Exhibit 1

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF RHODE ISLAND

In Re: Administrative Subpoena 25-1431-032 to Rhode Island Hospital	Misc. Action No. 1:26-mc-00007-MSM-AEM **EMERGENCY MOTION TO QUASH SUBPOENA DUCES TECUM** **REQUEST FOR EXPEDITED RELIEF PURSUANT TO LR CV 9**

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INTRODUCTION

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

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

BACKGROUND

I. Factual Background

A. RIH lawfully provides gender-affirming care.

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

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

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

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

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

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

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

Id. at 8.

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

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

C. RIH worked with the Government to negotiate compliance.

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

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

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

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

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

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

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

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

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

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

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

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

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

Ex. 4 at 2.

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

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

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[1] This Court may take judicial notice of the filings in this proceeding, which are attached as exhibits for reference. *Medtronic Med. CR SRL v. Feliciano-Soto*, 59 F.4th 51, 53 n.2 (1st Cir. 2023).
[2] This date is incorrect. RIH was served on July 9, 2025. Ex. 3-C.

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

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

II. Legal Background

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

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

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

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

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

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

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

LEGAL STANDARD

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

ARGUMENT

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

I. This challenge is timely.

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

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

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

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

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

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

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

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

II. The subpoena is unlawful.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

B. The Government has no proper purpose.

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

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

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

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

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

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

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

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

C. The subpoena is unduly broad and burdensome.

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

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

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

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

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

III. The Northern District of Texas's order does not prevent relief here.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CONCLUSION

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

Dated: May 9, 2026

Respectfully submitted,

/s/Stacey P. Nakasian

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CERTIFICATE OF SERVICE

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

Dated: May 9, 2026 *<u>/s/ Stacey P. Nakasian</u>*