No. 26-1568

In the

United States Court of Appeals
For the First Circuit

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

CHILD ADVOCATE FOR THE STATE OF RHODE ISLAND, *et al.*,

Plaintiffs-Appellees,

v.

UNITED STATES OF AMERICA,

Respondent-Appellant.

On Appeal from the United States District Court for the District of Rhode Island, Case No. 1:26-mc-00007-MSM
Hon. Mary S. McElroy, U.S. District Judge

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July 17, 2026

CORPORATE DISCLOSURE STATEMENT

Rhode Island Hospital is a Rhode Island not-for-profit corporation whose sole member is Lifespan Corporation d/b/a Brown University Health, a Rhode Island not-for-profit corporation. No publicly held company owns 10% or more of the stock of Rhode Island Hospital.

Dated: July 17, 2026

/s/ Eric G. Olshan
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REASONS WHY ORAL ARGUMENT SHOULD BE HEARD

Intervenor-Appellee Rhode Island Hospital believes oral argument would materially assist the Court in resolving this appeal given the importance and complexity of the issues presented.

INTRODUCTION

The Department of Justice is wielding its enforcement authority to accomplish a policy objective that Congress never authorized it to pursue. Last year, the Department issued a subpoena to Rhode Island Hospital demanding expansive categories of documents, including highly sensitive medical records of minor patients. Across the country, courts confronted with materially identical subpoenas have recognized the Department's conduct for what it is—not a legitimate investigative effort, but an attempt to pressure hospitals that provide gender-affirming care into abandoning it. The District Court correctly reached the same conclusion, and this Court should affirm.

The enforcement order that the Department obtained in the Northern District of Texas—without affording RIH notice or an opportunity to be heard—is no impediment to this result. Because the Texas district court denied due process to RIH, RIH was fully within its rights to join an independent challenge seeking to quash the subpoena in Rhode Island.

And on the merits of that challenge, the District Court below correctly held that the Department issued the subpoena not to

investigate crime, but to discourage disfavored medical care. As the District Court held, the Department's shifting and contorted theories of criminal liability for "misbranding" of prescription drugs do not support the subpoena. The subpoena is also breathtakingly overbroad, sweeping in virtually everything related to gender-affirming care, yet treating the very drug labeling the Department claims to be investigating as an afterthought.

These defects required quashing the subpoena, and they warrant affirmance here.

STATEMENT OF THE CASE

A. Rhode Island Hospital lawfully provides gender-affirming care.

Rhode Island Hospital, based in Providence, Rhode Island, provides gender-affirming care for minors through its pediatric division. JA228, 231. Where clinically appropriate, this care may include prescribing puberty blockers and cross-sex hormones on an "off-label" basis. JA17, 234, 236. Such "off-label" prescribing happens because the Food and Drug Administration has approved these drugs for other uses, but not for treating gender incongruence or dysphoria. Add.17-18. "[I]t is neither unusual nor unlawful for drugs to be used off-label," for gender-affirming

care and in many other scenarios. *United States v. Skrmetti*, 605 U.S. 495, 533 (2025) (Thomas, J., concurring). RIH provides this sort of gender-affirming care with the knowledge and consent of patients and their parents or legal guardians. JA235.

The gender-affirming care RIH provides is lawful in Rhode Island. *See* R.I. Gen. Laws §§ 23-101-1 to -9. Consistent with their traditional authority to regulate the practice of medicine, many States similarly protect this care within their borders. *See Skrmetti*, 605 U.S. at 524; UCLA Sch. of Law Ctr. on Reproductive Health, Law, & Policy, *Shield Laws for Reproductive and Gender-Affirming Health Care: A State Law Guide* (last updated July 2026), https://perma.cc/J43T-7464. Others have decided to prohibit it for minors. *See Skrmetti*, 605 U.S. at 504.

Minor patients receiving gender-affirming care at RIH disclose highly sensitive information to their providers, across topics like mental health, sexual health, and family medical history. JA235. Their providers use this information to develop individualized care plans. *Id.* Patients share this information with the understanding that RIH will maintain confidentiality, a cornerstone of medical care at RIH. JA231-32, 236.

B. As part of its effort to end gender-affirming care, the Department of Justice subpoenas hospitals.

The current Administration makes no bones about its goal to end gender-affirming care. Before his second term, President Trump announced his "plan to stop" gender-affirming care for minors, which included investigating "the big hospital networks" involved in such care. *President Trump's Plan to Protect Children from Left-Wing Gender Insanity* (Feb. 1, 2023), https://tinyurl.com/fc87ch27. On his first day back in office, the President issued Executive Order 14168, declaring that "the policy of the United States" is "to recognize two sexes, male and female" and that "[t]hese sexes are not changeable." Exec. Order No. 14168, § 2, 90 Fed. Reg. 8615, 8615 (Jan. 30, 2025). The order announced that "the Executive Branch will enforce all sex-protective laws to promote this reality." *Id.*

Eight days later, Executive Order 14187 pronounced gender-affirming care "a stain on our Nation's history" that "must end." Exec. Order No. 14187, § 1, 90 Fed. Reg. 8771, 8771 (Feb. 3, 2025). That order directed the Attorney General to "prioritize investigations and take appropriate action to end deception of consumers, fraud, and violations of the Food, Drug, and Cosmetic Act by any entity that may be misleading

the public about long-term side effects" of gender-affirming care, which the order characterized as "chemical and surgical mutilation."[1] *Id.* § 8(c), 90 Fed. Reg. at 8772.

The White House made explicit that the order's "intended effect" was to "prevent[]" gender-affirming care, praising "[h]ospitals around the country" that had "tak[en] action to downsize or eliminate" their gender-affirming care programs. News Release, The White House, *President Trump is Delivering on His Commitment to Protect Our Kids* (Feb. 3, 2025), https://perma.cc/EN3W-R932.

President Trump went on to call the practice of "alter[ing] [children's] sex with hormone therapy, puberty blockers, and sexual mutilation surgery" "one of the most prevalent forms of child abuse facing our country today." Proclamation No. 10911, 90 Fed. Reg. 15203, 15203 (Apr. 9, 2025). He "pledg[ed] to stop the atrocity of child abuse" in this form. *Id.* The President further proclaimed that "every perpetrator who inflicts violence on our children will be punished to the fullest extent of the law." *Id.*

[1] RIH does not perform gender-transition surgeries for minors. JA17. The Department's subpoena focuses on the use of prescription drugs in gender-affirming care. JA93-94.

The Department of Justice soon began implementing the President's directives. In April 2025, then-Attorney General Pam Bondi announced that "the Department of Justice will bring [gender-affirming care] to an end." Memorandum from Pamela Bondi, Att'y Gen., *Preventing the Mutilation of American Children* 6 (Apr. 22, 2025), https://perma.cc/9KSZ-834B. Bondi directed the Department "to undertake appropriate investigations of any violations of the Food, Drug, and Cosmetic Act by manufacturers and distributors engaged in misbranding by making false claims about the on- or off-label use of puberty blockers, sex hormones, or any other drug." *Id.* at 4.

On June 11, 2025, Assistant Attorney General Brett Shumate declared that the Civil Division would devote "all available resources to prioritize investigations of doctors, hospitals, [and] pharmaceutical companies." Memorandum from Brett A. Shumate, Assistant Att'y Gen., *Civil Division Enforcement Priorities* 2 (June 11, 2025), https://perma.cc/B3SV-TY9E ("Shumate Memorandum").

On the same day, the Department began issuing criminal administrative subpoenas to hospitals providing gender-affirming care. *See, e.g.*, JA277. The Department issued these subpoenas under the

purported authority of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), 18 U.S.C. § 3486, supposedly to further its investigation of "[f]ederal health care offenses as defined in 18 U.S.C. § 24(a)." *Id.*

Within weeks of receipt, multiple hospitals challenged the subpoenas by moving to quash or limit them. The earliest challenges were filed on July 8, 2025.[2]

The next day, the Department announced that it had "sent more than 20 subpoenas to doctors and clinics involved in performing transgender medical procedures on children." Press Release, U.S. Dep't of Just., *Department of Justice Subpoenas Doctors and Clinics Involved in Performing Transgender Medical Procedures on Children* (July 9, 2025), https://perma.cc/BS54-RSQA ("July 9 Press Release"). The Department stated that its "investigations include healthcare fraud, false statements, and more." *Id.* Bondi proclaimed that "[m]edical professionals and organizations that mutilated children in the service of

[2] *See, e.g.*, Mot. to Set Aside or Modify Subpoena, *In re Subpoena Duces Tecum No. 25-1431-016*, No. 25-mc-41 (W.D. Wash. July 8, 2025), Dkt. 1; Mot. to Quash, *In re Admin. Subpoena No. 25-1431-019*, No. 25-cv-91324 (D. Mass. July 8, 2025), Dkt. 3.

a warped ideology will be held accountable by this Department of Justice." *Id.*

Later that month, the White House boasted that President Trump had "delivered" on his "promise[] to end" gender-affirming care, citing a "growing list of health systems across the country . . . ending" their programs. Press Release, The White House, *President Trump Promised to End Child Sexual Mutilation — and He Delivered* (July 25, 2025), https://perma.cc/54DN-4EA9 ("July 25 Press Release").

Still, many health systems maintained their challenges to the Department's subpoenas. Over the next several months, federal district courts unanimously ruled that the Department issued the subpoenas for an improper purpose and quashed them.[3] Multiple courts also concluded

[3] Recipients pursued relief that varied in scope, meaning some quashals were partial. *See In re Subpoena Duces Tecum No. 25-1431-016*, No. 25-mc-41, 2025 WL 3562151, at *10-11 (W.D. Wash. Sep. 3, 2025), *appeal pending*, No. 26-4009 (9th Cir.); *In re Admin. Subpoena No. 25-1431-019*, 800 F. Supp. 3d 229, 239 (D. Mass. 2025), *appeal pending*, No. 25-2092 (1st Cir.); *QueerDoc, PLLC v. U.S. Dep't of Just.*, 807 F. Supp. 3d 1295, 1302-03 (W.D. Wash. 2025), *appeal pending*, No. 25-7484 (9th Cir.); *In re Subpoena No. 25-1431-014*, 810 F. Supp. 3d 555, 583 (E.D. Pa. 2025), *appeal withdrawn*, No. 26-1134 (3d Cir.); *In re 2025 UPMC Subpoena*, No. 25-mc-1069, 2025 WL 3724705, at *2 (W.D. Pa. Dec. 24, 2025), *judgment entered*, 2026 WL 570419 (W.D. Pa. Mar. 2, 2026), *appeal pending*, No. 26-1401 (3d Cir.); *In re Children's Nat'l Hosp.*, No. 25-cv-3780, 2026 WL 160792, at *8 (D. Md. Jan. 21, 2026), *appeal pending*, No.

that the subpoenas were unduly overbroad.[4]

C. After months of negotiations and without warning, the Department petitions to enforce the subpoena against RIH in Texas.

On July 9, the Department served a subpoena on RIH mirroring the many others issued across the country. JA60, 229. The return date was less than a month later, on August 7. JA60. The subpoena required production at the investigating division's Washington, D.C. office. JA60.

The subpoena to RIH, like the others, demanded 15 broad categories of records. JA60. Request 1 sought "[c]omplete personnel files" of all executives, prescribing providers, and billing staff. JA66. Requests 2 through 6 sought documents related to billing, coding, and insurance claims. JA66-67. Requests 7 through 10 and 14 sought internal and external communications regarding puberty blockers and hormones used for gender-affirming care. JA67. The remaining

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26-1104 (4th Cir.); *see also In re Admin. Subpoenas to Children's Hosps.*, No. 26-cv-1834, 2026 WL 1660098, at *14 (D. Md. June 9, 2026); *In re Dep't of Just. Admin. Subpoena No. 25-1431-030*, No. 25-mc-63, 2026 WL 33398, at *7 (D. Colo. Jan. 5, 2026) (report and recommendation).

[4] *See In re Admin. Subpoena No. 25-1431-019*, 800 F. Supp. 3d at 239; *In re Children's Nat'l Hosp.*, 2026 WL 160792, at *8; *see also In re Dep't of Just. Admin. Subpoena No. 25-1431-030*, 2026 WL 33398, at *4.

requests—11, 12, 13, and 15—sought patient records, including diagnoses, treatment outcomes, and consent documents. JA67-68. The subpoena required documents that "identify each patient (by name, date of birth, social security number, address, and parent/guardian information) who was prescribed puberty blockers or hormone therapy." JA67.

Rather than immediately move to quash, RIH chose to negotiate with the Department. JA134-35. At the outset, DOJ attorneys informed RIH that they did not believe RIH had engaged in any criminal wrongdoing, and that the Department subpoenaed RIH only as a potential witness. JA229.

RIH relayed that compliance in under a month would be impracticable, if not impossible. JA134. The Department informed RIH that partial compliance by the return date would be sufficient and that it was "willing to receive documents responsive to the subpoena past the return date." JA105, 362. At the Department's request, RIH made an initial production by the return date, while reserving its right to object to the subpoena and pursue judicial relief. JA229. After that production,

RIH continued to communicate with DOJ attorneys about ongoing compliance efforts, engaging in regular calls over several months. JA135.

In late January 2026, RIH notified the Department that it was prepared to produce more documents. JA135. And in early February, RIH sent proposed search terms for review.[5] JA239. The Department did not respond. JA238-39, 457.

RIH heard nothing back for months. JA238-39, 365-66. Finally, on April 28, a DOJ attorney resumed contact, requesting a "conference this week regarding status." JA238-39. RIH responded the next day, proposing a date. JA238.

The Department next contacted RIH on the evening of April 30, but not to confirm a conference date. JA238. Instead, the Department sent RIH a petition to enforce the subpoena that it had filed that day in the Northern District of Texas—roughly 1,500 miles from both RIH and the

[5] The Department's opening brief attaches the previously undisclosed February 4 letter, despite RIH's request for "confidential treatment" and advance notice in the event of intended disclosure. Opening Br. 14 n.2; Add.56. The Department did not provide that notice. Including this letter in the Department's addendum is improper, as it is not in the record and is non-public. *See* 1st Cir. R. 28.0(a)(2), (c). In any event, the letter does nothing but confirm RIH's good-faith efforts to engage with the Department.

D.C.-based DOJ attorneys RIH had communicated with during the preceding nine months. JA156-68, 238.

The petition misrepresented that the Department had served the subpoena nearly a week earlier than it had—on July 3, not July 9. JA156, 229. And the petition misleadingly stressed that RIH "remains non-compliant" and had "produced only one six-page document," without mentioning the parties' ongoing negotiations or RIH's unanswered search-term proposal. JA156, 159.

Although the Department's July 9 press release had referenced "healthcare fraud" and "false statements" in describing its investigation, the enforcement petition invoked only the Department's "statutory authority to investigate violations of the Federal Food, Drug, and Cosmetic Act." July 9 Press Release; JA156. The petition asserted that the subpoena fell within that authority, that the information sought was relevant to its investigation, and that "the subpoena is neither overbroad nor unduly burdensome." JA156.

The Department attached a supporting declaration from Lisa Hsiao, representing that "patient records including patient identities" can provide "essential investigative leads." JA104, 164. The declaration

did not mention that the Department had agreed to accept anonymized patient records from at least three other hospitals. *See* JA250, 255, 272-74. Instead, the Department's petition asserted that "other hospitals to whom the Department issued similar subpoenas have complied with the subpoena without any disruption or hindrance"—a claim contradicted by the Department's resounding litigation losses and repeated anonymization concessions. JA166-67.

D. Without giving RIH any opportunity to respond, the Texas district court enforces the subpoena.

The Texas district court granted the Department's petition on April 30, the same day the Department filed and served it. JA156, 169. The court gave RIH no opportunity to respond—indeed, RIH had not even entered an appearance in the action.[6] Highlighting the decision's reflexive nature, the court entered the Department's proposed order verbatim, including its incorrect statement that the Department had served the subpoena on July 3. JA169-70; *see* Proposed Order, *In the*

[6] It is unclear when on April 30 the Northern District of Texas entered its order, making it possible that the court signed the order before the Department even notified RIH it had filed the petition. *See* JA366-67, 418-19.

Matter of Admin. Subpoena 25-1431-032, No. 26-mc-6 (N.D. Tex. Apr. 30, 2026), Dkt. 1-4.

Although the court entered the order before RIH could file any opposition (and potentially before RIH even received notice of the petition), it adopted the Department's proposed conclusions wholesale, including that RIH had not "shown just cause for noncompliance." JA169. The order commanded RIH to "provide all records responsive to each request in the subpoena" within 14 days, warning that failure to comply could result in "sanctions up to and including . . . contempt." JA169-70.

RIH promptly appealed and sought a stay pending appeal, first from the Texas district court and then from the Fifth Circuit. The Texas district court denied the stay on May 10. Op. & Order, *In the Matter of Admin. Subpoena 25-1431-032*, No. 26-mc-6 (N.D. Tex. May 10, 2026), Dkt. 12. The Fifth Circuit denied the stay in an unreasoned order on May 12. Order, *United States v. R.I. Hosp.*, No. 26-10431 (5th Cir. May 12, 2026), Dkt. 34-2.

E. The Rhode Island district court quashes the subpoena.

Meanwhile, proceedings to quash the subpoena were underway in the District of Rhode Island, initiated by the Rhode Island Child Advocate's May 4 emergency motion to quash. JA6, 13. On May 10—rather than stand by while another proceeding about its records and obligations went forward without it, and with a May 14 compliance date approaching in Texas—RIH moved to intervene and filed its own motion to quash. JA8, 126.

After a May 12 hearing, the District Court granted both motions to quash.[7] JA8-9; Add.26. The court first concluded that the motions were properly filed in Rhode Island, reasoning that because RIH "was not provided notice and an opportunity to be heard before the Texas court ordered the administrative subpoena enforced," claim preclusion and the collateral-attack doctrine did not bar RIH's Rhode Island motion. Add.15. The court explained that RIH's ability to move for

[7] The Department emphasizes that it was not ordered to file a response to RIH's motion. Opening Br. 14 n.2, 16. The Department does not mention that the District Court offered an opportunity to file a response to RIH's motion, contingent on a stay of RIH's compliance deadline. JA326. The Department declined. JA326-27.

reconsideration in Texas did not cure the due process defect. Add.16. In the court's view, RIH "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." *Id.* Thus, it was not "precluded from litigating" in Rhode Island. *Id.*

On the merits, the District Court held that the Department's FDCA theory did not justify the subpoena. Add.17-21. The court reasoned that the Department's theory—that "any party in the distribution chain who helped place [a] drug in commerce," including the doctors who prescribe it, could be criminally liable for "misbranding" if that drug is prescribed for an off-label use—was irreconcilable with the settled rule that off-label prescribing is lawful. Add.17-20. The court also observed that the FDCA specifically exempts prescription drugs from the misbranding prohibition that the Department invoked once they are dispensed by a prescribing practitioner—another reason why "the DOJ's misbranding claim fails as applied to RIH." Add.20 (citing 21 U.S.C. § 353(b)(2)).

The court next found that the subpoena was issued for an improper purpose in bad faith, joining seven other courts. Add.21-22. It rejected the Department's contention that a legitimate investigatory motive

accompanied its objective of suppressing gender-affirming care, reasoning that the Department may not "immunize any coercive investigation from the improper purpose doctrine simply by appending an untenable legal theory to it." Add.22. And the court agreed with the Child Advocate that compliance with the patient-records requests would violate minor patients' informational privacy rights, explaining that compelling disclosure of intimate medical details from vulnerable child patients constituted a "drastic overreach" of the Department's investigative authority. Add.22-26.

The court further concluded that the Department had "misrepresented and withheld information" in both Rhode Island and Texas. Add.4. The enforcement petition "misleadingly . . . never acknowledged that [DOJ] had failed to respond in any way to the February message from RIH where it suggested search terms." Add.7. And "Ms. Hsiao neglected to inform the Texas court that DOJ had agreed to anonymized data in several other jurisdictions," making "[h]er

assertion that DOJ needed this information . . . at best, deceptive, if not intentionally and knowingly false."[8] Add.9.

The court quashed the subpoena in its entirety and enjoined the Department from "seeking, receiving, using, retaining, or disseminating any patient-identifying information or protected health information produced by RIH." Add.51-52. The Department appealed. JA10-11.

F. The Texas district court requires *in camera* production.

Days later, the Texas district court responded with its own order. Order, *In the Matter of Admin. Subpoena 25-1431-032*, No. 26-mc-6 (N.D. Tex. May 18, 2026), Dkt. 26. The court understood the quashal order to leave its enforcement order "in effect." *Id.* at 2-3. Asserting that RIH's litigation efforts raised concerns about preservation of responsive materials, the court ordered that RIH produce "all materials that it would have turned over to the Government in compliance with" the enforcement

[8] The District Court has initiated disciplinary proceedings for this matter. JA12. Although the Department submits that the court's findings about its misrepresentations "are not relevant to the questions on appeal," Opening Br. 17 n.3, that is hardly true. To the contrary, the Department's petition was premised on the supposed need for enforcement in the face of RIH's claimed non-compliance, and the validity of the Department's misleading claim to need patient-identifying information is a critical question here.

order, for the court to hold *in camera* pending the resolution of the appeals in the First and Fifth Circuits. *Id.* at 5-6. The order also enjoined RIH from seeking relief in other courts or encouraging others to do so. *Id.* at 6.[9]

This Court denied the Child Advocate's motion to enjoin RIH from engaging in the *in camera* production. *In re R.I. Hosp.*, 177 F.4th 21 (1st Cir. 2026). RIH has since made *in camera* productions to the Texas district court.[10]

STATEMENT OF THE ISSUES

1. Whether the District Court correctly held that the collateral-attack doctrine did not impede it from quashing the subpoena.

2. Whether the District Court correctly found that the subpoena was issued for an improper purpose in bad faith.

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[9] RIH has appealed this injunctive aspect of the May 18 order. RIH does not object to *in camera* production of responsive records during the pendency of the appeals.

[10] RIH clarified that it would anonymize any patient information "as agreed by the Government on the record during the May 12 hearing before the District of Rhode Island." Notice, *In the Matter of Admin. Subpoena 25-1431-032*, No. 26-mc-6 (N.D. Tex. May 19, 2026), Dkt. 30.

3. Whether the District Court's decision should be affirmed on the alternative ground that the subpoena is unreasonably broad and burdensome.

4. Whether the District Court properly exercised its discretion to enjoin the Department from collecting identifying information or protected health information of minor patients.

STANDARD OF REVIEW

This Court treats an appeal from a collateral attack on another order as an appeal from a ruling on "a motion for relief from a judgment pursuant to Federal Rule of Civil Procedure 60(b)(4), which permits a court to grant such relief where the judgment is void." *Fafel v. Dipaola*, 399 F.3d 403, 409-10 (1st Cir. 2005) (quotation omitted). This Court applies de novo review. *Id.*

This Court reviews a district court's decision to quash an administrative subpoena for abuse of discretion. *McLane Co. v. EEOC*, 581 U.S. 72, 75 (2017). Because the motive inquiry is "predominantly factbound," this Court "should disturb the district court's determination only if it is clearly erroneous" or the district court made "a mistake of law." *United States v. Gertner*, 65 F.3d 963, 970 (1st Cir. 1995). Thus, "if

there are two or more plausible interpretations of the evidence, the district court's choice among them must hold sway." *Id.*

This Court reviews injunctions for abuse of discretion. *Doe v. R.I. Interscholastic League*, 137 F.4th 34, 39 (1st Cir. 2025).

On all issues, this Court "may affirm on any ground supported by the record." *Cosenza v. City of Worcester*, 120 F.4th 30, 38 (1st Cir. 2024).

SUMMARY OF ARGUMENT

The Department seeks to shield its improper and overbroad subpoena from further judicial review by arguing that the District Court lacked authority to quash it. The Department is wrong. None of the comity-related principles that could potentially apply—the first-filed rule, preclusion, and the collateral-attack doctrine—have force here. The first-filed rule does not apply when a proceeding has been resolved by a final order. And preclusion principles do not bind a party that never received a fair opportunity to litigate. Nor does the collateral-attack doctrine bar review here, where entry of the Texas order denied RIH due process. That defect renders the order void and permits RIH to seek relief from it, including in the District Court and here. The Department's opening brief does not even acknowledge that this exception to the

collateral-attack bar exists, let alone argue that RIH somehow received due process.

On the substance, the District Court's quashal order is sound. The court properly exercised its discretion in concluding that the Department issued the subpoena to suppress gender-affirming care, not to pursue its insubstantial theories of FDCA misbranding liability, all predicated on the lawful act of off-label prescribing. The Trump Administration's express campaign to end gender-affirming care, compounded by the Department's litigation tactics—its shifting theories, its recasting of RIH from witness to suspect, and its aggressive pursuit of enforcement in a far-flung forum (fueled by repeated misrepresentations)—all support the court's finding of bad faith and pretext.

The Department asserts that its *sole* purpose was not improper because it was also motivated to enforce the FDCA. But a *de minimis* investigatory interest cannot salvage a campaign primarily designed to harass or coerce. And in any event, the District Court made the factual finding that the Department had a single, improper purpose. That finding is not clearly erroneous.

Even putting aside any motive inquiry, the subpoena remains invalid because its demands are far broader than any legitimate investigation could justify. It seeks complete personnel files, broad billing and insurance materials, sweeping communications, and deeply sensitive patient records. These requests are not tailored to any plausible misbranding investigation. The demand for patient-identifying information is especially unreasonable given that the Department has accepted anonymized records from multiple similarly situated hospitals. This unreasonableness and overbreadth provide an alternative basis to affirm.

Finally, the Department has identified no remedial flaw in the decision below. The court appropriately quashed the subpoena in full and enjoined the Department from seeking, obtaining, using, or disseminating unnecessary patient information. This Court should affirm in full.

ARGUMENT

I. RIH properly moved to quash in Rhode Island.

The Texas district court's enforcement order reflects an extraordinary denial of due process. The court entered that order *ex*

parte, within hours of the Department's filing, exactly as the Department drafted it—and all before RIH could say a single word in response. That due process defect disposes of the Department's procedural arguments.

A. The Texas order has no preclusive effect.

The Department contends that the Texas order barred RIH from "relitigat[ing]" the subpoena's validity in Rhode Island. Opening Br. 21. The Department invokes the first-filed rule for this proposition, hoping to confine this dispute to the forum it hand-picked. *Id.* at 21-22.

The first-filed rule does not fit. That rule informs a choice-of-venue analysis "[w]here identical actions are proceeding *concurrently* in two federal courts." *Cianbro Corp. v. Curran-Lavoie, Inc.*, 814 F.2d 7, 11 (1st Cir. 1987) (emphasis added); *see Maldonado-Cabrera v. Anglero-Alfaro*, 26 F.4th 523, 526 (1st Cir. 2022) (requiring "actions involving the same parties and similar subject matter" that "*are pending* in different federal district courts" (quotation omitted and emphasis added)). That was never the case here. As the Department itself recognizes, the Texas order was "a final and appealable judgment enforcing the subpoena on April 30"—before the Rhode Island litigation even began. Opening Br. 21. The first-filed rule cannot compel a transfer from a live case to a proceeding that

is already over. *Cf. Codex Corp. v. Milo Elec. Corp.*, 553 F.2d 735, 739 (1st Cir. 1977) (when litigation in the first-filed forum is "largely completed, there is no possibility of consolidation or coordination to promote judicial economy").[11]

By incorrectly invoking the first-filed rule, the Department pointedly ignores claim and issue preclusion, the relevant doctrines that govern whether a final judgment or adjudicated issue is binding in a subsequent action. No surprise, as those doctrines do not apply when a party "did not have an adequate opportunity . . . to obtain a full and fair adjudication in the initial action." Restatement (Second) of Judgments § 28(5)(c) (A.L.I. 1982); *see Taylor v. Sturgell*, 553 U.S. 880, 892 (2008). As the District Court correctly concluded, RIH never had any opportunity to litigate in Texas, much less a full and fair one. Add.15-16. The Texas

[11] Even if the first-filed rule were facially applicable, the Department's forum shopping and bad faith would prevent it from applying here. *See Wakaya Perfection, LLC v. Youngevity Int'l, Inc.*, 910 F.3d 1118, 1124, 1127-28 (10th Cir. 2018) (recognizing equitable exceptions to the first-filed rule); *see infra* Part II.B.3. In any event, the applicable transfer mechanism is 28 U.S.C. § 1404(a), which the Department cannot invoke, given that the Northern District of Texas is not remotely more convenient for RIH or the Department's D.C.-based attorneys.

order therefore is not binding in Rhode Island. And it did not require the District Court to defer to any other proceeding or ruling.

B. The Texas order is void for lack of due process.

The Department also wrongly seeks refuge in the collateral-attack doctrine. It argues that, whatever the Texas order's defects, this Court must leave them for resolution through the appellate process in the Fifth Circuit. Opening Br. 22-23. The Department is wrong.

The collateral-attack doctrine recognizes that direct appeal is the ordinary route for correcting judicial error. So, *in general*, a party may not challenge a final judgment's validity in a separate proceeding. *See Celotex Corp. v. Edwards*, 514 U.S. 300, 306, 312-13 (1995).

But exceptions exist. A judgment that is "void" may be attacked both directly, through reconsideration or on appeal, and collaterally, in an "independent action." Fed. R. Civ. P. 60(b)(4), (d)(1); *see* 18 MOORE'S FEDERAL PRACTICE § 130.04 (3d ed. 1997) ("Void judgments are subject to both direct and collateral attack.").

A judgment is void where it "is premised either on a certain type of jurisdictional error or on a violation of due process that deprives a party of notice or the opportunity to be heard." *United Student Aid Funds, Inc.*

v. Espinosa, 559 U.S. 260, 270-71 (2010); *see Carrasquillo-Serrano v. Mun. of Canovanas*, 991 F.3d 32, 39, 42 (1st Cir. 2021). Put differently, when there is no due process, there is no collateral-attack bar. The principle that federal courts' determinations "may not be assailed collaterally" requires that parties had been "brought before them in accordance with the requirements of due process." *Chicot Cnty. Drainage Dist. v. Baxter State Bank*, 308 U.S. 371, 376 (1940); *see Travelers Indem. Co. v. Bailey*, 557 U.S. 137, 153 (2009) (parties are barred from pursuing a collateral attack if they "were given a fair chance to challenge" the order).

The Texas enforcement order is premised on a due process violation—the failure to give RIH notice and an opportunity to be heard—and is therefore void. "No principle is more firmly embedded in American jurisprudence" than that "when a claim is proffered that threatens a person's life, liberty, or property, that person is entitled to notice and an opportunity to be heard before a court awards any substantial relief." *Vazquez-Robles v. CommoLoCo, Inc.*, 757 F.3d 1, 2 (1st Cir. 2014). This principle extends to subpoena recipients like RIH.

Enforcement petitions are not to be rubber-stamped. Instead, they are subject to adversarial testing in which "the subject of [the] administrative subpoena" receives "an opportunity to challenge the subpoena before yielding the information." *United States v. Sturm, Ruger & Co., Inc.*, 84 F.3d 1, 3 (1st Cir. 1996).[12] This adversarial process is what distinguishes an administrative subpoena from a warrant under the Fourth Amendment. *See Doe v. United States*, 253 F.3d 256, 263-64 (6th Cir. 2001); *In re Subpoena Duces Tecum*, 228 F.3d 341, 347-48 (4th Cir. 2000). Because administrative subpoenas are tested in this way (and warrants are not), they need only be reasonable, as opposed to supported by probable cause. *See Doe*, 253 F.3d at 263-64; *In re Subpoena Duces Tecum*, 228 F.3d at 347-48.

[12] *See United States v. Clarke*, 573 U.S. 248, 253-54 (2014) ("The summoned party must receive notice, and may present argument and evidence on all matters bearing on a summons's validity."); *Donaldson v. United States*, 400 U.S. 517, 525 (1971) ("[T]he summons is administratively issued but its enforcement is only by federal court authority in an adversary proceeding affording the opportunity for challenge and complete protection to the witness." (quotation omitted)); *United States v. Freedom Church*, 613 F.2d 316, 321 (1st Cir. 1979) ("[T]he taxpayer is entitled to a hearing prior to enforcement of a summons against him in order to prevent abuse of the court's process.").

The Texas district court's failure to give RIH notice and an opportunity to respond is precisely the kind of due process deprivation that justifies a collateral challenge. *See Espinosa*, 559 U.S. at 270-71. That deprivation alone is enough to dispel any collateral-attack bar—but the extraordinary circumstances here are especially stark. The Department obtained the same-day enforcement order in a courthouse some 1,500 miles from Rhode Island and D.C., based on representations the Rhode Island district court later deemed false or at least misleading. The Texas district court immediately entered that order, accepting the Department's one-sided assertions. RIH had no chance to inform that court of the parties' ongoing negotiations, the unanswered search-term proposal, or the Department's willingness to accept anonymized records elsewhere. Nor did it have a chance to raise other challenges to the subpoena's validity or breadth. This scenario is the opposite of the "adequate opportunity to present objections" that due process requires. *Okla. Press Publ'g Co. v. Walling*, 327 U.S. 186, 195 (1946).

Such an order entered in defiance of due process cannot bind the party stripped of its due process rights. Nor can such an order preclude that party from defending its interests in another forum. RIH had every

right to join the litigation that the Child Advocate initiated in Rhode Island. And the District Court had full authority to rule on RIH's motion to quash.

The Department's opening brief does not acknowledge that this due process exception to the collateral-attack bar exists, let alone attempt to grapple with its application here—even though the Department made due-process arguments below, and the District Court rested its decision in part on the due-process denial. Add.15-16. The Department has now abandoned any argument on this point. *See United States v. Mayendía-Blanco*, 905 F.3d 26, 32-33 (1st Cir. 2018).

The Department's retreat from the due process question is telling. Below, the Department urged that cases involving discovery orders under 28 U.S.C. § 1782 establish that *ex parte* orders satisfy due process because reconsideration is available. *E.g.*, JA414-15, 417. It does not press that argument here, likely because it is wrong. *Ex parte* § 1782 orders satisfy due process because they are interlocutory, not final, and the affected party may immediately seek full adversarial review. *See Banca Pueyo SA v. Lone Star Fund IX (US), L.P.*, 55 F.4th 469, 474-76

(5th Cir. 2022). Not so for the Texas court's order, which was final upon entry and now subject only to abuse of discretion review on appeal.

The Department has also tried to absolve the Texas court's due process denial on the ground that RIH's opposition would have been futile. *See* Opp. to Emergency Mot. for Stay Pending Appeal 13, *United States v. R.I. Hosp.*, No. 26-10431 (5th Cir. May 12, 2026), Dkt. 28-1. But when a party has been deprived of "the most basic tenets of due process, it is no answer to say that in his particular case due process of law would have led to the same result because he had no adequate defense upon the merits." *Peralta v. Heights Med. Ctr., Inc.*, 485 U.S. 80, 86-87 (1988) (quotation omitted). And in any event, RIH's success below—along with the success of every other challenger to these subpoenas—refutes any notion of futility. Plainly, RIH's arguments have merit.

Because the Texas district court denied RIH due process, its order was void, and the collateral-attack doctrine does not apply. The subpoena's validity was thus properly before the District Court below and is properly subject to this Court's review.

II. The Department of Justice issued the subpoena for the improper purpose of ending gender-affirming care.

On the merits, the Department asks this Court to second-guess a factual finding that requires deference. *See Gertner*, 65 F.3d at 970. Weighing the evidence in the public record—which the Department recounts and embraces in its opening brief—the District Court found that the Department issued the subpoena not to further a legitimate criminal investigation, but to pressure RIH into abandoning gender-affirming care for minors. Add.21; *see* Opening Br. 10-12. The Department provides no basis for overturning that conclusion.

A. The subpoena lacks a congressionally authorized purpose.

The Department backs its subpoena with an "untenable legal theory" that bases "misbranding" liability under the FDCA on the lawful act of physicians' off-label prescribing. Add.22. This approach is irremediably flawed. Congress has not authorized the Department to investigate off-label prescribing as criminal misconduct that violates the FDCA, whether as a standalone offense or under any of the alternative rationales that the Department now advances.

1. The FDCA does not criminalize off-label prescribing.

The Department's "authority to issue subpoenas is created solely by statute." *Consumer Fin. Prot. Bureau v. Accrediting Council for Indep. Colls. & Schs.*, 854 F.3d 683, 690 (D.C. Cir. 2017) (quotation omitted). Thus, the statute the Department relies on as its source of authority imposes enforceable limitations on the Department's subpoena power. *See id.*

The Department invokes HIPAA and asserts it is investigating the "[f]ederal health care offense" of misbranding in violation of the FDCA. 18 U.S.C. § 3486(a)(1)(A)(i)(I). The FDCA governs the manufacturing, labeling, and distribution of drugs in interstate commerce. Among other offenses, the statute prohibits "misbranding," 21 U.S.C. § 331, which (as relevant here) relates to a drug's "labeling," *see id.* § 352.

A drug's "labeling" refers to "all labels and other written, printed, or graphic matter" that manufacturers and distributors of a drug associate it with to identify the drug and its uses. *Id.* § 321(m). To constitute a drug's "labeling," the material must be "upon" or "accompanying" the drug. *Id.* Materials may satisfy that standard when they supplement the drug's affixed label or are disseminated as part of

the drug's sale, promotion, or distribution. *See Kordel v. United States*, 335 U.S. 345, 348-51 (1948).

The FDCA provides that a drug is misbranded if its labeling does not include "adequate directions for use," including instructions that reflect its "intended use." 21 U.S.C. § 352(f)(1); *see* 21 C.F.R. §§ 201.5, 201.100. A drug's "intended use" is based on "the objective intent of the persons legally responsible for the labeling of an article (or their representatives)"—i.e., the drug's "packer, distributor, or seller." 21 C.F.R. § 201.128.

But after the chain of distribution ends, and a physician prescribes a drug to a patient, the FDCA's misbranding provisions apply differently. "*Prior* to being dispensed a prescription drug must meet the misbranding requirements of section 352," including the "adequate directions for use" requirement. *United States v. Articles of Drug*, 625 F.2d 665, 670 (5th Cir. 1980) (emphasis added). "After a prescription drug has been lawfully prescribed," in contrast, "it is exempt from most of the requirements of section 352 but must meet the labeling requirements of section 353(b)(2)." *Id.*

That is because the text of the FDCA explicitly exempts drugs dispensed to patients from the "adequate directions for use" requirement of 21 U.S.C. § 352(f)(1). The statute provides that "[a]ny drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of section 352 of this title"—including the "adequate directions for use" requirement of § 352(f)(1)—"if the drug bears a label containing," as relevant, "the directions for use and cautionary statements, if any, contained in such prescription." 21 U.S.C. § 353(b)(2).

In other words, once a prescription drug is dispensed to a patient on a doctor's order, the FDCA exempts that drug from § 352(f)(1)'s "adequate directions for use" requirement. Instead, it is enough that the label affixed to the drug includes the prescription-specific information § 353(b)(2) requires, including the prescriber's directions for use. In this manner, the "adequate directions for use" strand of misbranding liability under the FDCA targets potential inadequate labeling by manufacturers and distributors involved in the distribution chain for prescription drugs.

The FDCA does *not* oversee physicians' treatment decisions or, more specifically, their decisions to prescribe drugs for purposes other

than their FDA-approved use. As this Court has confirmed, the FDCA "does not prohibit doctors from prescribing drugs for off-label uses." *In re Celexa & Lexapro Mktg. & Sales Pracs. Litig.*, 915 F.3d 1, 5 (1st Cir. 2019); *see United States v. Facteau*, 89 F.4th 1, 15 (1st Cir. 2023). In fact, permitting off-label use "is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001).

Congress, through the FDCA, not only declined to disturb off-label prescribing, but also left intact States' traditional authority to regulate the practice of medicine. As the District Court correctly recognized, because the regulation of medical practice "has long been understood to remain within the states' prerogative," the Executive "may not adopt novel interpretations of federal statutes to displace a state's medical regulatory framework without clear congressional authorization." Add.18 (citing *Gonzales v. Oregon*, 546 U.S. 243, 269-70 (2006)). Rhode Island has exercised its reserved authority to protect gender-affirming care as a lawful medical practice. The FDCA's misbranding provisions do not override that judgment. *See Skrmetti*, 605 U.S. at 524-25.

2. The Department's claimed investigation does not justify the subpoena.

The Department accepts—at least nominally—that the FDCA does not regulate, much less criminalize, "merely writing off-label prescriptions." Add.18; *see* Opening Br. 35. And, in turn, the Department does not contend that providing minors gender-affirming care is itself an offense that HIPAA permits it to investigate. *See* 18 U.S.C. § 3486(a)(1)(A)(i)(I).

But the Department still asserts that its investigation has congressional authorization, pinning RIH as both a potential witness to and a potential suspect in "misbranding" violations. Neither characterization justifies the subpoena.

First, the Department claims that it can investigate misbranding by manufacturers and distributors, and that hospitals like RIH are potential witnesses to such misconduct. Opening Br. 36. But to prove misbranding by manufacturers and distributors upstream in the distribution chain, the Department would have to investigate *their* conduct and intent—not that of hospitals and their providers.

Through its subpoenas, the Department has not trained its eye on evidence of inadequate drug labeling—what the FDCA actually

criminalizes—by manufacturers and distributors. Instead, the Department is pursuing evidence reflecting RIH's lawful off-label prescribing and associated billing and insurance practices. That evidence does not further an FDCA misbranding investigation because it says nothing about manufacturers' or distributors' drug labeling in the distribution chain.

The Department strains to tie these disconnected strands together, suggesting that physicians can somehow change a drug's "intended use" and thereby cause or participate in "misbranding." The Department's chain of logic starts with the uncontested premise that a drug is "misbranded" if "its labeling does not bear adequate directions for its intended use." Opening Br. 5 (citing 21 U.S.C. § 352(f)(1)). And, invoking an FDA regulation, the Department states that "intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer." *Id.* (quoting 21 C.F.R. § 201.128). True enough. For instance, a distributor may intend a use for a drug that its manufacturer did not. Misbranding liability can then attach to the distributor if the distributor does not supply appropriate directions for that use. *See* 21 C.F.R. § 201.128.

But the malleability of a drug's "intended use" under § 201.128 does nothing to impede a *physician* from prescribing an FDA-approved drug for off-label use. When a physician prescribes a drug, the drug is *exempt* from the "adequate directions for use" requirement, irrespective of the drug's "intended use." 21 U.S.C. § 353(b)(2).[13]

Thus, the "intended use" that matters under the FDCA's "adequate directions for use" standard is that of the manufacturers and distributors. A physician's prescription of a drug off-label does not define or control a drug's "intended use" under the FDCA and its implementing regulations.

FDA regulations confirm this distinction. The FDA tethers a drug's "intended use" to the "objective intent" of a drug's "packer, distributor, or seller." 21 C.F.R. § 201.128. And its regulations specifically state that such an entity "would not be regarded as intending an unapproved new

[13] The Department protests that the District Court misread § 353(b)(2) to provide "complete immunity from misbranding liability," stressing that § 352(a)'s "false or misleading" labeling prohibition applies. Opening Br. 38. But that "false or misleading labeling" theory is newly concocted in the Department's opening brief. The core of its theory, up to this point, was the "adequate directions for use" requirement, and the District Court correctly concluded that this requirement does not apply by virtue of § 353(b)(2). Add.20; *see* JA157-58. Regardless, this newly posited theory also fails to justify the investigation. *See infra* at 43-44.

use for an approved drug based solely on that firm's knowledge that such drug was being prescribed or used by health care providers for such use." *Id.* That is, the uses intended by a prescriber do not dictate the directions its labeling must bear.

Yet the Department justifies much of the evidence it seeks by pointing to the potential intent of RIH personnel, not manufacturers or distributors. Consider how the Department justifies its demand for patient records and billing information. It posits that, by matching patient records against billing data, it can detect "patterns of misbranding or false billing." Opening Br. 31. A mismatch between treatment and billing codes, the Department contends, "suggest[s] concealment of off-label use of puberty blockers and hormones." *Id.* But the FDCA does not restrict "off-label use of puberty blockers and hormones." *Id.* The Department is thus hunting for evidence that someone at RIH concealed conduct that the Department admits is perfectly lawful. It is not looking for evidence of what a manufacturer or distributor intended a drug's use to be or whether a drug's labeling aligns with that intent.

The Department's other justification for patient records—their potential utility in "identify[ing] patients' adverse health outcomes"—fares no better. *Id.* at 32. The Department seeks patient records to uncover negative consequences of off-label prescribing, but that evidence does not bear on manufacturers' or distributors' intended use for a drug or the adequacy of a drug's labeling based on that intended use. It bears only on the lawful act of off-label prescribing.

Second, the Department contends that RIH could itself be criminally liable for misbranding. It proposes multiple iterations of that theory. None work.

To start, the Department contends that RIH could be criminally liable for "conspir[ing] with manufacturers and distributors who were misbranding drugs." *Id.* at 36. But again, off-label prescribing by physicians is lawful. And as the District Court concluded, a physician does not unlawfully facilitate, conspire in, or aid and abet an FDCA violation merely by exercising her lawful authority to prescribe a drug off-label. Add.19. Accepting the Department's contrary theory would transform every lawful act of off-label prescribing into a federal crime. *See Gonzales*, 546 U.S. at 262 (denouncing the "power to criminalize even

the actions of registered physicians, whenever they engage in conduct" deemed "illegitimate"). That result is plainly contrary to what Congress authorized in the FDCA.

Beyond RIH's furtherance of lawful off-label prescribing, the Department has provided no other basis to suspect it of conspiring with manufacturers and distributors in any misbranding conspiracy. Indeed, the Department has identified no potential bad actor or provided any details about the nature of such a conspiracy.

To validly enforce an administrative subpoena, the Department need not show probable cause to believe that RIH is involved in some misbranding conspiracy. *See Okla. Press*, 327 U.S. at 209. But the Department must make a showing of reasonableness, *see id.*, which requires "an indication of a realistic expectation rather than an idle hope that something may be discovered," *e.g.*, *United States v. Goldman*, 637 F.2d 664, 667 (9th Cir. 1980) (quoting *United States v. Harrington*, 388 F.2d 520, 524 (2d Cir. 1968)); *EEOC v. United Air Lines, Inc.*, 287 F.3d 643, 652-53 (7th Cir. 2002) (same). The Department's amorphous

allusions to potential conspiracy liability do not pass this threshold.[14]

The Department also asserts that "RIH or its employees could have engaged in misbranding by altering a drug's labeling, such as by providing false or misleading 'written, printed, or graphic matter . . . accompanying' the drug." Opening Br. 36-37 (quoting 21 U.S.C. § 321(m)). False and misleading labeling is another kind of misbranding offense, 21 U.S.C. § 352(a), separate from the lack of "adequate directions for use," *id.* § 352(f)(1). The Department did not articulate this theory of altering labeling below, so it should not provide support on appeal. *See B & T Masonry Constr. Co., Inc. v. Pub. Serv. Mut. Ins. Co.*, 382 F.3d 36, 40 (1st Cir. 2004). In any event, the subpoena does not seek production of materials that accompanied drugs prescribed by RIH's physicians or evidence regarding purported alteration of drug labeling by RIH. *See* Opening Br. 30-31. The Department claims that "[m]isleading or deceiving minors and their parents about the risks of gender-related

[14] The only "evidence" the Department cites involves later-than-typical diagnoses for central precocious puberty; an increase in diagnoses for both gender dysphoria and "endocrine disorder"; and more insurance claims for "endocrine disorder" than "gender dysphoria." Opening Br. 13-14, 37; JA100-01. But the Department links none of this to actual "misbranding." This purported evidence of a "fraudulent intent" means nothing if no legitimate theory of misbranding exists. Opening Br. 14.

treatments could . . . violate the FDCA." Opening Br. 12. But the FDCA does not prohibit any assertedly "[m]isleading or deceiving" communication detached from a drug's labeling. *Id.* The subpoena does not plausibly further an investigation based on this unworkable theory.

The Department's shifting collection of liability theories confirms the weakness of each. Below, the Department argued that RIH may have "itself . . . violated the FDCA by causing distribution of misbranded drugs." RIH.Add.7; *see* RIH.Add.9. But RIH prescribes drugs rather than distributing them—a distinction the Department evidently now recognizes. Hsiao's declaration also advanced the theory that "to the extent these drugs are intended to treat gender dysphoria in minors, they constitute unapproved new drugs under federal law." JA94; *see* 21 U.S.C. § 331(d). Now, recognizing that prescribing an approved drug for an off-label use does not render it a "new drug" under the FDCA or render it "unapproved," the Department omits this theory from its brief.

No amount of statutory or semantic gymnastics can overcome the fundamental principle that defeats the Department's varying theories: a physician's off-label prescribing is not "misbranding" under the FDCA. It is the lawful practice of medicine, and the FDCA does not empower the

Department to investigate it as a potential crime. The Department thus lacks any legitimate investigative purpose in issuing the subpoena.

B. The Department's purpose is improper.

The District Court properly looked past the Department's investigative façade. As the court concluded, the Department is not using its subpoenas to detect criminal wrongdoing. The Department is instead leveraging the threat of criminal liability and the exposure of highly sensitive patient information to burden providers of gender-affirming care and weaken their relationships with their patients. Although off-label prescribing is an ordinary and widespread practice across many areas of medicine, the Department is only interested in off-label prescribing tied to gender-affirming care for minors. Singling out and suppressing that care is the point.

1. The Department's shifting statutory justifications show pretext.

In *United States v. Gertner*, this Court affirmed an improper purpose finding after citing, among other things, the agency's "stonewalling—its unexplained refusal to answer the [recipient's] repeated inquiries as to whether it was in fact under investigation." 65 F.3d at 970. Here, the Department engaged not in stonewalling, but

in whipsawing. For one, the Department initially assured RIH that it was not under investigation but now advances a shifting amalgamation of unsound theories to argue that, well, it might be.

And when defending identical HIPAA subpoenas, the Department appealed explicitly to "potential consumer-protection violations: false statements made to induce patient and parental consent to off-label drug use and other life-altering procedures." *In re Subpoena Duces Tecum No. 25-1431-016*, 2025 WL 3562151, at *11 (quotation omitted); *see also, e.g.*, Resp. to Mot. to Quash, *In re Admin. Subpoena No. 25-1431-019*, No. 25-cv-91324 (D. Mass. July 23, 2025), Dkt. 21. It abandoned such an effort here, instead newly raising an untenable "false or misleading labeling" theory, as discussed above. *See supra* at 43-44.

The Department has also expressed interest in pursuing "claims under the False Claims Act against health care providers that bill the federal government for impermissible services." Shumate Memorandum 3. The Department has not identified support for any level of suspicion that RIH has engaged in such misconduct, which again is not an FDCA violation.

The Department cannot weaponize a HIPAA subpoena under the pretextual claim that it intends to investigate *FDCA* violations when it actually seeks to investigate violations of other laws. Neither HIPAA nor any other statute confers "unfettered authority to cast about for potential wrongdoing." *In re Sealed Case (Admin. Subpoena)*, 42 F.3d 1412, 1418 (D.C. Cir. 1994).

The Department's shifting theories—as to both this subpoena and the many others in its investigation—"indicate[] that [it] had no apparent reason to suspect [RIH] of any . . . impropriety" related to misbranding, suggesting that the Department "never really suspected [RIH] of any questionable activity," and was never really interested in bringing misbranding violations to light. *Gertner*, 65 F.3d at 970. Instead, the Department's tactics show that it "issued the subpoena first and searched for a justification second." *QueerDoc*, 807 F. Supp. 3d at 1303.

2. Public statements confirm the Department's purpose of ending gender-affirming care.

The Administration's many "public statements" confirm the investigation's pretextual nature. *Gertner*, 65 F.3d at 969. As the District Court recounted, "[t]he Administration has publicly characterized gender-affirming care for minors as abuse, directed the

DOJ to bring its practice to an end, and celebrated" with self-congratulatory press releases "when hospitals curtailed such programs as a result of this subpoena campaign." Add.21. Altogether, the executive orders, memoranda, and press releases by the Administration "strongly suggest that the purpose of investigating possible violations of the FDCA" is "to end gender-related treatment for minors." *In re Subpoena Duces Tecum No. 25-1431-016*, 2025 WL 3562151, at *11. These pronouncements reflect that the investigation "is designed less to monitor [RIH's] compliance with the . . . laws," and more to pressure it into compliance with the Administration's policy aims. *Gertner*, 65 F.3d at 969.

The timeline is also revealing. The former Attorney General declared that providers who "mutilated children" would be held "accountable" just one day after the first motions to quash were filed, and the same day the Department served RIH its subpoena. July 9 Press Release. Within weeks, the White House celebrated its success in pressuring hospitals to halt gender-affirming care. *See* July 25 Press Release. The close temporal connection confirms the causal link that motivated the Department—it correctly predicted that at least some

hospitals placed under its microscope would acquiesce. These public documents eliminate any need for speculation into the Department's hidden motives.

3. The Department's litigation conduct reveals bad faith.

The Department's litigation conduct, detailed in the District Court's findings, only corroborates its desire to end gender-affirming care under the guise of investigation. After the Department's "investigative tactics" were "rejected by every other court to review them," the Department redirected its efforts to the Northern District of Texas. Add.4. That "distant forum" had no previous apparent ties to the investigation, but the Department (rightly) deemed it "friendly to its political positions." *Id.*; *see* 18 U.S.C. § 3486(c). In taking this course, the Department not only forum-shopped but also displayed a "blatant disregard for the proper course of negotiations." Add.5. And it "misrepresented and withheld" salient information from both the Texas court and the District Court below. Add.4.

As the Department continues to shoehorn litigation into the Texas court, multiple other courts have denounced its tactics. And so the Department has begun to pivot away from its infirm HIPAA subpoenas

in favor of grand jury subpoenas calling for nearly identical records and issued from the Northern District of Texas—a maneuver one court has called out as "minimiz[ing] judicial review of constitutional infirmities." Transcript of Teleconference Decision at 8, *Coe v. Blanche*, No. 26-cv-4641 (S.D.N.Y. June 24, 2026) (docketed at *Z.A. v. Blanche*, No. 26-cv-4998 (N.D. Cal. June 26, 2026), Dkt. 89), *appeal pending*, No. 26-1886 (2d Cir.); *see Z.A.*, No. 26-cv-4998, 2026 WL 1907181, at *17 (N.D. Cal. July 2, 2026), *appeal pending*, No. 26-4388 (9th Cir.) ("The unavoidable conclusion is that DOJ issued its grand jury subpoena to avoid another loss and force Packard and its patients to pursue any challenge to DOJ's demands in a forum that DOJ deems friendlier."). This aggressive forum (and judge) shopping confirms the Administration's departure from regularity and its associated bad faith. *See* Add.26.

In sum, the record reflects the Department's bad faith and improper motive in issuing the subpoena to RIH and pursuing its enforcement in Texas.

C. The District Court properly examined the Department's motives.

The Department advances three objections to the District Court's conclusions. First, the Department protests that the court wrongly

analyzed substantive liability questions. Second, the Department contends that the court's improper-purpose finding is fatally flawed because a subpoena can withstand challenge so long as the Department's *sole* purpose is not improper. Third, the Department argues that the Administration's desire to end gender-affirming care cannot constitute an improper purpose. These arguments fail.

1. The court correctly assessed statutory questions.

The Department stresses that a subpoena should survive review "if the agency's assertion of investigative 'authority is not obviously apocryphal,'" arguing that the District Court's motive inquiry went too far. Opening Br. 29 (quoting *Sturm*, 84 F.3d at 5). It is the Department that takes this rule too far.

To be sure, the court's function at the subpoena enforcement stage "is not to test the final merits" of a potential criminal prosecution. *Sugarloaf Funding, LLC v. U.S. Dep't of the Treasury*, 584 F.3d 340, 347 (1st Cir. 2009). For that reason, the court should not examine fact-bound questions about "the application and coverage of the federal . . . laws before responding to subpoenas designed to produce the very information that may be needed to shed light upon those questions." *SEC v. Howatt*,

525 F.2d 226, 229-30 (1st Cir. 1975). Those fact-intensive questions—i.e., whether someone engaged in conduct to which criminal liability would attach—must await any subsequent criminal prosecution. Thus, just as a court enforcing an SEC subpoena need not decide whether securities laws ultimately cover transactions under investigation, *see id.*, no court here needed to decide whether the facts ultimately would establish misbranding.

But legal questions about a statute's scope and an agency's resulting authority are fair game. *See EEOC v. Karuk Tribe Hous. Auth.*, 260 F.3d 1071, 1077 (9th Cir. 2001) (distinguishing impermissible "factual challenges based on a lack of statutory 'coverage'" from permissible challenges over "whether an agency has regulatory jurisdiction"). Otherwise, the congressional-authorization requirement would be a nullity: the government could bootstrap investigatory jurisdiction over any target by citing any statute and defer any meaningful degree of scrutiny to a prosecution it need never bring.

And in leaning so heavily on the "obviously apocryphal" standard, the Department omits that a reviewing court must *also* examine its motive as part of the follow-on abuse-of-process inquiry, separate from

the congressional-authorization analysis. *See United States v. Am. Target Advert., Inc.*, 257 F.3d 348, 354 (4th Cir. 2001) ("[R]egardless of whether the [agency] would ordinarily possess the authority to investigate potential violations" of a statute, "it has no authority to exercise its investigative prerogative as a tool of intimidation and harassment."). A weak investigatory purpose, even if literally within statutory bounds, is relevant to that analysis.

Here, the District Court acted well within its authority when inquiring into the motives behind the Department's subpoena. Although judicial review should be expeditious and focused, the court's role is "neither minor nor ministerial." *FTC v. Texaco, Inc.*, 555 F.2d 862, 872 (D.C. Cir. 1977) (en banc) (quoting *Okla. Press*, 327 U.S. at 217 n.57). The proceedings are designed to be "summary" in that discovery is not warranted upon a mere allegation of improper purpose; the challenger must first "introduce some evidence" to that effect. *Sylvestre v. United States*, 978 F.2d 25, 28 (1st Cir. 1992) (per curiam); *see United States v. Comley*, 890 F.2d 539, 542-43 (1st Cir. 1989); *Clarke*, 573 U.S. at 254-55. Still, courts must "ensure" that the government "is using its broad authority in good faith and in compliance with the law." *Gertner*, 65 F.3d

at 966. A court properly "intrude[s] into the investigative agency's function" when there is "firm evidence of bad faith." *Comley*, 890 F.2d at 543 (quotation omitted).

Without such review, the Executive Branch would "virtually exercise judicial powers by issuing subpoenas that are automatically enforced by the courts." *United States v. Trs. of Bos. Coll.*, 718 F.3d 13, 23 (1st Cir. 2013). This Court should reject the Department's invitation to engage in "[s]uch subservience." *Id.*

2. Abuse of process may involve a primary improper purpose.

The Department next urges that quashal "is only warranted when the 'sole purpose' is an improper one," claiming that the District Court necessarily erred by rejecting its asserted statutory basis, however slight. Opening Br. 39 (quoting *Gertner*, 65 F.3d at 970). This argument also fails.

To start, even if the Department's "sole purpose" must be improper, the District Court correctly concluded that it was. Add.21-22. Given the inadequacy of the Department's various misbranding theories, all based on the lawful conduct of off-label prescribing, the court concluded that no "legitimate FDCA investigation" exists to "immunize" the Department's

"coercive investigation." *Id.* With the sole exception of the Texas court—the only court not to entertain argument from any opposing party—every federal court to have examined these subpoenas has agreed that these subpoenas are abusive and improper. The Department's unfounded disagreement with that near-unanimous judicial evaluation of the facts offers no reason to reverse.

And in any event, the Department is wrong on the law. Abuse of process occurs when one "uses a legal process . . . against another *primarily* to accomplish a purpose for which it is not designed." Restatement (Second) of Torts § 682 (A.L.I. 1977) (emphasis added). An "incidental" improper purpose is not sufficient for abuse of process, but a "primary" improper purpose is. *Vahlsing v. Com. Union Ins. Co.*, 928 F.2d 486, 490 (1st Cir. 1991); Opening Br. 39-40. This is the same "primary purpose" standard that applies to grand jury proceedings. *United States v. Flemmi*, 245 F.3d 24, 28 (1st Cir. 2001); *see In re Grand Jury Subpoenas Nos. [Redacted] & [Redacted]*, 823 F. Supp. 3d 1, 8 (D.D.C. 2026) (collecting cases across circuits that assess the "primary" or "dominant" purpose); *Okla. Press*, 327 U.S. at 216 (stating that the government's "investigative function" in issuing administrative

subpoenas is "essentially the same as the grand jury's . . . and governed by the same limitations").

The Department's "improper purpose" does not "simply 'fall[] away'" if it can invoke any semblance of congressional authorization (and, of course, it fails to do so here). Opening Br. 40, 46 (quoting *In re R.I. Hosp.*, 177 F.4th at 26 (Dunlap, J., concurring)). None of the Department's cited authorities support that rule.

In *Gertner*, this Court observed that successful challengers produced enough evidence to show that the government's "sole purpose" in pursuing certain IRS summonses was improper. 65 F.3d at 963. But nothing in that opinion suggests that "sole purpose" is a necessary condition, as opposed to a sufficient one. Indeed, this Court has never since cited *Gertner* for the rule the Department attempts to derive from it.

Donaldson v. United States and its progeny are also inapt. In *Donaldson*, the Supreme Court addressed an IRS summons where the investigation was "likely to lead to civil liability as well as to criminal prosecution." 400 U.S. at 532. Against a challenge arguing that the IRS summons "may not be used at all in aid of an investigation that has the

potentiality of resulting" in criminal prosecution, the Court clarified that only where "the *sole objective* of the investigation is to obtain evidence for use in a criminal prosecution, the purpose is not a legitimate one and enforcement may be denied." *Id.* at 533 (emphasis added). The dual purpose of pursuing civil and criminal liability was permissible because "Congress has created a law enforcement system in which criminal and civil elements are inherently intertwined." *United States v. LaSalle Nat'l Bank*, 437 U.S. 298, 309 (1978).

Donaldson's rule that an IRS investigation is improper if "solely criminal in nature" is unique to that context. *Id.* at 314; *see Copp v. United States*, 968 F.2d 1435, 1436 (1st Cir. 1992); *Lynn v. Biderman*, 536 F.2d 820, 824 & n.3 (9th Cir. 1976). The "sole criminal purpose defense" is not implicated here, where HIPAA only justifies subpoenas related to criminal investigations. *Copp*, 968 F.2d at 1437. Instead, the ordinary "primary purpose" analysis applies. Restatement (Second) of Torts § 682.

The Department's "sole purpose" rule also conflicts with the burden-shifting framework that governs in the administrative subpoena context. The Department "first must make a prima facie showing" of

validity, including by showing "that the investigation will be conducted pursuant to a legitimate purpose." *Sugarloaf*, 584 F.3d at 345. Once the Department makes that "minimal showing," "the burden shifts to the [challenger] to disprove one or more of the *Powell* requirements, *or* to show that enforcement would be an abuse of process," including that the subpoena "was issued in bad faith for an improper purpose." *Id.* at 346 (emphasis added); *see United States v. Powell*, 379 U.S. 48, 58 (1964).

That is, the subpoena recipient may avoid enforcement by disproving the Department's statutory purpose or by otherwise showing abuse of process. The inquiry into purpose does not end merely because the Department has established that its investigation could fall within statutory bounds. *See Comley*, 890 F.2d at 542 (evaluating whether the agency was truly motivated by "some sort of vendetta" even after concluding that the agency adequately showed a proper congressional purpose).

3. Suppressing gender-affirming care is not a proper purpose.

The Department's last effort is to fight the premise. It asserts that its "policy preferences"—by which it means its desire to end gender-affirming care—are not an improper purpose. Opening Br. 40. Not so.

The Department is using criminal legal process to pressure hospitals to yield to the Administration's policy preferences. That is precisely the kind of harassing, improper purpose that *Powell* condemns. *See* 379 U.S. at 58. Harassment and intimidation do not become permissible just because they further an Administration's policy preferences.

And recognizing this improper purpose does not amount to "immunizing illegal conduct." Opening Br. 42. The Department may, as always, investigate potential crimes in good faith and set its own enforcement priorities. It must simply ensure it has (1) legitimate statutory authorization and (2) no overriding improper purpose. The Department's "prioritization" here does not meet these requirements, because it is an effort to misuse the FDCA to bully hospital systems out of providing lawful medical care.

III. The subpoena is unreasonably broad and burdensome.

Apart from its illegitimate purpose, the Department's subpoena suffers from another fatal flaw: unreasonable scope. This Court may affirm on this alternative ground. *See Cosenza*, 120 F.4th at 38.

Reasonableness in administrative subpoenas requires "specification of documents to be produced" that are "adequate, but not

excessive, for the purposes of the relevant inquiry." *Okla. Press*, 327 U.S. at 209; *see United States v. Morton Salt Co.*, 338 U.S. 632, 652-53 (1950). And "because the court [is] given the duty of reviewing the agency's decision to issue a subpoena, it [does] not simply have to accept the agency's opinion as to what is and is not relevant to agency investigations." *Doe*, 253 F.3d at 267. Courts "weigh the likely relevance of the requested material to the investigation against the burden of producing the material." *Id.*

Overbreadth is an independent basis for quashing a subpoena. *See Okla. Press*, 327 U.S. at 209. Yet the Department's opening brief omits any argument regarding the overall reasonableness of its subpoena's scope—seemingly ignoring that the reasonableness requirement exists. It is a curious approach given that multiple courts have held the subpoenas unlawful on that basis. *See supra* n.4.

The Department cannot show reasonableness. To start, the Department's request for "[c]omplete personnel files" of all hospital personnel engaged in management, prescribing and treating, or billing extends far beyond a reasonable scope. JA66. This request includes no tailoring to personnel involved in gender-affirming care, let alone

tailoring to employees "in any position to witness any off-label use." *In re Dep't of Just. Admin. Subpoena*, 2026 WL 33398, at *7. The request therefore does not "correspond[] with the FDCA investigation that [the Department's] investigation supposedly targeted." *Id.*

The requests for billing, coding, and insurance claims documents, as well as communications with others in the distribution chain, are likewise unreasonably overbroad. They extend to documents and communications "regarding the treatment of gender dysphoria" and gender-related care generally, not just off-label use of prescription drugs. *QueerDoc*, 807 F. Supp. 3d at 1304; *see In re Admin. Subpoena No. 25-1431-019,* 800 F. Supp. 3d at 238; *In re Dep't of Just. Admin. Subpoena No. 25-1431-030*, 2026 WL 33398, at *4.

Moreover, the Department "already has in its possession . . . documents it seeks through the subpoena," another consideration cutting against reasonableness. *Doe*, 253 F.3d at 271; *see Freedom Church*, 613 F.2d at 322. Citing "insurance claims data, billing records, and other lawfully obtained material," the Department claims it has analyzed diagnoses at RIH. JA100-01. Yet the Department has not limited its subpoena to exclude these records it already possesses.

The Department's request for highly sensitive patient data is the most unreasonable aspect of its subpoena. There is no dispute that RIH engages in gender-affirming care through off-label prescriptions. Collecting private medical records to confirm that practice is thus unnecessary. The subpoena casts a dragnet over all patient data associated with any prescription of puberty blockers or hormone therapy, capturing much more than could possibly be useful for investigating misbranding in the distribution chain. These documents are simply "ancillary and unimportant" to any misbranding investigation. *Doe*, 253 F.3d at 268. By seeking them, the Department seeks to invade RIH's patient-provider relationships, rather than further any legitimate investigatory purpose.

The strong privacy interests of both RIH and its patients confirm the overbreadth and burdensomeness of this demand. In balancing burden and need, courts impose a heightened showing of need when a subpoena seeks personal records. *See In re Gimbel*, 77 F.3d 593, 596 (2d Cir. 1996). While the "[r]equirements for enforcement of an administrative subpoena are not onerous," that generalization weakens when a case "raise[s] . . . concerns" regarding personal records. *Sturm*,

84 F.3d at 4 (citing *In re Gimbel*, 77 F.3d at 596-600). For instance, more exacting scrutiny applies to personal records than "corporate documents." *Id.*

Whatever relevance patient records may have to the Department's sham investigation is far outweighed by the burden such production would place on RIH and its patients. During treatment, patients share deeply sensitive information, including intimate details about their lives and bodies. That information can encompass mental health, sexual health, fertility, relationships, family medical history, and other personal matters. JA235; *see U.S. Dep't of Just. v. Ricco Jonas*, 24 F.4th 718, 736 (1st Cir. 2022). Maintaining patient trust through confidentiality is essential to physician-patient relationships at RIH. JA231-32, 236.

The Department identifies two cases involving the production of patient records in response to a subpoena. Opening Br. 32. But the Department's own cited authority confirms that reasonableness "cannot always be determined in the abstract," and is "variable in relation to the nature, purposes and scope of the inquiry." *In re Subpoena Duces Tecum*, 228 F.3d at 350. If the Department suspects fraud involving each patient, that suspicion could justify reviewing all patient files. *See id.*

But even in the case involving that fact pattern, the subpoena was saved from "overbreadth and oppressiveness" because the court offered to let the subpoena recipient retain patient files "subject to the call of the U.S. Attorney expressing a 'need to review particular patient files.'" *Id.* at 350-51.[15]

Here, although the Department has not identified any similarly broad-ranging suspicion, RIH has received no accommodation to save the subpoena from the unreasonableness of "the sheer volume of documents, the substantial expense incurred for their reproduction, and the disruption" to its business. *Id.* at 350. The Department has not attempted to limit patient-file requests to those containing alleged billing or coding irregularities. *See Doe*, 253 F.3d at 271.

As to patient-identifying information, the Department's demand is especially unreasonable and unnecessary. The Department told the

[15] The only appellate decision the Department cites to support its demand for patient records is the Sixth Circuit's decision in *Doe v. United States*, 253 F.3d at 265. *See* Opening Br. 32. There, the challenger "no longer dispute[d] the reasonableness of the government's request for patient documents," so the court did not address the issue. *Doe*, 253 F.3d at 265. The court did affirm the approach of "balancing the likely relevance of documents against the burden of their production," a weighing that the Department does not endeavor to undertake here. *Id.* at 268.

Texas district court that this identifying information could round up patients and parents as "essential investigative leads." JA104. The Department does not press that concept of necessity any longer, likely given its concession that it accepted anonymized records in other cases and would accept them from RIH. JA447-48, 491; *see* Opening Br. 31-32. The subpoena is clearly overbroad in at least this respect.

IV. The District Court properly quashed the subpoena and enjoined the Department.

The Department last objects to the relief entered by the District Court. The court quashed the subpoena in full and enjoined the Department from "seeking, receiving, using, retaining, or disseminating any patient-identifying information or protected health information produced by RIH." Add.52. That relief is appropriate.

To begin with, the Department is wrong that the injunctive relief somehow "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." Opening Br. 48. Federal courts "may issue all writs necessary *or appropriate* in aid of their respective jurisdictions." 28 U.S.C. § 1651(a) (emphasis added). The District Court issued injunctive relief as an additional protective measure on top of full

quashal, and in response to the parties' requests. The Child Advocate requested injunctive relief "to enjoin the Government from taking any actions to enforce the subpoena elsewhere," and RIH sought an injunction on similar grounds. JA360, 503. Granting those requests was not an implied acknowledgment that quashal was insufficient.

The Department's assertion that the District Court "fail[ed] to engage" with "the four-factor test the Supreme Court has established for permanent injunctive relief" is likewise baseless. Opening Br. 48. Although the District Court did not expressly cite the four-factor framework, the Department identifies no authority requiring that incantation. "Every order granting an injunction" must simply "state the reasons why it issued"; "state its terms specifically"; and "describe in reasonable detail . . . the act or acts restrained or required." Fed. R. Civ. P. 65(d)(1). The District Court's order meets those requirements and addresses the substance of each consideration.[16]

[16] As the Department concedes, any error in this regard would at most warrant vacatur and remand "so that the District Court may apply that framework in the first instance." *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388, 394 (2006); *see* Opening Br. 49.

The Department's objection that the court mistakenly applied the standard for "preliminary, not permanent, injunctive relief" is likewise unfounded. Opening Br. 49. The District Court couched certain findings on the collateral-attack doctrine in terms of likelihood—i.e., stating that the collateral-attack doctrine "likely . . . does not bar RIH's intervention." Add.15; *see* Add.12. That is because the District Court reasoned that the circumstances of this case did not clearly implicate the collateral-attack doctrine, making firm conclusions unnecessary. *See* Add.12. The District Court also found that irreparable harm to minor patients was "likely," Add.24, but that statement simply reflects that an injunction may issue to prevent impending harm. None of this language suggests that the District Court somehow applied an incorrect standard.

The Department also contends that relief should be "narrowed to apply only to those portions of the subpoena as to which the [Child] Advocate has standing." Opening Br. 47. But RIH undisputedly has standing to challenge the Department's entire demand for its own documents.[17] RIH's standing is sufficient to support the scope of the

[17] RIH asserts its standing to protect the records in its custody without prejudice to the Child Advocate's standing to assert the interests of the children she represents.

District Court's remedy. *See Town of Chester v. Laroe Ests., Inc.*, 581 U.S. 433, 439 (2017).

CONCLUSION

For these reasons, this Court should affirm.

Dated: July 17, 2026

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on July 17, 2026, the foregoing was filed with the Clerk of the United States Court of Appeals for the First Circuit using the appellate CM/ECF system, which will automatically serve all counsel of record electronically.

/s/ Eric G. Olshan
Eric G. Olshan

CERTIFICATE OF COMPLIANCE

This brief complies with Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 12,901 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

This brief complies with the typeface and type-style requirements of Fed. R. App. P. 32(a)(5) and 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word, in 14-point Century Schoolbook font.

/s/ Eric G. Olshan
Eric G. Olshan

ADDENDUM

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District Court Docket

Federal Statutes

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF RHODE ISLAND

In Re: Administrative Subpoena 25-1431-032 to Rhode Island Hospital	Misc. Action 1:26-mc-00007-MSM-AEM

GOVERNMENT'S RESPONSE IN OPPOSITION

Less than a week ago, but over ten months after the issuance of the subpoena in question, a judge in the Northern District of Texas—the district where this criminal investigation is being conducted—ordered Rhode Island Hospital to comply with the subpoena. Rather than intervene in that existing case to seek reconsideration or review of that order, Rhode Island's Child Advocate (Child Advocate or Plaintiff) asks this Court to quash the subpoena or, in the alternative, order Rhode Island Hospital not to comply. But this Court lacks the authority to set aside the Northern District's order, and the Child Advocate lacks Article III standing to seek that relief. The Child Advocate's problems do not end there. The Child Advocate also lacks standing under the relevant statutory scheme, and her action is untimely. Beyond that, the Child Advocate's challenges to the subpoena itself are both misguided and meritless. This Court should deny the motion and dismiss the case.[1]

BACKGROUND

On July 3, 2026, the Government issued a subpoena pursuant to its 18 U.S.C. § 3486 subpoena authority to Rhode Island Hospital. Doc. 1-2. The subpoena's return date was August 7, 2025. Doc. 1-2 at 1. The Hospital chose not to move to quash the subpoena, and in fact

[1] These arguments are made in the alternative to the Government's motion to transfer filed today. Doc. 8. As a threshold issue, a stay or transfer is necessary under the "first-to-file" rule.

the statute's standing requirement. Again, this scheme makes sense. Congress coupled the subpoena authority in Section 3486 with a firm deadline: any motion to quash must be filed before the return date. That bright line was no accident. To excuse the motion's nine months of tardiness would convert a clear statutory command into an open invitation for endless obstruction—paralyzing large-scale healthcare offense investigations by patient challenges brought at will. That is not the law.

III. The Subpoena Is Valid and Enforceable

Turning to the merits, Plaintiff argues that the subpoena is unenforceable, principally because it is supposedly motivated by an improper purpose. That argument fails. The subpoena readily satisfies all the requirements for enforceability, and Plaintiff's "improper purpose" argument depends on a failure to understand that the Executive Branch can both have, express, and pursue policy goals and enforce existing federal laws. Expressing policy opposition to a particular practice or industry does not immunize that industry from compliance with existing federal law. And it is unsurprising that the Executive Branch would seek to enforce patient protection laws like the Food, Drug, and Cosmetic Act in an industry in which it has concerns about patient safety—concerns that the Supreme Court has recognized at minimum have "a rational basis." *United States v. Skrmetti*, 605 U.S. 495, 523 (2025).

a. The Subpoena Satisfies the Essential Prerequisites for a Valid Administrative Subpoena.

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. No showing of probable cause is

necessary. *See United States v. Powell*, 379 U.S. 48, 57 (1964). And in its investigation, the Department is entitled to any evidence unless it is "plainly incompetent or irrelevant to any lawful purpose" of the Department in investigating federal healthcare offenses. *Endicott Johnson Corp. v. Perkins*, 317 U.S. 501, 509 (1943).

In accord with these principles, the First Circuit has long recognized 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 to Rhode Island Hospital easily meets these minimal requirements.

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); *FTC v. Texaco, Inc.*, 555 F.2d 862, 874 (D.C. Cir. 1977) (en banc) ("[I]n the pre-complaint stage, … the relevance of the agency's subpoena requests may be measured only against the general purposes of its investigation."). 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 civil or criminal 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 Plaintiff challenges 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. Rhode Island Hospital houses a "Gender and Sexuality Program" and prescribes the drugs at issue. Doc. 1-3 at 15. The subpoena seeks information relevant to the Department's investigation in two different ways. First, the Department seeks records to determine whether Rhode Island Hospital itself may have engaged in conduct that implicates the FDCA. Second, the Department seeks records from Rhode Island Hospital 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. Doc. 1-2 at 7. 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* Doc. 1-2 at 7-8. Requests 7 through 10 seek documents related to the relationship between BCH and drug manufacturers, which can provide evidence of misbranding and fraudulent intent. Doc. 1-2 at 8. 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. Doc. 1-2 at 8–9. 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 ascertain a mismatch between the patient's diagnosis and the bill submitted to the patient's insurer. *See* Doc. 1-3 at 17–18. 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. Doc. 1-3 at 15.

Patient records may also be necessary to identify patients' adverse health outcomes, which are often significant in FDCA and other health care offenses. *See* Doc. 1-3 at 18.[4] 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. Doc. 1-3 at 18–19. Investigations of FDCA and other health care offenses thus regularly involve use of patient records. Doc. 1-3 at 3 (HIPAA subpoenas "are routinely used to obtain … medical, billing, and related information in federal healthcare offense investigations"); *see, e.g.*, *In re*

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

Subpoena Duces Tecum, 228 F.3d at 350; *Doe v. United States*, 253 F.3d 256, 265 (6th Cir. 2001) (enforcing subpoena that included "requests for the files of patients").

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 to the extent 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 341, 350 (4th Cir. 2000) ("[I]f Bailey had treated 15,000 patients over a period of seven years and all of them were reimbursed on claims he submitted, a suspicion of fraud on these claims would justify a review of Bailey's documentation of services to these patients, of the claims submitted on their behalf, and of the reimbursements collected."); *see also In re Grand Jury Subpoenas Duces Tecum Dated January 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).

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 Rhode Island Hospital, and calls for the production of nonprivileged documents relevant to the investigation within 500 miles of Rhode Island Hospital. *See* 18 U.S.C. § 3486(a)(3).

b. Plaintiff's Contrary Arguments Are Meritless.

Plaintiff argues that the requested documents are not relevant to any legitimate FDCA theory, that the Department lacks a proper purpose for the subpoena, and that patient privacy interests outweigh the government's interests in enforcing the laws regulating the distribution of pharmaceuticals. Those arguments all fail.

Plaintiff argues that the subpoena lacks a valid purpose because the Department's FDCA theories are invalid and because medical records are not relevant to the investigation. Both arguments are plainly foreclosed.

FDCA Liability. First, Plaintiff argues that the Department has not articulated a valid theory of FDCA liability that it is investigating via the challenged subpoena. That is wrong. As explained, the Department is investigating both whether manufacturers or distributors of puberty blockers and cross-sex hormones are violating the FDCA by engaging in misbranding via off-label promotion (that is, whether Rhode Island Hospital is a witness to others' FDCA violations) and whether Rhode Island Hospital itself has violated the FDCA by causing distribution of misbranded drugs.

Plaintiff never contests that manufacturers and distributors can violate the FDCA's prohibition on misbranding by promoting their drugs for off-label uses. That is all the Court needs to know to reject their argument that the Department lacks any valid FDCA theory.

(Plaintiff instead argues that some of the subpoena's requests are not relevant to that investigation, but that distinct relevance argument fails for the reasons explained below.)

Nor can the Court indulge Plaintiff's desire to litigate the possible statutory and constitutional scope of potential FDCA liability for Rhode Island Hospital in a subpoena enforcement posture. *See* Mot. at 26–33. The First Circuit and the Supreme Court alike have repeatedly made clear that subpoena enforcement or quashal proceedings are "summary in nature," *United States v. Comley*, 890 F.2d 539, 541 (1st Cir. 1989), and that courts cannot evaluate the underlying merits of a potential future enforcement action in such proceedings, *Sturm, Ruger & Co.*, 84 F.3d at 5. "[A]n agency's investigations should not be bogged down by premature challenges to its regulatory jurisdiction." *Sturm, Ruger & Co.*, 84 F.3d at 5. Were it otherwise, every subpoena recipient could seek to pre-litigate issues of potential liability or statutory coverage, which would "stop much if not all of investigation in the public interest at the threshold of inquiry." *Oklahoma Press*, 327 U.S. at 213. Other courts have repeatedly rejected the same maneuver just as emphatically. *See, e.g.*, *Swanson*, 560 F.2d at 2 (whether agency can enforce FTC Act against subpoena recipient "is not, however, the sort of dispute that ought to be settled in a subpoena enforcement proceeding," even though FTC's "regulatory jurisdiction over appellants" was "clouded"); *EEOC v. Karuk Tribe Hous. Auth.*, 260 F.3d 1071, 1076-77 (9th Cir. 2001) (a subpoena recipient "may not avoid an administrative subpoena on the ground that it has a valid defense to a potential subsequent lawsuit" and cannot raise "factual challenges based on a lack of statutory 'coverage'" of a recipient's activities); *Donovan v. Shaw*, 668 F.2d 985, 989 (8th Cir. 1982) ("[A] subpoena enforcement proceeding is not the proper forum in which to litigate the question of coverage under a particular federal statute."); *Am. Target Advert.*, 257 F.3d at 353 (evaluating underlying merits of potential future enforcement action "places the cart before the horse" and falls outside the "scope of inquiry" in subpoena-stage proceedings). That principle

dates back over 80 years to Supreme Court decisions rejecting efforts to contest subpoenas based on claims that the investigating agency lacked authority over the matter. *Oklahoma Press Pub. Co. v. Walling*, 327 U.S. 186, 213-14 (1946); *Endicott Johnson Corp. v. Perkins*, 317 U.S. 501, 508–09 (1943).

Regardless, it is at minimum not "obviously apocryphal," *Storm, Ruger, & Co.*, 84 F.3d at 5, for the government to investigate whether Rhode Island Hospital has itself engaged in any conduct that constitutes distributing or causing the distribution of an approved drug with false or misleading labeling for an unapproved use or has conspired with any manufacturer or distributor to misbrand drugs. Doc. 1-3 at 6. Rhode Island Hospital's potential FDCA liability in no way depends on physicians merely writing prescriptions for off-label use.

Relevance. Plaintiff also attempts a misbegotten relevance argument, contending that the subpoena's requests for medical records are not "narrowly tailored" to a "legitimate investigative theory." Mot. at 35.

That's not even close to right. The relevance inquiry for administrative subpoenas is "not especially constraining" and must be "generously construed." *E.E.O.C. v. Shell Oil Co.*, 466 U.S. 54, 68-69 (1983). "In the investigatory context, 'ordinary relevance' embodies a broad reading of the concept of relevance." *Trustees of Bos. College*, 718 F.3d at 24. "[T]he governing standard is not 'necessity,'" and courts "have no warrant to decide whether [an agency] could conduct the investigation just as well without" a particular request. *E.E.O.C. v. McLane Co.*, 857 F.3d 813, 816 (9th Cir. 2017). Moreover, the relevance inquiry is keyed to the *investigation*, not to the elements of the potential healthcare offense. *See United States v. Comley*, 890 F.2d 539, 542 (1st Cir. 1989) (Agency "must show that the information sought by the subpoena is relevant to the purpose of the investigation"); *NLRB v. North Bay Plumbing, Inc.*, 102 F.3d 1005, 1009 (9th Cir. 1996) ("[T]he focus is on relevancy to the investigation[.]" (quotation omitted)); *E.E.O.C. v.*

Lockheed Martin Corp., 116 F.3d 110, 113 (4th Cir. 1997) ("We determine relevancy in terms of the investigation rather than in terms of evidentiary relevance."). In other words, administrative subpoenas can and do permissibly seek information that is not relevant to any element of the offense under investigation, so long as the information advances the investigation itself. Thus, for example, subpoenas may seek information solely to inform future requests that may ultimately go to the elements of the offense under investigation. *See, e.g.*, *Lockheed Martin*, 116 F.3d at 113 (permitting subpoena that sought information to allow agency "to tailor subsequent requests to obtain the most relevant data"); *Federal Express Corp.*, 558 F.3d at 854 (enforcing broad subpoena designed to "help the [agency] craft additional information requests that may produce evidence of discriminatory treatment").

The subpoena's requests for medical records readily meet the standard for relevance. As the Department has explained already, patient medical records can reveal the scope of potential violations, permit identification of billing patterns, provide powerful evidence of intent to misbrand and to conceal violations of federal law by falsely coding diagnoses, identify adverse health outcomes that are directly relevant to prosecutions for healthcare offenses, and generate leads for further investigation.

Last, even if Plaintiff were to prevail on its relevance argument, that could lead at most to quashal of the portion of the subpoena seeking medical records and as to only the small number of people whom Plaintiff represents. Plaintiff never claims that the subpoena's other categories of requests are irrelevant, even on its mistakenly narrow conception of relevance.

c. There is no basis to quash the subpoena for improper purpose.

Plaintiff's improper-purpose arguments depend on two errors. First, Plaintiff misstates the standard governing consideration of improper purpose for administrative subpoenas. Second, Plaintiff claims that the administration's policy views amount to an improper purpose. But an

administration's policy view that particular practices or industries should be regulated or even banned cannot immunize those practices or industries from investigations into their compliance with existing federal law. Even if such policy positions could potentially be treated as establishing an improper purpose (despite the absurd consequences that would produce), there is no indication that such an "improper" purpose is the sole purpose for the subpoena, as binding precedent requires.

The Supreme Court has explained that, when called upon to enforce an administrative subpoena, a district court can ensure that "its process" is not "abused." *Powell*, 379 U.S. at 58. "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.*

Given that the improper purpose inquiry asks whether an otherwise valid subpoena seeking evidence relevant to an investigation should nevertheless be quashed or denied enforcement, the Supreme Court has recognized that the subpoena recipient bears a "heavy" burden in proving the subpoena was issued pursuant to an improper purpose. *United States v. LaSalle Nat'l Bank*, 437 U.S. 298, 316 (1978); *see United States v. Arthur Andersen & Co.*, 623 F.2d 725, 729 (1st Cir. 1980); *Comley*, 890 F.3d at 542-43 (showing of "firm evidence" required); *United States v. Gertner*, 65 F.3d 963, 967 (1st Cir. 1995) (showing of "specific allegations of bad faith" and "reasonably particularized evidence"). Quashal is only warranted when the "sole purpose" is an improper one. *Gertner*, 65 F.3d at 970; *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.* Restatement (Second) of Torts § 682 cmt. b (A.L.I. 1977), Westlaw (database updated Sep. 2025) (explaining that tort of abuse of process will not lie where there is both a legitimate motive and "an incidental motive of spite or an ulterior purpose of benefit to the defendant"); *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.").

Given this heavy burden, it is no surprise that the First Circuit and others have consistently rejected "improper purpose" claims. For example, in *Comley*, the First Circuit rejected an "improper purpose" defense when the subpoena recipient made "forceful allegations about the bad faith of certain [Nuclear Regulatory Commission] officials" uninvolved in the investigation. 890 F.2d at 543. And in *Sugarloaf Funding*, the First Circuit rejected an "improper purpose" argument based on, among other things, an alleged threat of "the imposition of severe penalties if [the subpoena recipients] did not settle" and an alleged threat to the recipients' counsel that the counsel could face a "disciplinary referral" if counsel did not provide complete responses to document requests in another case. 584 F.3d at 349–50; *see also United States v. Whispering Oaks Residential Care Facility, LLC*, 673 F.3d 813, 819 (8th Cir. 2012) (per curiam) (rejecting improper purpose argument where "no credible evidence on the record … demonstrate[d] the subpoenas were actually motivated by an improper purpose"); *United States v. Markwood*, 48 F.3d 969, 983–84 (6th Cir. 1995) (rejecting improper purpose argument and concluding that the Plaintiff's claimed "'evidence' of impropriety … [wa]s merely an assertion of impropriety, and d[id] not amount to a substantial demonstration that the government [wa]s abusing the court's process").

There is no basis for concluding that the subpoena to Rhode Island Hospital was motivated solely by an improper purpose.

1. Plaintiff focuses principally on statements expressing the Executive Branch's views opposing gender-related medical interventions for children as untested, unsafe, unnecessary, and unethical. Those policy views—which rest on a "rational basis," *United States v. Skrmetti*, 605 U.S. 495, 523 (2025)—cannot immunize entire industries or practices from scrutiny to determine if they have complied with existing federal law by establishing an improper purpose for any such investigation.

There is no dispute that the President, Attorney General Bondi, and others in the administration have expressed strong moral, ethical, and policy opposition to the practice of irreversibly altering minors' bodies as a way to address diagnoses of gender dysphoria. The administration believes these interventions are untested, unsafe, unnecessary, and unethical—concerns that are gaining traction within the medical community in the United States and abroad. *See* Admiral Brian Christine, *Evidence-Based Care for Children and Adolescents with Gender Dysphoria* ("HHS Statement"), Dep't of Health & Hum. Servs. (Dec. 18, 2025), https://health.gov/sites/oash/files/Message_Pediatric_Gender_Dysphoria_Treatment.pdf; 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 executive orders, Bondi Memo, and Shumate Memo 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 Department is simply prioritizing enforcement of federal law in an industry of special concern for policy reasons.

Plaintiff'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 further an investigation into 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). Such logic would immunize from investigation any industry or practice that an administration is opposed to as a policy matter.

By that logic, an administration that takes a position on a particular policy question necessarily renders any investigation that touches on that policy as pretextual. That logic would preclude government investigations into anything touching on gender-related treatment—from fraud on government insurance to drug adulteration—effectively immunizing illegal conduct in this space. And it would produce absurd and harmful consequences across the board. 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 Plaintiff's logic, tax or other investigatory subpoenas to sports gambling operations and related businesses could be quashed based on the administration's opposition to such gambling. Similarly, an administration that pursued or supported new legislation that would ban or limit 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.

Or consider an administration that supports new gun control measures, while heightening its enforcement of existing regulations governing firearm dealers. Applying Plaintiff's reasoning, subpoenas issued in any of those investigations would have to be quashed based on improper

purpose. The government's opposition to a particular industry or practice does not immunize that industry or practice from scrutiny to ensure that it is being carried out in a lawful manner. 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.

That is not the law. Accepting Plaintiff's argument would contravene the well-established doctrine that the Executive Branch has the power to exercise enforcement discretion in prioritizing what misconduct to investigate. "The Executive Branch—not the Judiciary—makes arrests and prosecutes offenses on behalf of the United States." *United States v. Texas*, 599 U.S. 670, 678–79 (2023). Indeed, 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).

Here, at most, Plaintiff'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 First Circuit 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.

The few statements that Plaintiff tries to stretch beyond mere policy opposition to pediatric gender-related medical interventions do no such thing, on any fair reading. For example, the public statement that the Department is "[W]orking on it" clearly referenced the previous speaker's suggestion that the Department should investigate and prosecute use of "diagnosis codes that were … fraudulent" in order to "h[o]ld accountable" providers who are breaking the healthcare fraud laws—a plainly permissible purpose. Transcript of The Dangers of "Gender-Affirming Care" for Minors, Federal Trade Commission (July 9, 2025), https://www.ftc.gov/system/files/ftc_gov/pdf/FTC-The-Dangers-of-Gender-Affirming-Care-for-Minors-Transcript.pdf. Plaintiff also misleadingly quotes a Department of Justice attorney at a hearing in another subpoena quashal action as saying that the Executive Branch's policy desire "to reduce or eliminate gender-related care to minors" is "what this investigation is about." Doc. 1 at 23 (quoting *In re Administrative Subpoena No. 25-1431-019*, No. 1:25-mc-91324 (D. Mass. Sep. 1, 2025), Doc. 30, at 25). As a review of the cited transcript reveals, in making the same argument that policy views could not provide a basis to quash a subpoena advanced here, the attorney stated twice within the same sentence that the "investigation is about" the medical treatments at issue here: "medicalized gender-related care to minors" or "medicalized gender-affirming care of minors." *In re Administrative Subpoena*, Doc. 30, at 25. That is no more than a correct description of the scope of the investigation. Similarly, Plaintiff cites a July 9 press release stating that the Department of Justice has sent subpoenas "to doctors and clinics involved in performing transgender medical procedures on children" and that the Department is investigating "healthcare fraud, false statements, and more." Press Release, U.S. Dep't of Just., *Department of Justice Subpoenas Doctors and Clinics Involved in Performing Transgender*

Medical Procedures on Children (July 9, 2025), https://perma.cc/XL8X-X7J2. In the press release, the Attorney General promised to hold individuals or entities "accountable" for "healthcare fraud, false statements," or other violations of the law. *Id.* That is a core duty of the Executive Branch, not an improper purpose for an investigation. A White House press release announcing hospitals and clinics that have stopped providing puberty blockers, hormone therapy, and sex-change surgeries to children, without reference to any subpoenas or investigations whatsoever, further illustrates Plaintiff's inability to grapple with the basic issue presented here. Nor is it at all surprising, improper, or inaccurate for the Department to refer to efforts to enforce patient protection laws like the FDCA as seeking to "protect innocent children." Mot. at 38.

Plaintiff's claim (at 37) that the Department issued subpoenas "without any particularized allegations of wrongdoing" at specific hospitals entirely mistakes the relevant burdens. Subpoenas themselves do not include a statement of their evidentiary purposes, nor are they required to do so. And even in enforcement proceedings, it is long established that administrative subpoenas permit an agency to "investigate merely on suspicion that the law is being violated, or even just because it wants assurance that it is not," in a role "analogous to the Grand Jury." *Morton Salt*, 338 U.S. at 642-43.

Finally, Plaintiff's argument makes no sense on its own terms, since the subpoenas do not and cannot "end[]" the interventions the administration opposes. 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. The Department does not contend that the act of writing a prescription for an off-label use would, in and of itself, give rise to FDCA liability. But it is beyond question that such drugs may be misbranded in violation of federal law or that a hospital could engage in fraudulent billing practices related to such drugs.

Ensuring that such violations have not occurred with respect to those drugs is plainly a legitimate purpose, and that is precisely what the Bondi and Shumate memoranda direct be investigated: potential FDCA violations "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, Bondi Memo 4, and 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," Shumate Memo 2-3.

2. At all events, even if an administration's policy views might be treated as an improper purpose, there is no basis for quashing the subpoena here. As discussed, the First Circuit has recognized that an improper purpose must be the "sole purpose" of the subpoena for quashal to be proper, *Gertner*, 65 F.3d at 970, such that the subpoena cannot be quashed based on purportedly mixed motives. For example, in the sole case of which the government is aware where the First Circuit concluded that a subpoena should be quashed based on improper purpose, the subpoena recipient demonstrated that the Internal Revenue Service had issued a subpoena purportedly to investigate the recipient law firm's compliance with the tax laws but in fact was solely interested in investigating the firm's clients, thereby circumventing statutory limits on IRS "John Doe" subpoenas. *Id.* at 965–66, 69.

Here, there is no serious doubt that the Department is in fact pursuing a real investigation, and that such an investigation is within the Department's statutory authority. It is undisputed that Rhode Island Hospital prescribes puberty-blockers and other drugs that have never been FDA-approved for treating gender dysphoria. And, as discussed further below, even if Rhode Island Hospital has not itself violated federal law, Rhode Island Hospital may have communicated with

pharmaceutical companies who have. Indeed, neither Rhode Island Hospital nor Plaintiff has ever argued that Rhode Island Hospital lacks evidence relevant to the Department's investigation. That is enough to demonstrate that the Department has a permissible purpose for the subpoena. A holding that mixed motives are sufficient for quashal would mean that no investigation—no matter how compelling the facts or indications of wrongdoing—could proceed so long as a particular administration continued to hold policy views on the relevant topic.

d. Plaintiff's privacy-based arguments fail.

Plaintiff also argues that children's privacy interests in their medical records should outweigh the government's interest in the information sought, even if the subpoena is validly issued. That mistakes governing law, too.

As the Fourth Circuit has previously concluded, "[t]he government has a compelling interest in identifying illegal activity and in deterring future misconduct," and that interest "outweighs the privacy rights of those whose [medical] records" are sought via a properly issued HIPAA subpoena, "particularly in light of the limitation placed on uses of subpoenaed information by § 3486." *In re Subpoena Duces Tecum*, 228 F.3d at 351. That is especially so because "patients have a reduced expectation of privacy in patient records," given that nearly every patient has agreed pursuant to their insurance policies and releases to allow their medical records to be reviewed." *Id*. Other courts have likewise readily concluded that HIPAA subpoenas can be used to obtain medical records—an unsurprising conclusion in the context of a statute enacted to protect patient privacy while permitting government investigations. *Doe v. United States*, 253 F.3d 256, 265 (6th Cir. 2001) (enforcing subpoena that included "requests for the files of patients").

Here, Plaintiff's claimed expectation of privacy in records is incompatible with the functional realities of modern medical practice and the disclosures that Rhode Island Hospital

Health Insurance Portability & Accountability Act of 1996

18 U.S.C. § 3486 – Administrative Subpoenas

(a) Authorization. —

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

…

(e) Limitation on Use. —

(1) Health information about an individual that is disclosed under this section may not be used in, or disclosed to any person for use in, any administrative, civil, or criminal action or investigation directed against the individual who is the subject of the information unless the action or investigation arises out of and is directly related to receipt of health care or payment for health care or action involving a fraudulent claim related to health; or if authorized by an appropriate order of a court of competent jurisdiction, granted after application showing good cause therefor.

(2) In assessing good cause, the court shall weigh the public interest and the need for disclosure against the injury to the patient, to the physician-patient relationship, and to the treatment services.

Upon the granting of such order, the court, in determining the extent to which any disclosure of all or any part of any record is necessary, shall impose appropriate safeguards against unauthorized disclosure.

Federal Food, Drug, and Cosmetic Act

21 U.S.C. § 321 – Definitions; generally

For the purposes of this chapter—

(m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

Federal Food, Drug, and Cosmetic Act

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

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

(2) Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of section 352 of this title, except paragraphs (a), (i)(2) and (3), (k), and (l), and the packaging requirements of paragraphs (g), (h), and (p), if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber, and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription. This exemption shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail, or to a drug dispensed in violation of paragraph (1) of this subsection.

21 C.F.R. § 201.5 Drugs; adequate directions for use.

Adequate directions for use means directions under which the layman can use a drug safely and for the purposes for which it is intended. (Section 201.128 defines "intended use.") Directions for use may be inadequate because, among other reasons, of omission, in whole or in part, or incorrect specification of:

(a) Statements of all conditions, purposes, or uses for which such drug is intended, including conditions, purposes, or uses for which it is prescribed, recommended, or suggested in its oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drug is commonly used; except that such statements shall not refer to conditions, uses, or purposes for which the drug can be safely used only under the supervision of a practitioner licensed by law and for which it is advertised solely to such practitioner.

(b) Quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions.

(c) Frequency of administration or application.

(d) Duration of administration or application.

(e) Time of administration or application (in relation to time of meals, time of onset of symptoms, or other time factors).

(f) Route or method of administration or application.

Preparation for use, i.e., shaking, dilution, adjustment of temperature, or, other manipulation or process.

21 C.F.R. § 201.100 Prescription drugs for human use.

A drug subject to the requirements of section 503(b)(1) of the act shall be exempt from section 502(f)(1) if all the following conditions are met:

(d) Any labeling, as defined in section 201(m) of the act, whether or not it is on or within a package from which the drug is to be dispensed, distributed by or on behalf of the manufacturer, packer, or distributor of the drug, that furnishes or purports to furnish information for use or which prescribes, recommends, or suggests a dosage for the use of the drug (other than dose information required by paragraph (b)(2) of this section and § 201.105(b)(2) contains:

(1) Adequate information for such use, including indications, effects, dosages, routes, methods, and frequency and duration of administration and any relevant warnings, hazards, contraindications, side effects, and precautions, under which practitioners licensed by law to administer the drug can use the drug safely and for the purposes for which it is intended, including all conditions for which it is advertised or represented; and if the article is subject to section 505 of the act, the parts of the labeling providing such information are the same in language and emphasis as labeling approved or permitted, under the provisions of section 505, and any other parts of the labeling are consistent with and not contrary to such approved or permitted labeling; and

(2) The same information concerning the ingredients of the drug as appears on the label and labeling on or within the package from which the drug is to be dispensed

(3) The information required, and in the format specified, by §§ 201.56, 201.57, and 201.80.

21 C.F.R. § 201.128 Meaning of "intended uses".

The words intended uses or words of similar import in §§ 201.5, 201.115, 201.117, 201.119, 201.120, 201.122, and 1100.5 of this chapter refer to the objective intent of the persons legally responsible for the labeling of an article (or their representatives). The intent may be shown by such persons' expressions, the design or composition of the article, or by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. Objective intent may be shown, for example, by circumstances in which the article is, with the knowledge of such persons or their representatives, offered or used for a purpose for which it is neither labeled nor advertised; provided, however, that a firm would not be regarded as intending an unapproved new use for an approved drug based solely on that firm's knowledge that such drug was being prescribed or used by health care providers for such use. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he or she received the article, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses.