

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF RHODE ISLAND

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

MEMORANDUM AND ORDER

Mary S. McElroy, United States District Judge.

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

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

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

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

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

I. BACKGROUND

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

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

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

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

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

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

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

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

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

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

(ECF 1-3 ¶ 46.)

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

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

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

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

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

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

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

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

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

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

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

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

II. DISCUSSION

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

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

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

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

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

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

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

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

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

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

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

application in Anglo-American jurisprudence that one is not bound by a judgment in personam in a litigation in which he is not designated as a party or to which he has not been made a party by service of process.” *Id.* at 761 (quoting *Hansberry v. Lee*, 311 U.S. 32, 40 (1940)). Thus, “[a] judgment or decree among parties to a lawsuit resolves issues as among them, but it does not conclude the rights of strangers to those proceedings.” *Id.* at 762.⁸

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

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

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

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

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

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

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

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

C. The Merits

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

1. The Subpoena Lacks A Congressionally Authorized Purpose

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

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

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

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

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

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

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

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

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

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

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

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

2. Improper Purpose

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

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

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

therefore cannot be satisfied. *See* 65 F.3d at 970. But this would require a genuine legitimate investigative purpose, not merely a legal theory, which, as described above, is not legally cognizable as applied to a prescribing hospital. To hold otherwise would allow the DOJ to immunize any coercive investigation from the improper purpose doctrine simply by appending an untenable legal theory to it.

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

3. The Fourteenth Amendment Right to Informational Privacy

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

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

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

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

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

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

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

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

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

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

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

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

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

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

III. CONCLUSION

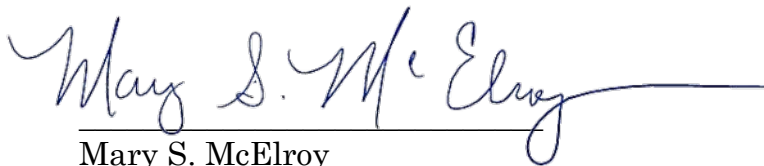
Ultimately, the Court's decision is based solely on its application of the law to the administrative subpoena at issue here. But the discrepancy between the honorable conduct expected of federal prosecutors and DOJ's tactics in this case is unsettling. The Court cannot help but share the sentiment that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

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

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

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

IT IS SO ORDERED.

A handwritten signature in blue ink, reading "Mary S. McElroy", followed by a horizontal line extending to the right.

Mary S. McElroy
United States District Judge

May 14, 2026