UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

In Re: Administrative Subpoena No. 25-1431-014	Misc. Action No. 2:25-mc-00054-MAK

REPLY IN SUPPORT OF
MOTION TO QUASH SUBPOENA DUCES TECUM

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The Subpoena served on Children's Hospital of Philadelphia is what it appears to be—an unapologetic effort by the Administration to end gender-affirming care by threatening medical institutions and doctors with prosecution and invading the privacy of children. It should be quashed.

ARGUMENT

I. Movants Have Standing to Move to Quash the Subpoena

"[T]o have Article III standing, a litigant invoking the power of a federal court must plausibly allege (i) an injury-in-fact (ii) that is fairly traceable to the conduct of the party sued, and (iii) that is judicially redressable." *Lutter v. JNESO*, 86 F.4th 111, 124 (3d Cir. 2023).[1] For that reason, courts routinely find that a third party seeking to quash a subpoena has standing to do so when they have a "sufficiently important, legally-cognizable interest[ ] in the materials or testimony sought." *In re Grand Jury*, 111 F.3d 1066, 1073 (3d Cir. 1997) (collecting cases); *In re Grand Jury Matter*, 802 F.2d 96, 98 (3d Cir. 1986); *United States v. Lazar*, No. 04-20017-DV, 2006 WL 3761803, at *6 (W.D. Tenn. Dec. 20, 2006) ("Defendant has standing to challenge whether the government exceeded the scope of § 3486 in issuing subpoenas post-indictment to hospitals in order to obtain records of hospital peer-review committees.").

[1] This Court, with jurisdiction under 28 U.S.C. § 1331, has various bases on which to entertain this motion. *See Free Enter. Fund v. Pub. Co. Acct. Oversight Bd.*, 561 U.S. 477, 491 n.2 (2010) ("equitable relief has long been recognized as the proper means for preventing entities from acting unconstitutionally") (citation modified); Fed. R. Civ. P. 81 ("These rules apply to proceedings to compel . . . the production of documents through a subpoena issued by a United States officer or agency"); Fed. R. Civ. P. 45(3) (proceedings to quash subpoena).

Movants, whose constitutional privacy interests the government seeks to invade and whose medical care the government seeks to eliminate, easily meet this test: They "would be injured in fact by further invasion of their privacy from disclosure . . . [, t]he cause[ ] of this injury [is] the subpoena . . . , and the injury is redressable by quashing the subpoena." *In re Grand Jury*, 111 F.3d at 1071. Practical realities may *also* allow the party served with a subpoena to assert underlying interests of a third party in the material summoned. *See United States v. Westinghouse Elec. Corp.*, 638 F.2d 570, 574 (3d Cir. 1980) (employer can raise claim for employees); *see also In re Search Warrant (Sealed)*, 810 F.2d 67, 71 (3d Cir. 1987) (allowing physician to raise claim for privacy rights of patients.). But that standing is additive, not a replacement for the ability of citizens to vindicate their own rights. *See Westinghouse*, 638 F.2d at 581 (providing employees an opportunity to object even after employer raised objections to the subpoena served upon it).

DOJ now posits that HIPAA subpoenas are different; that by providing that "the person or entity summoned may . . . petition for an order modifying or setting aside the summons," 18 U.S.C. § 3486(a)(5), Congress evinced an intent to deprive citizens of the right to protect their own privacy, no matter the scale of intrusion. DOJ Br. 4-8, Dkt. No. 16. In other words, it "argues that the provision of one mechanism for judicial review, at the behest of parties other than those whose privacy may be compromised by the seizure, impliedly precludes review" by those with privacy interests at stake. *Am. C.L. Union v. Clapper*, 785 F.3d 787, 804 (2d Cir. 2015).

"[W]here Congress intends to preclude judicial review of constitutional claims its intent to do so must be clear." *Webster v. Doe*, 486 U.S. 592, 603 (1988). Yet DOJ has the history of the statute wrong and Congress' intent backward: Congress intended to protect citizens from subpoena abuses—regarding healthcare or the other regimes that use section 3486—not make citizens dependent on the benevolence of a third party to assert their rights.

When HIPAA was enacted, it remained silent on the contours of a statutory right to quash a subpoena. *See* Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, § 248, 110 Stat. 1936, 2018-19 (1996). Then in 2000, Congress consolidated multiple administrative subpoena provisions from differing statutes into section 3486 and added in additional protections. *See* Presidential Threat Protection Act of 2000, Pub. L. No. 106-544, § 5(a), 114 Stat. 2715, 2716-18 (2000). First, through section 3486(a)(5), it conferred the same practical standing to subjects of the subpoenas that the Third Circuit already bestowed in other circumstances. *See id.* And second, in section 3486(a)(7), it expressly adopted general norms and standards for existing subpoena enforcement, prohibiting "the production of anything that would be protected from production under the standards applicable to a subpoena duces tecum issued by a court of the United States." Pub. L. No. 106-544, § 5(a). In other words, the amendment ensured that the law's administrative subpoenas accorded with general principles of oversight and discovery in federal courts, while also recognizing that institutions might be in the best position to make challenges to them.

Congress repeatedly made plain that the purpose of these amendments was: to "give citizens *added protections* against misuse of these subpoenas." H.R. REP. No. 106-669, at 6-7 (2000) (emphasis added).[2] Congress was "mak[ing] explicit that any summons issued under the section is not to be construed to require the production of anything that would be protected from production under the standards applicable to a subpoena duces tecum issued by a United States court. Simply stated, the committee intends that administrative subpoenas do not have any greater scope than would a subpoena issued by a United States court." *Id.* at 12-13. The goal was clear:

[2] "Legislative history can play a confirmatory role in resolving ambiguity when statutory language and structure support a given interpretation." *G.L. v. Ligonier Valley Sch. Dist. Auth.*, 802 F.3d 601, 621-22 (3d Cir. 2015).

"to protect the rights of citizens." *Id.* at 12; *see also* 146 CONG. REC. S10546-01, at S10547 (daily ed. Oct. 13, 2000) (speech of Sen. Patrick Leahy prior to passage describing same). Contrary to DOJ's characterization, legislation designed to protect the rights of citizens does not evince a clear intent to reduce their rights instead.

Finally, standing is also conferred upon third parties to challenge subpoenas that injure them and which were, like this one, allegedly issued in bad faith. *In re Grand Jury*, 619 F.2d 1022, 1025-27 (3d Cir. 1980). It's no secret, nor is it "political rhetoric," DOJ Br. 22, that DOJ is using these subpoenas to end gender-affirming care in states like Pennsylvania where it remains legal. They admit that purpose while they celebrate that it is working. *See* § IV, *infra*. Movants, patients who were receiving this recognized, legal care, are injured by DOJ's issuance of this subpoena. Under Article III they have standing to redress that injury in this proceeding.

II. Sovereign Immunity Provides No Shield to the Government's Incursion

DOJ's argument that "sovereign immunity principles" foreclose the Motion is baseless. The Third Circuit has recognized for more than forty years that, where a party seeks non-monetary relief, the Administrative Procedures Act ("APA") waives sovereign immunity. *Jaffee v. United States*, 592 F.2d 712, 719 (3d Cir. 1979) (although plaintiff's "claim for medical care is an action for money damages," his "claim for warning . . . is equitable," and therefore falls within the non-monetary relief exception of Section 702 of the APA); *see also Johnson v. Folio*, 528 F. Supp. 2d 548, 550 (E.D. Pa. 2007) ("[C]ourts have concluded that the APA waives sovereign immunity when the relief sought from the federal government is other than monetary relief[.]" (citations omitted)). This waiver is not limited to claims under the APA itself. *See Treasurer of N.J. v. U.S. Dep't of Treasury*, 684 F.3d 382, 399 (3d Cir. 2012) ("the waiver of sovereign immunity contained in § 702 is not limited to suits brought under the APA" (citation omitted)); *accord Gillette v.*

Warden Golden Grove Adult Corr. Facility, 109 F.4th 145, 154 (3d Cir. 2024) ("[T]he United States waives its sovereign immunity in non-monetary actions in federal court." (citation omitted)).

DOJ does not cite any law to the contrary. In fact, in four out of the five cases the DOJ cites, the party opposing the government sought monetary damages. *See Bah v. United States*, 91 F.4th 116, 122 (3d Cir. 2024); *Lane v. Peña*, 518 U.S. 187, 189 (1996); *F.D.I.C. v. Meyer*, 510 U.S. 471, 474, 486 (1994); *United States v. Mitchell*, 445 U.S. 535, 536 (1980). And in the fifth case, *Ponsford v. United States*, the Ninth Circuit merely affirmed a district court's refusal to quash five Internal Revenue Service summonses where a taxpayer was provided notice of a subpoena and a statutory process for quashing it, but failed to do so within the time frames the statute required. 771 F.2d 1305, 1309 (9th Cir. 1985). Sovereign immunity does not bar the Motion.

III. Movants Are Not Time-Barred from Challenging a Stayed Subpoena They Were Never Served

DOJ argues that Movants are out of time to quash a Subpoena that they were never served. They are wrong. To start, DOJ erroneously presumes Movants' rights are proscribed by an alleged jurisdictional limit in section 3486. *See* § I, *supra*. Even if that were true, the cases DOJ cites each have something that is missing from this matter: service. *See, e.g., Ponsford*, 771 F.2d at 1309 (service presumed); *Sarnowski v. United States*, No. 05-242, 2006 WL 2172615, at *2 (W.D. Pa. July 31, 2006) (service provided).

Here, with no statutory limit, no service, and a stayed return date, the Court's considerations are practical, not jurisdictional, and "district courts have broad discretion to consider untimely motions to quash where good cause or compelling reasons exist." *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."). In such circumstances, courts will

consider whether a moving party is "acting in good faith," *Concord Boat Corp. v. Brunswick Corp.*, 169 F.R.D. 44, 48 (S.D.N.Y 1996), and whether any delay has caused prejudice, *Michalski*, 2025 WL 2108202, at *2. The good faith of Movants, who were not served with the underlying Subpoena, is not in dispute. With the return date on the Subpoena stayed, neither is a lack of prejudice to the Department of Justice, who is litigating these very issues before this Court. Movants' motion is not time-barred.

IV. DOJ's Declaration Provides No Cover for its Bad Faith

Subpoenas are issued in bad faith when they are used "to put pressure on [a recipient] to settle a collateral dispute," *United States v. Powell*, 379 U.S. 48, 58 (1964), when an agency "is knowingly pursuing frivolous allegations in bad faith" or when an agency is "motivated by . . . animus." *Sec. & Exch. Comm'n v. Wheeling-Pittsburgh Steel Corp.*, 648 F.2d 118, 129 (3d Cir. 1981). DOJ's arguments here, which involve tortured justifications to support a supposed FDCA investigation centered around off-label prescriptions, *see, e.g.*, DOJ Br. 2-3, defies positions previously taken by DOJ, including its Office of Legal Counsel ("OLC"), and well-established precedent.

DOJ goes to great lengths to cast this Subpoena and the underlying investigation as routine and typical, DOJ Br. 2; Hsiao Decl. ¶ 10, Dkt. No. 16-1, when it's in fact an extraordinary attempt to use the FDCA to regulate, and indeed criminalize, the practice of medicine. Gender-affirming care is legal in Pennsylvania. So are the doctors' off-label prescription, administration, and use of puberty blockers and cross-sex hormones for this care: "[O]nce the FDA approves a drug, healthcare providers generally may prescribe the drug for an unapproved use when they judge that it is medically appropriate for their patient." *Understanding Unapproved Use of Approved Drugs "Off Label,"* FOOD AND DRUG ADMIN. (Feb. 5, 2018), https://www.fda.gov/patients/learn-about-

expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label.[3] The off-label use of medical devices "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 v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001). The FDCA expressly states that it does not interfere with the authority of a medical provider to "prescribe or administer any legally marketed device to any patient for any condition or disease within a legitimate health care practitioner-patient relationship." *Id.*; 21 U.S.C. § 396.

OLC is fully aligned, stating that the "FDA does not regulate the practice of medicine, which includes 'off-label' prescribing." Steven A. Engel, *Whether the Food and Drug Administration Has Jurisdiction over Articles Intended for Use in Lawful Executions,* 43 OP. O.L.C. 81, 85 (2019).[4] "[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." *Id.* (emphasis added).[5] DOJ

[3] 2011 FDA guidance regarding unsolicited requests for off-label information notes: "[O]nce a drug or medical device has been approved or cleared by FDA, generally, health care professionals can lawfully use or prescribe that product for uses or treatment indications that are not included in the product's approved labeling . . . the FDA recognizes that these off-label uses . . . may even constitute a medically recognized standard of care." FOOD & DRUG ADMIN, DRAFT GUIDANCE FOR INDUSTRY ON RESPONDING TO UNSOLICITED REQUESTS FOR OFF-LABEL INFORMATION ABOUT PRESCRIPTION DRUGS AND MEDICAL DEVICES, 2 (Dec. 2011), https://www.fda.gov/media/82660/download (announced at 76 Fed. Reg. 82303, 82303-04 (Dec. 30, 2011)).

[4] "Memoranda issued by the OLC, including this one, are binding on the Department of Justice and other Executive Branch agencies and represent the official position of those arms of government." *Tenaska Washington Partners II, L.P. v. U.S.,* 34 Fed. Cl. 434, 439 (1995).

[5] DOJ tacitly concedes the entire enterprise, noting that a physician may "prescribe an approved drug for an unapproved use without violating the FDCA." *See* Hsiao Decl. ¶. 12, n.1. But it never reconciles the contradictions between the Hsiao Declaration and OLC's opinion. For example, OLC's opinion states that the practice of medicine, which the FDA does not regulate, includes both prescribing and administering medicine. 43 OP. O.L.C. at 85. The Hsiao Declaration, meanwhile, suggests "administering" medicine is "distribution," and thus is now under DOJ's purview. Hsiao Decl. ¶ 23. The Declaration also suggests that doctors prescribing off-label is

made this same representation to the Third Circuit just six weeks ago. *Penelow v. Janssen Prods. LP*, No. 25-1818, at 8 (3d Cir. Aug. 27, 2025), Dkt. No. 56 (stating that the FDA does not regulate the practice of medicine and that once a drug "is approved for one use at one dosage, doctors are free to prescribe it for unapproved uses or at other dosages—a practice sometimes called 'off-label' prescribing." (citing *Washington Legal Found. v. Henney*, 202 F.3d 331, 332-33 (D.C. Cir. 2000)). DOJ explained, "[o]ff-label prescription of a drug can sometimes be both medically accepted and reasonable and necessary for a given patient." *Id.* at 9 (citing Fed. Reg. 4194, 4261 (Jan. 28, 2005)). And the FDA's "misbranding provisions govern how drugs may be marketed; they do not govern whether federal healthcare programs will reimburse for the drugs, as prescribed for particular patients." *Id.* at 36.

Within that framework, DOJ purportedly seeks records to investigate possible violations of the FDCA, specifically, the "distribution, promotion, and use of puberty blockers and cross-sex hormones in minors." DOJ Br. 22. But because the FDCA did not (and does not) prohibit the conduct DOJ now seeks to criminalize, DOJ attempts to justify the Subpoena by offering tortured and novel arguments that the FDCA somehow prohibits this disfavored medical care. Among other things, DOJ repeatedly obscures and confuses the differences between the legal obligations of *manufacturers* related to the approval, labeling, branding, and distribution of drugs with the *doctors* who prescribe approved drugs for off-label purposes, who the DOJ targets through the Subpoena. *Compare Understanding Unapproved Use of Approved Drugs "Off Label,"* U.S. FOOD & DRUG ADMIN. (Feb. 5, 2018), https://www.fda.gov/patients/learn-about-expanded-access-and-

"possible," and a narrow exception, whereas OLC emphasizes that the general rule is noninterference with the practice of medicine. Hsiao Decl. ¶ 12, n.1; 43 Op. O.L.C at 85.

other-treatment-options/understanding-unapproved-use-approved-drugs-label, 21 U.S. Code §§ 331, 352.

Moreover, the lack of alignment between the requested documents, the justifications, and the alleged violations DOJ is investigating speaks volumes. For example, DOJ seeks all patient records, including those to evaluate "billing and insurance claims," Hsiao Decl. ¶ 38, while not purporting to investigate violations of healthcare fraud statutes, including Sections 1035 and 1347 of Title 18. And the fact that DOJ issued identical subpoenas at virtually the same time to at least nineteen other medical institutions with slim to no evidence of any coherent violations of the FDCA is further indication that this Subpoena and the others lack substance and a proper purpose.[6]

These sorts of leaps cannot obscure reality: The Attorney General issued a memorandum beginning these investigations with a specific purpose: "bring[ing] [gender-affirming care] to an end."[7] There is a straight line from that directive to these subpoenas. As its counsel stated in related litigation, DOJ believes "it is a rational governmental objective or purpose to eliminate the medicalized gender-affirming care of minors and that's exactly what this investigation is about." Tr. of Mot. Hr'g 25:14-17, *In Re: Administrative Subpoena No. 25-1431-019*, 1:25-mc-91324 (D. Mass. Sep. 1, 2025), Dkt. No. 30; *see also* Movants' Br. 4-6, Dkt. No 2. The Trump Administration celebrates that these efforts have worked.[8]

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[6] DOJ includes three Children's Hospital specific allegations in its declaration. One justification is that Children's Hospital's clinic is large. Hsiao Decl. ¶ 34. Another is immaterial to the drummed up FDCA violations. *Id.* ¶ 35. The third was materially amended the day after it was submitted. *Id.* ¶ 36. Accordingly, the Court should read those paragraphs for what they are: post hac rationalizations of that which cannot be justified.

[7] U.S. OFF. OF THE ATT'Y GEN., MEMORANDUM FOR SELECT COMPONENT HEADS: PREVENTING THE MUTILATION OF AMERICAN CHILDREN, 6 (Apr. 22, 2025), https://www.justice.gov/ag/media/1402396/dl.

[8] *President Trump Promised to End Child Sexual Mutilation—and He Delivered*, THE WHITE HOUSE (July 25, 2025), https://www.whitehouse.gov/articles/2025/07/president-trump-promised-

The Subpoena is precisely what it seems: the raw use of government power to advance that policy agenda. It should be quashed. [9]

V. The Court has the Inherent Power to Quash a Subpoena and to Protect the Rights of Third Parties

Movants acknowledge and appreciate Children's Hospital's effort to limit the reach of the Subpoena, and Children's Hospital is in a position to acquire relief as to all its patients. *See In re Search Warrant (Sealed)*, 810 F.2d at 71 (allowing physician to raise claim for privacy rights of patients). Even still, courts have the inherent power to quash a subpoena *sua sponte* and to exercise that power to protect the rights of third parties. *See Rivera v. Lehigh Cnty*., No. 13-CV-04748, 2015 WL 12834389, at *1 n.1 (E.D. Pa. Nov. 20, 2015) ("Defendants have not asserted any privilege with respect to the documents requested in plaintiff's subpoenas. The court may, however, issue a *sua sponte* order quashing subpoenas."); *see also Williams v. Moody*, No. CIV.A.98-1211, 1999 WL 320914, at *1 n.1 (E.D. Pa. May 18, 1999) ("this court could quash the subpoenas *sua sponte*"). This Court should quash the Subpoena as to all patient records.

CONCLUSION

Movants respectfully request that this Court quash those parts of the Subpoena that seek production of the identities or health information of patients and their parents.

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to-end-child-sexual-mutilation-and-he-delivered/ (touting hospital systems' suspension of gender-affirming care to minors)

[9] The substance of DOJ's argument regarding *Westinghouse*—the DOJ's need for these documents and the broader public interest together trump the serious privacy interests at stake in this matter—runs aground on the same rocks, with an attempted invasion of privacy intended to accomplish a political agenda through dubious means. Moreover, DOJ's argument that *Westinghouse* does not apply is wrong: *Westinghouse*, a case regarding an administrative subpoena, makes clear that where an individual's informational privacy interest is at stake, its judicial balancing test is appropriate. *See C.N. v. Ridgewood Bd. of Educ.*, 430 F.3d 159, (3d Cir. 2005) (questionnaire); *F.D.I.C. v. Wentz*, 55 F.3d 905, 908 (3d Cir. 1995) (administrative subpoena); *In re Search Warrant* 810 F.2d 67 (3d Cir. 1987) (search warrant).

Dated: October 8, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Daniel Urevick-Ackelsberg, hereby certify that on the 8th of October, 2025, I caused the foregoing document to be filed electronically with this Court, where it is available for viewing and downloading from the Court's ECF system by the Court and all parties.

/s/ Daniel Urevick-Ackelsberg
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