.A. No. 1:26-mc-0007-MSM-AEM

**JUDGMENT**

IT IS ORDERED AND ADJUDGED:

Judgment hereby enters in accordance with the Memo and Order of 5/13/2026.

Enter:  
/s/ C. Potter  
Deputy Clerk  
Dated 5/13/2026

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF RHODE ISLAND

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In Re: Administrative Subpoena 25-1431-032	)	C.A. No. 1:26-mc-0007-MSM-AEM
to Rhode Island Hospital.	)	
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**MEMORANDUM AND ORDER**

Mary S. McElroy, United States District Judge.

The United States Department of Justice (“DOJ”) possesses immense prosecutorial authority and discretion. As citizens, we trust that federal prosecutors, when wielding this awesome power against a state, a company, or certainly against vulnerable children, will play fair and be honest with its counterparts and the judiciary.

DOJ has proven unworthy of this trust at every point in this case. It has misrepresented and withheld information to both this Court and the United States District Court for the Northern District of Texas (the “Texas court”). It did so in an obvious effort to shield its recent investigative tactics—previously rejected by every other court to review them—from this Court’s review, in favor of a distant forum that DOJ deems friendly to its political positions.<sup>1</sup> Its representatives have, under oath,

<sup>1</sup> The presiding judge in the Texas court has branded “the Department of Justice, the world's largest law firm” a “frequent forum shopper.” Opening Remarks from Judge Reed O'Connor [2024 TX Chapters Conference], The Federalist Society (Oct. 22, 2024), <https://www.youtube.com/watch?v=HMTt9pxWBhA> [https://perma.cc/GR7A-H6N8]. It is clear that the DOJ has done so here.

misrepresented salient facts. It has misled the parties with whom it was negotiating in Rhode Island, who have now been placed in an untenable and unprecedented procedural position. And when its attorneys came to this Court to explain their conduct, the senior attorney—who was present at many of the events that took place in this case—sat silently by as his counterpart, a junior attorney who has been practicing law for approximately six months and had no relevant information, was forced to answer questions about DOJ’s blatant disregard for the proper course of negotiations.

Now before the Court is the petitioner, the Child Advocate for the State of Rhode Island’s (the “Child Advocate”) Emergency Motion to Quash a subpoena duces tecum issued by DOJ as well as Rhode Island Hospital’s (“RIH”) Motion to Quash the same subpoena. (ECF Nos. 1, 28.) For the following reasons, the Court GRANTS both Motions to Quash and enjoins the DOJ from seeking or receiving any documents related to this now invalid subpoena.

## I. BACKGROUND

This matter arises out of an ostensible nationwide healthcare fraud investigation that seeks to examine the manner in which children throughout the United States receive gender-affirming care. Because the issue decided here occurred during what appears to be the preliminary phase of one aspect of this wide-ranging investigation, the Court begins by laying the foundation that prompted the instant dispute.

Beginning in July 2025, DOJ issued a broad and sweeping administrative subpoena—pursuant to 18 U.S.C. § 3486—to RIH seeking over half a decade of

sensitive medical information of *every* minor patient that had received gender affirming care at that hospital.<sup>2</sup> (ECF No. 1-2.) Specifically, this subpoena sought to sweep in information about these children including: (1) their names; (2) Social Security numbers; (3) addresses; (4) diagnoses; (5) clinical histories; and (6) familial information. *Id.* at 5–7. Upon its receipt of this HIPAA subpoena, RIH elected to negotiate with DOJ over the subpoena’s applicability and scope. No. 4:26-mc-00006-0 (N.D. Tex.), ECF No. 1-3. Following an initial production, the parties began to negotiate the more granular aspects of RIH’s compliance with this subpoena, including the proper search terms and parameters needed to make a more fulsome production to DOJ. Notwithstanding the parties’ active engagement with one another, beginning in February 2026, DOJ appears to have inexplicably ceased communicating with RIH.<sup>3</sup> (ECF No. 28-11.) The hearing before this Court on May 12, 2026, was the first time that this Court was made aware of the ongoing nature of these negotiations and of the fact that several conferences had been held since the issuance of the subpoena. Prior to this, DOJ had represented to this Court that “[t]he Hospital chose not to move to quash the subpoena, and in fact engaged with the

<sup>2</sup> The DOJ issued this subpoena as authorized by the Health Insurance Portability and Accountability Act, otherwise known as HIPAA. *See* 18 U.S.C. § 3486. Sometimes, individuals colloquially refer to these subpoenas as “HIPAA subpoenas.”

<sup>3</sup> With respect to the parties’ negotiation of RIH’s options to comply with the subpoena, Counsel Gunn for DOJ stated that he cannot “specifically recall” whether the parties discussed accepting anonymized patient information. (ECF No. 32-1.) The attorney for RIH represented that DOJ had not discussed that with them. The Court credits RIH’s representation.

Government and led the Government to believe it would comply with the subpoena. However, the Hospital never complied and never moved to quash.” (ECF No. 9 at 2.) Notably, and misleadingly, DOJ never acknowledged that it had failed to respond in any way to the February message from RIH where it suggested search terms for compliance with the subpoena.

Thereafter, on April 28, 2026, email correspondence between DOJ and RIH reveals that DOJ reinitiated contact with RIH, explained that the responsible prosecutor had “been out for a few weeks[,]” and requested that the parties conference “this week” regarding Rhode Island Hospital’s next production. (ECF No. 28-11.) Notwithstanding this representation to RIH, and roughly forty-eight hours later, DOJ instead decided to file an unannounced Petition for Enforcement of this *same* administrative subpoena in the Northern District of Texas, Fort Worth Division. No. 4:26-mc-00006-O, ECF No. 1. At 6:10 PM on April 30, DOJ emailed RIH reversing its previous negotiating position and announcing that there was “[n]o immediate need to connect now.” (ECF No. 28-11 at 2.) This omission leads the Court to conclude this request was a subterfuge to prevent RIH from realizing that DOJ had decided to go to Texas for an order compelling production of the very records that they had been discussing for months.<sup>4</sup>

<sup>4</sup> It is well established that counsel are responsible for working in a cooperative, rather than an adversarial manner, and to confer in good faith when negotiating the parameters of a subpoena. *In re Risner*, 338 F.R.D. 380, 383 (S.D. Ohio 2021). The parties had done so up until DOJ’s about face on April 30, when it repaired to the Texas court and presented RIH with a *fait-accomplie* motion to enforce (after it had submitted it), followed a few hours later by an order granting that motion. The Child

Alongside its Petition for Enforcement, the DOJ attached: (1) the subpoena itself; (2) preliminary email correspondence between the DOJ and Rhode Island Hospital; (3) and, of particular relevance here, a declaration from the Acting Director of the Enforcement & Affirmative Litigation Branch within the Civil Division of the DOJ, Lisa K. Hsiao. (ECF No. 1-1-3.) With respect to Ms. Hsiao's declaration itself, she represented that RIH had failed to comply with the subpoena and provided the following factual summary to the Texas court:

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

(ECF 1-3 ¶ 46.)

This representation that the communication with RIH had ceased as of February 4, 2026, was clearly misleading, if not utterly false. At the hearing on this Motion, DOJ's attorney attempted to justify the glaring omission by saying that the February 4, 2026 email was the last "such" communication. This is patently untrue because, just the day before filing the declaration containing this representation the attorneys for RIH had sent an email in response to DOJ's request for a conference to

Advocate learned of the subpoena and motion that targeted its children's private information by a DOJ press release the next day.

discuss the terms provided in the February 4th email. This reckless disregard for the duty of candor owed to a federal court is appalling.<sup>5</sup>

Ms. Hsiao also represented that requests regarding “patient-level clinical practices and drug safety” (Requests 11–15) were necessary because “without this information, DOJ cannot fully determine the scope of the violations, identify patterns of misbranding or fraudulent billing, or assess whether the conduct was undertaken with intent to defraud or mislead, as required for felony liability under 21 U.S.C. § 333(a)(2).”<sup>6</sup> But Ms. Hsiao neglected to inform the Texas court that DOJ had agreed to anonymized data in several other jurisdictions. Her assertion that DOJ *needed* this information was therefore, at best, deceptive, if not intentionally and knowingly false.

With respect to this case’s purported nexus to Texas, the DOJ claims that its investigation is taking place in the Northern District of Texas. Notwithstanding the DOJ’s belated disclosure, this update came as a surprise to RIH and the Child Advocate. Ms. Hsiao as well as all other attorneys, save one Assistant U.S. Attorney,

<sup>5</sup> This is not the first time Ms. Hsiao and her subordinates have, in their crusade to obtain transgender children’s medical records, acted in ways that appear to deviate from the norms of professional conduct expected of attorneys representing the United States. *See, e.g., In re Subp. No. 25-1431-014*, 810 F. Supp. 3d 555, 582 (E.D. Pa. 2025) (taking note of an “inconsistency” in Ms. Hsiao’s sworn declaration there and reminding counsel “sworn declarations filed in federal court must reflect verified facts, not speculation recast as fact”); *QueerDoc, PLLC v. U.S. Dept. of J.*, 807 F. Supp. 3d 1295, 1303 n.2 (W.D. Wash. 2025) (describing a filing reflecting “a fundamental misunderstanding—or deliberate misuse—of court procedure”).

<sup>6</sup> During the Court’s hearing on this matter, RIH’s counsel represented that the parties had not yet conferred at any time regarding production of Requests 11–15.

who appear to be assigned to this nationwide investigation, and to this matter itself, are based in Washington D.C., where the DOJ's Civil Division/Enforcement and Affirmative Litigation Branch is located. *See* No. 4:26-mc-00006-O (N.D. Tex.). At all times, RIH conferred with counsel based in Washington D.C. or Rhode Island. The records sought were in Rhode Island, from a Rhode Island corporation, and of Rhode Island citizens. Additionally, during the hearing before this Court, counsel for DOJ represented that the investigation began in Washington D.C. but could not specify when it transferred this investigation to the Northern District of Texas.

Following its receipt of DOJ's motion, the Texas court summarily granted it, without any notice to or response from RIH. No. 4:26-MC-0006-O (N.D. Tex. Apr. 30, 2026), ECF No. 2. That order commanded RIH to "provide all records responsive to each request in the subpoena" by May 14, 2026, and warned that "failure to fully comply with the subpoena or show just cause for continued noncompliance" could result in sanctions, up to and including contempt. *Id.*

RIH moved to stay the Texas court's order pending its appeal in the Fifth Circuit. The Texas court denied RIH's motion to stay and refused to "exercise [its] judicial discretion" to "grant extraordinary relief" because it determined that RIH had not demonstrated a likelihood of success on any of its claims. No. 4:26-MC-0006-O (N.D. Tex. Apr. 30, 2026), ECF No. 12 at 2, 8. In reaching this decision, the Texas court relied on the "Government's representation in the initial Hsiao Declaration" and the facts as presented to it at that time. *Id.* at 8. RIH simultaneously moved to stay pending its appeal to the Fifth Circuit, which promptly denied its motion in a

one sentence order. *See United States v. Rhode Island Hospital*, No. 26-10431 (5th Cir. May 12, 2026).

This Court held a hearing on the Child Advocate’s and RIH’s Emergency Motion to Quash on May 12, 2026. Further facts are set forth, as necessary, below.

## II. DISCUSSION

### A. The Child Advocate Has Standing to Challenge the Administrative Subpoena

DOJ contests the Child Advocate’s standing to challenge the administrative subpoena. (ECF No. 9 at 3–5.) To have standing, a plaintiff must demonstrate “(1) an injury in fact, (2) a causal connection between the injury and the conduct complained of, and (3) a likelihood that the injury will be redressed by a favorable decision.” *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560–61 (1992). An injury sufficient to establish standing “does not arise only when a defendant causes a tangible harm to a plaintiff, like a physical injury or monetary loss. It can also arise when a defendant burdens a plaintiff’s constitutional rights.” *First Choice Women’s Res. Ctrs., Inc. v. Davenport*, No. 24-781, 2026 WL 1153029, at \*8 (U.S. Apr. 29, 2026).

The Child Advocate meets the requirements to have standing here. First, as addressed below, the children represented by the Child Advocate have individual rights to informational privacy that will surely be injured by the disclosure of their extremely personal medical information under these circumstances. *See In re Children’s Nat’l Hosp.*, No. 1:25-CV-03780-JRR, 2026 WL 160792, at \*4–6 (D. Md. Jan. 21, 2026); *In re: 2025 UPMC Subpoena*, 2025 WL 3724705, at \*1 (W.D. Pa. Dec. 24, 2025). Second, this imminent injury is causally connected to the administrative

subpoena they challenge here. Third, as the following discussion explains, the injury is redressable by this Court notwithstanding the Texas court's Order.

**B. The Collateral Attack Doctrine Does Not Bar the Child Advocate or RIH's Requested Relief**

“A ‘collateral attack’ is a tactic whereby a party seeks to circumvent an earlier ruling of one court by filing a subsequent action in another court.” *Pratt v. Ventas, Inc.*, 365 F.3d 514, 519 (6th Cir. 2004). This tactic is generally prohibited by the “collateral attack doctrine,” under which a district court “lacks authority to hear an appeal of the rulings made by another federal judge.” *Verogna v. Johnstone*, 583 F. Supp. 3d 331, 337 (D.N.H. 2022) (collecting cases), *aff'd*, No. 22-1364, 2022 WL 19795808 (1st Cir. Nov. 14, 2022). Instead, the proper avenue for challenging a district court's order is typically through a motion with that court or through appeal.

The DOJ contests the ability of both the Child Advocate and RIH to seek quashal here given the Texas court's Order. (ECF No. 9 at 5–6.) According to DOJ, the parties seek an order here that would effectively circumvent the Texas court's Order. *Id.* at 6. Were the circumstances of this case akin to those that typically implicate the collateral attack doctrine (for example, where a party seeks to invalidate one court's pecuniary or penal judgment by petitioning another court for injunctive relief) the DOJ would likely be correct. But the peculiar facts of this case—including RIH's lack of notice prior to the Texas court's Order, the Child Advocate's nonparty status with respect to that case, and the underlying challenge here being to

an agency's administrative subpoena rather than to a court's judgment—appear to be distinguishable from the typical case.<sup>7</sup>

The collateral attack doctrine is based on the principles underpinning *res judicata*, i.e., claim preclusion. *Cf. Baella-Silva*, 454 F.3d 5, 9 (1st Cir. 2006) (“A district court’s express or implicit determination that it has jurisdiction is open to direct review, but it is *res judicata* when collaterally attacked.”) (italics in original). The elements of *res judicata* are “(1) a final judgment on the merits in an earlier suit, (2) sufficient identity between the causes of action asserted in the earlier and later suits, and (3) sufficient identity between the parties in the two suits.” *In re Iannochino*, 242 F.3d 36, 43 (1st Cir. 2001) (quoting *Mass. School of Law v. American Bar Assoc.*, 142 F.3d 26, 37 (1st Cir.1998)). For the Child Advocate, the third element is most at issue here because it was not itself party to the Texas court proceedings.

In *Martin v. Wilks*, the Supreme Court evaluated what it termed the “impermissible collateral attack doctrine.” 490 U.S. 755, 765 (1989). The plaintiffs there were white employees challenging alleged race-conscious employment decisions that were made pursuant to consent decrees entered in collateral litigation between the defendants and the NAACP. *Id.* at 759–60. The Supreme Court found that the plaintiffs were not precluded from challenging the employment decisions because they were not parties to the litigation from which the consent decrees stemmed. *Id.* at 761–62. As the Court explained, “[a]ll agree that ‘it is a principle of general

<sup>7</sup> The Court is unaware of any similar case where a party has petitioned a court to quash an administrative subpoena that another court ordered enforced without prior notice or opportunity to be heard.

application in Anglo-American jurisprudence that one 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.” *Id.* at 761 (quoting *Hansberry v. Lee*, 311 U.S. 32, 40 (1940)). Thus, “[a] judgment or decree among parties to a lawsuit resolves issues as among them, but it does not conclude the rights of strangers to those proceedings.” *Id.* at 762.<sup>8</sup>

Here, the Child Advocate alleges injuries that flow from another court’s decision to which it was not a party. And, similarly to how the white firefighters in *Wilks* had distinct interests from those litigated in the consent decree to which they were not parties, the interests of the children that the Child Advocate represents (the “legal, civil, and special rights of children” under protective care, *see* R.I. Gen. Laws § 42-73-7) are distinct from those that either were or could have been litigated in the Texas court—a fact that was acknowledged by the Texas court itself. *See In Re: Administrative Subpoena 25-1431-032*, No. 4-26MC-006-0 (N.D. Tex.) ECF No. 9 at 9 (“Thus, RIH has not shown how it would be harmed rather than its patients, who are third parties.”). And while *Wilks* recognized an exception to the general rule against nonparty preclusion in “limited circumstances” where a nonparty “has his interests adequately represented by someone with the same interests who is a party,” 490 U.S. at 762 n.2, this exception typically applies to class actions and suits involving

<sup>8</sup> The Supreme Court has since found *Wilks* to have been superseded by statute, insofar as it allows collateral attacks on consent decrees. *See Landgraf v. USI Film Products*, 511 U.S. 244, 251 (1994). But *Landgraf* did not repudiate *Wilks*’s reasoning.

fiduciaries, and is inapplicable here, particularly given that the record reflects that the Child Advocate's interests were *not* adequately represented in the Texas court. *See Taylor v. Sturgell*, 553 U.S. 880, 894 (2008) ("Representative suits with preclusive effect on nonparties include properly conducted class actions, and suits brought by trustees, guardians, and other fiduciaries.") (internal citations omitted).

It also appears unlikely that quashal—the primary relief sought by the Child Advocate here—constitutes a collateral attack on the Texas court's Order, notwithstanding the fact that quashal necessarily implicates that Order. Unlike a traditional judicial subpoena issued under the authority of a court, such as one issued under Federal Rule of Civil Procedure 45, the administrative subpoena here is the product of the DOJ's own statutory authority, *see* 18 U.S.C. § 3846. It was not issued by the Texas court, whose order is premised on that subpoena's legal force. It seems to follow that, as with APA claims—where a district court has the power to vacate challenged agency action even where vacatur may necessarily implicate other courts' judgments regarding that same action—the Court has the power to effectively vacate (i.e., quash) the administrative subpoena at issue here despite the fact that doing so necessarily implicates the parties' responsibilities under the Texas court's Order.

As such, the collateral attack doctrine poses no barrier to the Child Advocate's Petition. It also seems likely that, based on the underlying principles of *res judicata*, the collateral attack doctrine does not bar RIH's intervention here because it was not provided notice and an opportunity to be heard before the Texas court ordered the administrative subpoena enforced. As the Supreme Court has explained:

The doctrine of res judicata rests at bottom upon the ground that the party to be affected, or some other with whom he is in privity, has litigated or had an opportunity to litigate the same matter in a former action in a court of competent jurisdiction. The opportunity to be heard is an essential requisite of due process of law in judicial proceedings.

*Postal Telegraph Cable Co. v. City of Newport, Ky.*, 247 U.S. 464, 476 (1918). Thus, this Court “may not, consistently with the Fourteenth Amendment, enforce a judgment against a party named in the proceedings without a hearing or an opportunity to be heard.” *Id.*; see also *Blonder-Tongue Laboratories, Inc. v. U. of Illinois Found.*, 402 U.S. 313, 329 (1971) (“Some litigants—those who never appeared in a prior action—may not be collaterally estopped without litigating the issue.”).

While RIH may have subsequently had an opportunity to seek reconsideration of the Texas court’s Order, the preclusive effect of that order seems questionable given that it was granted *before* RIH had any notice or opportunity to be heard as due process requires. Further, “[r]econsideration of a judgment after its entry is an extraordinary remedy that should be used sparingly.” *Templet v. HydroChem Inc.*, 367 F.3d 473, 479 (5th Cir. 2004). Thus, RIH (and, by extension, the Child Advocate) was deprived of any opportunity to argue the propriety of the subpoena in a posture that did not demand “extraordinary relief” or was not summary in nature, and should not be precluded from litigating that issue here.

### C. The Merits

Given that the collateral attack doctrine does not preclude consideration of the Petitioners’ Motions to Quash, the Court proceeds to the merits of those Motions.

### 1. The Subpoena Lacks A Congressionally Authorized Purpose

To enforce an administrative subpoena issued under 18 U.S.C. § 3486, the DOJ must show that “(1) the subpoena is issued for a congressionally authorized purpose, the information sought is (2) relevant to the authorized purpose and (3) adequately described, and (4) proper procedures have been employed in issuing the subpoena.” *U.S. Dep’t of Just. v. Ricco Jonas*, 24 F.4th 718, 726 (1st Cir. 2022) (quoting *United States v. Sturm, Ruger & Co.*, 84 F.3d 1, 4 (1st Cir. 1996)). Here, the DOJ fails to meet the first element, and that failure is fatal to its subpoena.

The DOJ asserts that it issued this subpoena to investigate potential violations of the Food, Drug, and Cosmetic Act (“FDCA”), specifically the FDCA’s prohibition on misbranding. Its argument proceeds as follows: when a physician prescribes a drug for an off-label use, the drug’s “intended use” within the meaning of 21 C.F.R. § 201.128 changes. This changed intended use then renders the drug’s labeling inadequate under 21 U.S.C. § 352(f)(1), and then any party in the distribution chain who helped place that drug in commerce—including a hospital whose physicians wrote the prescriptions—faces criminal liability under 21 U.S.C. §§ 331, 333(a)(1), which also potentially includes individual administrators under the responsible corporate officer doctrine of *United States v. Park*, 421 U.S. 658 (1975).

But the First Circuit has held that “medical professionals may lawfully prescribe and administer a device for an off-label use as long as that device has received [FDA] clearance for any intended use.” *United States v. Facticeau*, 89 F.4th 1, 15 (1st Cir. 2023), *cert. denied*, 145 S. Ct. 137 (2024). The drugs at issue—puberty

blockers and cross-sex hormones—are FDA-approved for various uses, and RIH’s physicians prescribe and administer them in clinical care. The DOJ’s theory that off-label prescribing by licensed practitioners gives rise to FDCA criminal liability cannot be squared with *Facteau*. See also *In re Celexa & Lexapro Mktg. & Sales Pracs. Litig.*, 915 F.3d 1, 5 (1st Cir. 2019) (“The FDCA . . . does not prohibit doctors from prescribing drugs for off-label uses.”).

Congress did not merely leave off-label prescribing unregulated: it affirmatively protected it. Section 396 of the FDCA provides that “[n]othing 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.” 21 U.S.C. § 396. Further, the regulation of the practice of medicine has long been understood to remain within the states’ prerogative, and the Executive may not adopt novel interpretations of federal statutes to displace a state’s medical regulatory framework without clear congressional authorization to do so. See *Gonzales v. Oregon*, 546 U.S. 243, 269-70 (2006). Rhode Island has expressly protected gender-affirming care as lawful medical practice. R.I. Gen. Laws §§ 5-37.8-1, 23-101-2. The DOJ acknowledges that merely writing off-label prescriptions is not an FDCA offense but attempts to reach prescribing hospitals indirectly by characterizing their participation in a supply chain as causing the distribution of misbranded drugs. That reframing does not save the theory.

Because off-label prescribing by physicians is lawful, which the DOJ does not dispute, it is therefore logically impossible to construct an aiding-and-abetting, facilitation, or conspiracy theory predicated on nothing more than the physician's own lawful prescribing act.<sup>9</sup> No court has extended FDCA misbranding liability to a hospital or physician on this basis. As one court considering a similar subpoena observed, the DOJ "seeks all this while not offering one iota of suspicion" that RIH engaged in the off-label promotion that the FDCA does actually prohibit. *In re Admin. Subpoena No. 25-1431-019*, 800 F. Supp. 3d 229, 238 (D. Mass. 2025).

The DOJ's current litigation position is also in direct conflict with its own prior legal interpretations of the same statutory scheme. The FDA has stated publicly that once a drug is approved, healthcare providers may generally prescribe it for unapproved uses when they determine that doing so is medically appropriate. FDA, *Understanding Unapproved Use of Approved Drugs "Off Label"* (Feb. 5, 2018), <https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label>. The FDA, in guidance that is final but pending before the Office of Management and Budget, restated that position in guidance issued as recently as January 2025. *See FDA, Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products; Questions and Answers; Guidance for Industry* 8–9 (Jan. 2025), <https://www.fda.gov/media/184871/download>.

<sup>9</sup> The DOJ has also made references, in the Hsiao Declaration and at oral argument, to theories based on conspiracy, billing fraud, and healthcare fraud. But these theories are also tethered to off-label use and fail for the same reasons.

More significantly, the DOJ's own Office of Legal Counsel ("OLC") has concluded that the "FDA does not regulate the practice of medicine, which includes 'off-label' prescribing," and that "[w]hile the FDCA bars a manufacturer or distributor from selling any drug or device for an unapproved use, physicians may, with limited exceptions, prescribe and administer FDA-approved drugs and devices for unapproved uses." Steven A. Engel, *Whether the Food & Drug Administration Has Jurisdiction Over Articles Intended for Use in Lawful Executions*, 43 Op. O.L.C. 81, 85 (2019).

There also is a separate and independently sufficient basis on which the DOJ's misbranding claim fails as applied to RIH. Section 353(b)(2) exempts from the requirements of § 352 any drug "dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug." 21 U.S.C. § 353(b)(2). Thus, § 352(f) (the adequate-directions-for-use requirement on which the DOJ's entire misbranding theory rests) does not apply to prescription drugs dispensed pursuant to a licensed practitioner's prescription. RIH's physicians prescribe medications to patients in the clinical setting pursuant to their medical judgment. That conduct falls squarely within § 353(b)(2)'s exemption.

In sum, the DOJ's FDCA theory does not constitute a legally cognizable basis for this investigation as applied to a prescribing hospital. *See Facticeau*, 89 F.4th at 15. The off-label prescribing conduct at the core of the DOJ's theory is not illegal under the FDCA. Section 353(b)(2) exempts the specific misbranding provision the DOJ invokes. The DOJ's own OLC has interpreted the same statutory scheme in a

manner that directly contradicts its current litigation position. The subpoena therefore lacks a congressionally authorized purpose and must be quashed. *See Ricco Jonas*, 24 F.4th at 726.

## 2. Improper Purpose

The Court additionally concludes that the subpoena should be quashed because it was issued for an improper purpose in bad faith. A subpoena “issued for an improper purpose, such as to harass” a recipient or “to put pressure on him” or “for any other purpose reflecting on the good faith of the particular investigation” cannot be enforced. *United States v. Powell*, 379 U.S. 48, 58 (1964); *United States v. Comley*, 890 F.2d 539, 542 (1st Cir. 1989) (recognizing that courts have “adequate justification to deny enforcement of [a] subpoena” when there is evidence of bad faith). Where the DOJ issues a subpoena for an improper purpose, quashal is warranted when that improper purpose is the sole purpose of the investigation. *United States v. Gertner*, 65 F.3d 963, 970 (1st Cir. 1995).

The evidence of improper purpose here is in the DOJ’s own public record and detailed in the decisions of the seven other federal courts that have considered identical subpoenas. The Administration has publicly characterized gender-affirming care for minors as abuse, directed the DOJ to bring its practice to an end, and celebrated when hospitals curtailed such programs as a result of this subpoena campaign. (ECF No. 20-1 at 22, 23 n.8.)

The DOJ, however, contends that even if a policy purpose exists, a legitimate FDCA investigation runs alongside it and the *Gertner* sole-purpose standard

therefore cannot be satisfied. *See* 65 F.3d at 970. But this would require a genuine legitimate investigative purpose, not merely a legal theory, which, as described above, is not legally cognizable as applied to a prescribing hospital. 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.

Seven other federal courts have found these subpoenas to have been issued for an improper purpose, and this Court finds their reasoning persuasive and applies it here. *See QueerDoc, PLLC v. U.S. Dep't of Just.*, 807 F. Supp. 3d 1295, 1303–04 (W.D. Wash. 2025); *In re Admin. Subpoena No. 25-1431-019*, 800 F. Supp. 3d 229, 239 (D. Mass. 2025); *In re Subpoena Duces Tecum No. 25-1431-016*, No. 25-mc-41, 2025 WL 3562151, at \*12–13 (W.D. Wash. Sept. 3, 2025); *In re Dep't of Just. Admin. Subpoena No. 25-1431-030*, No. 25-mc-63, 2026 WL 33398, at \*11 (D. Colo. Jan. 5, 2026); *In re Children's Nat'l Hosp.*, No. 1:25-cv-03780-JRR, 2026 WL 160792, at \*8 (D. Md. Jan. 21, 2026); *In re Subpoena No. 25-1431-014*, 810 F. Supp. 3d 555, 580 (E.D. Pa. 2025); *In re 2025 UPMC Subpoena*, No. 2:25-MC-01069-CB, 2026 WL 570419 (W.D. Pa. Mar. 2, 2026).

### **3. The Fourteenth Amendment Right to Informational Privacy**

But there is another ground warranting quashal. The Child Advocate contends that the children who are the subject of the medical records themselves possess a Fourteenth Amendment right to informational privacy in these records and that

RIH's compliance with the full scope of the requests contained within the subpoena would violate this right. (ECF No. 1 at 39–41.) The Court agrees.<sup>10</sup>

Nearly half a century ago, the Supreme Court recognized a right to informational privacy, which prevents the compelled disclosure of personal matters. *See Whalen v. Roe*, 429 U.S. 589, 599 (1977) (describing the “individual interest in avoiding disclosure of personal matters[.]”). Following its initial acknowledgement of this right, the Supreme Court has repeatedly acknowledged its existence in the decades that followed. *See Nat’l Aeronautics & Space Admin. v. Nelson*, 562 U.S. 134, 138 (2011) (Alito, J.) (“We assume, without deciding, that the Constitution protects a privacy interest of the sort mentioned in *Whalen* and *Nixon*.”); *Dobbs v. Jackson Women’s Health Organization*, 597 U.S. 215, 219 (2022) (Alito, J.) (“But *Roe* conflated the right to shield information from disclosure and the right to make and implement personal decisions without governmental interference.”) (citing *Whalen*, 429 U.S. at 599–600).

Throughout its history, the First Circuit has also acknowledged the existence of an individual’s constitutional right to informational privacy. *See Borucki v. Ryan*, 827 F.2d 836, 845–49 (1st Cir. 1987) (grappling with *Whalen*’s “paucity of concrete guidance”); *see also Vega-Rodriguez v. Puerto Rico Telephone Co.*, 110 F.3d 174 (1st Cir. 1997) (Selya, J.) (“Even if the right of confidentiality has a range broader than that associated with the right of autonomy, that range has not extended beyond

<sup>10</sup> In doing so, the Court provides no view on whether, as asserted by the Child Advocate, the Fourth Amendment provides a separate, independent source of constitutional protection in this context.

prohibiting profligate disclosure of *medical*, financial, and other intimately personal data.”) (emphasis added).

Finally, at least one court within the First Circuit has also: (1) concluded that the constitutional right to informational privacy exists; and (2) applied it to litigants appearing before it in that matter. *See Arroyo Gonzelez v. Rossello Nevares*, 305 F. Supp. 3d 327, 333 (D.P.R. 2018) (determining that Puerto Rico’s ban on changing the gender markers in the plaintiffs’ birth certificates violates their right to informational privacy).<sup>11</sup>

Here, the Child Advocate has successfully demonstrated that the subpoena’s enforcement in full would violate the right to informational privacy of the children that it represents. Specifically, the Court determines that DOJ’s request for intimate medical details from one of this country’s most vulnerable populations constitutes a drastic overreach of its investigative authority. As discussed elsewhere, not only has DOJ failed to specify *how* this information is related to its legitimate authority to conduct its investigation, but it has also failed to assuage the Court of its serious concerns for how DOJ would adequately protect and otherwise safeguard this information. When faced with the very real — and likely irreparable — harm to the children in the State’s current or former care that unfettered, compelled disclosure

<sup>11</sup> Notwithstanding the legal developments that have taken place within the First Circuit, courts across the country have had a myriad of opportunities to address, and develop, the constitutional right to informational privacy. *See Carmel Shachar & Carleen Zubrzycki, Informational Privacy After Dobbs*, 75 ALA. L. REV. 1, 19 (2023). Separately, the Court thanks the amici for their helpful and speedy submissions in this matter.

that compliance with this subpoena would create, this Court concludes that RIH's compliance would violate affected children's rights to informational privacy.<sup>12</sup> As a result, the Court determines that the application of this right constitutes a separate basis for quashal of the subpoena.

The Court turns to the scope of relief this separate finding would require. DOJ argued that any remedy grounded in the children's constitutional right should be limited to records pertaining to children in DCYF custody or care—those whose rights the Child Advocate represents. The Court rejects this proposed limitation on practical grounds.

To implement a carveout limited to DCYF children, RIH would first have to identify which among its minor patients are DCYF wards: reviewing each responsive record to determine which patients are in state custody or care before segregating those records from the rest. That identification process would itself expose precisely the sensitive intersection of information the constitutional right is designed to protect: which gender-affirming care patients are vulnerable wards of the state. When asked at oral argument how DOJ envisioned this segregation process working in practice, DOJ offered no adequate answer. The Court is left with no basis to conclude that a DCYF-only carveout is operationally feasible, and every reason to conclude it is not.

<sup>12</sup> To provide a more concrete example of the potential harm at issue here, the DOJ conceded during the Court's hearing that its investigative efforts would include attempting to locate and question both children and their caregivers in its search for criminal conduct.

There is no way to protect the informational privacy rights of DCYF children without first doing what the constitutional right forbids: identifying them as DCYF wards in the process of separating their records from those of other minor patients. The relief this Court grants therefore necessarily extends to the records of all minors. This extension flows not from any expansion of the Child Advocate’s standing, but from the practical impossibility of implementing a narrower remedy without violating the very right the remedy is designed to vindicate.

### III. CONCLUSION

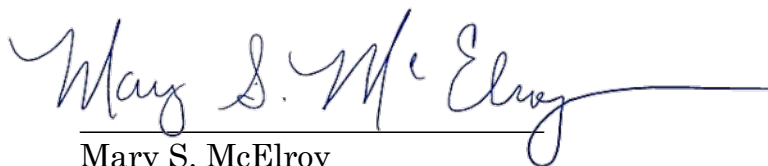
Ultimately, the Court’s decision is based solely on its application of the law to the administrative subpoena at issue here. But the discrepancy between the honorable conduct expected of federal prosecutors and DOJ’s tactics in this case is unsettling. The Court cannot help but share the sentiment that “[t]he presumption of regularity that has previously been extended to [DOJ] that it could be taken at its word—with little doubt about its intentions and stated purposes—no longer holds.” *United States v. Oregon*, No. 6:25-CV-01666-MTK, 2026 WL 318402, at \*11 (D. Or. Feb. 5, 2026). It is regrettable that this is now the case.

The Emergency Motions to Quash (ECF Nos. 1 & 28) are GRANTED. In granting these Motions, this Court quashes the administrative subpoena—the instrument issued by DOJ—not the enforcement order entered by the Texas court. What this Court holds is that the subpoena itself lacks a congressionally authorized purpose, was issued for an improper purpose, and demands the production of records that cannot be obtained consistent with the constitutional privacy rights of

Rhode Island children. Those are independent grounds for quashal of the subpoena that this Court has authority to adjudicate.

In addition, DOJ is hereby ENJOINED from seeking, receiving, using, retaining, or disseminating any patient-identifying information or protected health information produced by RIH in response to Administrative Subpoena No. 25-1431-032, including but not limited to all materials responsive to Requests 11 through 15 and any other materials that identify, or reasonably permit the identification of, Rhode Island's children.

IT IS SO ORDERED.

A handwritten signature in cursive script, reading "Mary S. McElroy", with a long horizontal flourish extending to the right.

Mary S. McElroy  
United States District Judge

May 14, 2026



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February 4, 2026

**FOIA CONFIDENTIAL TREATMENT REQUESTED**

**By Email (david.gunn@usdoj.gov)**

David Gunn  
Trial Attorney  
Consumer Protection Branch  
Civil Division  
U.S. Department of Justice  
450 Fifth Street NW  
Washington, DC 20001

Re: HIPAA Subpoena Issued to Rhode Island Hospital, No. 25-1431-032

Dear Mr. Gunn:

On behalf of our client, Lifespan Corp. d/b/a Brown University Health (“Brown Health”), we write to provide you with the following list of search terms Brown Health has used in its efforts to identify records that are responsive to document requests 7-10 and 14 of the subpoena (No. 25-1431-032) issued to Rhode Island Hospital, a subsidiary of Brown Health, pursuant to the Health Insurance Portability & Accountability Act (“HIPAA”) of 1996, 18 U.S.C. § 3486:

- “off label”
- “on label”
- (F64 OR Z87 OR E34)
- Unapproved AND drug
- “Not approved” AND drug
- (FDA OR “Food and Drug Administration”) AND approved OR evaluated
- (Promotion OR ad\*) AND (drug OR medication)
- “Ask your doctor”
- “Reminder ad”
- “Reminder piece”
- “Results may vary”
- “Scientific exchange”
- “First and only”
- “First in class”
- “Mechanism of action”

- “Randomized controlled trial”
- “Clinical trial”
- “Safety profile”
- “Risk profile”
- “Benefit profile”
- “Well tolerated”
- “Response rate”
- “Response duration”
- (shown OR proven) AND (safe OR effective OR “help” OR “treat” OR “reduce”)
- (solicited OR unsolicited) w/10 request
- “Fair balance”
- gender w/3 (care OR dysphoria OR incongruence OR disorder OR clinic)
- LGBTQ OR LGBTQIA
- nonbinary
- “assigned male at birth” OR AMAB
- “assigned female at birth” OR AFAB
- “puberty blocker\*”
- “GnRH agonist\*” OR “gonadotropin-releasing hormone”
- leuprolide OR “Lupron”
- triptorelin
- histrelin
- testosterone
- estrogen
- hormon\* w/5 (therapy OR sex OR care OR gender)
- GAHT
- “off label” w/15 (“puberty blocker\*” OR hormone\*)
- (“ICD code\*” OR “diagnosis code\*” OR “billing code\*”) AND (f64 OR Z87 OR E34)
- (insurance OR claim OR bill\*) AND (f64 OR Z87 OR E34)
- (bill\* OR insurance OR claim) AND endocrin\* AND ((gender\* w/5 (treatment OR care OR hormon\*)) OR puberty)
- (bill\* OR insurance OR claim) AND ((gender w/5 (treatment OR care OR hormon\*)) OR puberty)
- endocrine w/15 ((gender w/5 (treatment OR care OR hormon\*)) OR puberty)
- (“alt\* diagnosis” OR “alt\* ICD code\*”) AND (f64 OR Z87 OR E34)
- (protocol\* OR guidance OR train\* OR cod\*) AND ((gender w/5 (treatment OR care OR hormon\*)) OR puberty)
- presentation\* AND (gender OR hormone OR puberty)
- (pharmac\* OR medical) w/5 liaison
- (informed W/5 consent) AND ((gender W/5 (treatment OR care OR hormon\*)) OR puberty)
- (patient W/5 intake) AND ((gender W/5 (treatment OR care OR hormon\*)) OR puberty)
- (parent OR guardian) AND authoriz\* AND ((gender W/5 (treatment OR care OR hormon\*)) OR puberty)
- (minor W/5 patient\*) AND ((gender W/5 (treatment OR care OR hormon\*)) OR puberty)

- (adverse OR side OR unfavorable) w/3 (effect OR event OR consequence OR complication)
- (“off label” w/5 disclosure) AND ((gender w/5 (treatment OR care OR hormon\*)) OR puberty)
- (FDA OR “food and drug administration” OR agency) AND (puberty OR hormone OR gender)
- (contract\* OR agreement\*) AND pharmac\* AND ((gender W/5 (treatment OR care OR hormon\*) OR puberty)
- (sponsor\* OR consult\*) AND agreement AND ((gender W/5 (treatment OR care OR hormon\*)) OR puberty)
- grant\* AND ((gender W/5 (treatment OR care OR hormon\*)) OR puberty)
- (“off label” OR unapproved OR “FDA approved” OR directions) AND (gender W/5 (treatment OR care OR hormon\* OR drug OR puberty))
- (financial OR promo\* OR speak\*) AND (arrang\* OR engage\*) AND ((gender W/5 (treatment OR care OR hormon\*)) OR puberty)
- (“abbvie” OR “accord” OR “acerus” OR “actavis” OR “agile” OR “alembic” OR “alkem” OR “allergan” OR “alvogen” OR “alza” OR “amarin” OR “american regent” OR “amneal” OR “amphastar” OR “ani” OR “annora” OR “antares” OR “apotex” OR “ascend” OR “ascot” OR “aspen global” OR “aurobindo” OR “auxilium” OR “avion” OR “azurity” OR “barr” OR “barr” OR “bausch health” OR “bayer” OR “bel mar” OR “besins” OR “blue water biotech” OR “breckenridge” OR “bristol myers squibb” OR “cadence health” OR “chartwell” OR “chemo research” OR “cipla” OR “cmp development” OR “dr reddy’s” OR “duramed” OR “eli lilly and” OR “elkins” OR “encube ethicals” OR “endo” OR “epic pharma” OR “esi pharmacal” OR “eugia” OR “exeltis” OR “fosun pharma” OR “foundation consumer healthcare” OR “gd searle” OR “ge healthcare” OR “gedeon richter” OR “genzyme corporation” OR “glenmark” OR “graviti” OR “healthcare pharmaceuticals” OR “heather drug” OR “heritage pharma” OR “hetero labs” OR “hikma” OR “hong kong king friend industrial” OR “impax” OR “invagen” OR “inwood” OR “ivax” OR “janssen” OR “jubilant” OR “kv pharmaceutical” OR “l perrigo” OR “lannett” OR “lederle” OR “lotus pharmaceutical” OR “lpi holdings” OR “lupin” OR “marius” OR “mayne pharma” OR “medicines360” OR “meitheal” OR “millicent” OR “mutual pharmaceutical” OR “mylan” OR “naari pte” OR “natco pharma” OR “nexus” OR “novartis” OR “novast” OR “novel” OR “noven” OR “novitium pharma” OR “novo nordisk” OR “organon” OR “janssen” OR “ortho mcneil” OR “oxford” OR “padagis” OR “parke davis” OR “perrigo” OR “pfizer” OR “ph health” OR “pharmacia and upjohn” OR “pharmobedient” OR “population council” OR “prasco” OR “private formulations” OR “purepac” OR “quagen” OR “rising pharma” OR “rk pharma” OR “rubicon research” OR “sandoz” OR “savage laboratories” OR “schering” OR “shire development” OR “solaris pharma” OR “solvay” OR “strides pharma” OR “sumitomo pharma” OR “sun pharma” OR “superpharm” OR “tablicaps” OR “teva” OR “tolmar” OR “twi” OR “ubi pharma” OR “upsher smith” OR “usl pharma” OR “valeant” OR “vanguard” OR “verity” OR “vertical” OR “viatris specialty” OR “warner chilcott” OR “watson” OR “west ward pharma” OR “wilshire” OR “women first healthcare” OR “wyeth” OR “xiromed” OR “zydus”)AND (“desogestrel” OR “dienogest estradiol valerate” OR “drospirenone” OR “elagolix sodium” OR “estradiol” OR “norethindrone acetate” OR “medroxyprogesterone acetate” OR “testosterone cypionate” OR “testosterone enanthate” OR “levonorgestrel” OR

“relugolix” OR “estrogens” OR (“ethynodiol diacetate” “ferrous fumarate”) OR “norethindrone” OR “norelgestromin” OR “norgestimate” OR “norgestrel” OR “segesterone acetate” OR “finasteride” OR “tadalafil” OR “fluoroestradiol” OR “histrelin acetate” OR “hydrochlorothiazide spironolactone” OR “leuprolide acetate” OR “mestranol” OR “methyltestosterone” OR “polyestradiol phosphate” OR “spironolactone” OR “testosterone”)

Brown Health reserves the right to modify the foregoing terms.

As we have noted previously, Brown Health’s agreement to produce information and records responsive to the subpoena does not constitute a waiver of any objection that Brown Health may have to the subpoena or to any of its requests, and Brown Health expressly reserves, and does not waive, (1) its right to object to certain of the government’s requests as unduly burdensome, irrelevant, or otherwise requiring the production of material or information protected from disclosure under federal or state law; or (2) its right to seek a protective order or any other judicial relief in any litigation arising in connection with the subpoena.

This letter and any material contained in the accompanying production are not intended to, and do not, waive any applicable privilege. To the extent this letter or any material contained in the production discloses otherwise privileged matters, such disclosure is unintentional.

We request that all materials and information provided by Brown Health to the U.S. Department of Justice (DOJ), including this letter and the accompanying exhibits, receive confidential treatment. Because the enclosed materials constitute investigatory records obtained by the government in connection with a potential law enforcement proceeding, they are subject, at least at present, to the exemption from mandatory disclosure under Exemption 7(A) of the Freedom of Information Act (“FOIA”), 5 U.S.C. § 552(b)(7). In addition, we believe that FOIA Exemptions 4, 6 and 7(C), *id.* § 552(b)(4), (b)(6), (b)(7)(C), are also applicable to materials contained in the production, and that the protections available under the Privacy Act of 1974, 5 U.S.C. § 552a, also apply. In the event that DOJ intends to disclose this letter or any materials produced by Brown Health in response to the above-referenced subpoena to non-governmental third-parties, we request ten business days’ notice of such intended disclosure.

Please do not hesitate to contact us if you have any questions regarding these search terms.

Sincerely,



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Eric G. Olshan  
Clint Narver  
McGuireWoods LLP

**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 112813 of the Social Security Act (42 U.S.C. 1320a-7b); or
- (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, [1] if the violation or conspiracy relates to a health care benefit program.

**(b)** As used in this tide, 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.

**Health Insurance Portability & Accountability Act of 1996**

**18 U.S.C. § 3486 - 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 caused to be served a subpoena requiring the production and testimony described in subparagraph **(B)**.

. . .

**(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.

## **Federal Food, Drug, and Cosmetic Act**

### **21 U.S.C. § 331 – Prohibited Acts**

The following acts and the causing thereof are 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 344, 350d, 355,<sup>1</sup> 360bbb-3, or 364c of this title.
- (e)** The refusal to permit access to or copying of any record as required by section 350a, 350c, 350f(j), 350e, 354, 360bbb-3, 364a, 373, 374(a), 379aa, or 379aa-1 of this title; or the failure to establish or maintain any record, or make any report, required under section 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 of this title 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 2223 of this title (except when such violation is committed by a farm).
- (f)** The refusal to permit entry or inspection as authorized by section 374 of this title.
- (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 333(c)(2) of this title, which guaranty or undertaking is false, except by a person who relied upon a guaranty or undertaking to the same effect signed by, and 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 333(c)(3) of this title, 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 344 or 379e of this title.

(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 chapter, any information acquired under authority of section 344, 348, 350a, 350c, 355, 360, 360b, 360c, 360d, 360e, 360f, 360h, 360i, 360j, 360ccc, 360ccc-1, 360ccc-2, 374, 379, 379e, 387d, 387e, 387f, 387g, 387h, 387i, or 387t(b) of this title concerning any method or process which as a trade secret is entitled to protection; or the violating of section 346a(i)(2) of this title or any regulation issued under that section..<sup>1</sup> 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 – 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<sup>1</sup>, 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) 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 355, 360(k), 360c(f)(2), or 360e of this title or section 262 of Title 42 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 355, 360(k), 360c(f)(2), or 360e of this title or section 262 of Title 42. The requirements set forth in section 355, 360(k), 360c(f)(2), or 360e of this title or section 262 of Title 42 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.

...

### **(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. § 355 – New Drugs**

### **(a) NECESSITY OF EFFECTIVE APPROVAL OF APPLICATION**

No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug.

...

### **(d) GROUNDS FOR REFUSING APPLICATION; APPROVAL OF APPLICATION; “SUBSTANTIAL EVIDENCE” DEFINED**

If the Secretary finds, after due notice to the applicant in accordance with subsection (c) and giving him an opportunity for a hearing, in accordance with said subsection, that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b), do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions; or (5) evaluated on the basis of the information submitted to him as part of the application and any other information before him with respect to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or (6) the application failed to contain the patent information prescribed by subsection (b); or (7) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that clauses (1) through (6) do not apply, he shall issue an order approving the application. As used in this subsection and subsection (e), the term “substantial evidence” means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have

the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof. If the Secretary determines, based on relevant science, that data from one adequate and well-controlled clinical investigation and confirmatory evidence (obtained prior to or after such investigation) are sufficient to establish effectiveness, the Secretary may consider such data and evidence to constitute substantial evidence for purposes of the preceding sentence. The Secretary shall implement a structured risk-benefit assessment framework in the new drug approval process to facilitate the balanced consideration of benefits and risks, a consistent and systematic approach to the discussion and regulatory decisionmaking, and the communication of the benefits and risks of new drugs. Nothing in the preceding sentence shall alter the criteria for evaluating an application for marketing approval of a drug.