UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: ADMINISTRATIVE SUBPOENA NO. 25-1431-014	Misc. Action No. 2:25-mc-00054-MAK

MEMORANDUM OF THE UNITED STATES IN OPPOSITION TO CHOP PATIENTS' MOTION TO QUASH SUBPOENA DUCES TECUM

When it enacted the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Congress gave the Attorney General a specific tool to investigate federal healthcare offenses—administrative subpoenas under 18 U.S.C. § 3486. It also expressly set the conditions for challenging such a subpoena: only the subpoenaed party may object, and any petition must be filed before the return date specified on the subpoena. Plaintiffs ignore both commands. Congress did not authorize Plaintiffs to challenge this subpoena even as it authorized the recipient to do so, and Plaintiffs in any event bring this challenge almost two months after expiration of the statutory deadline. For those two independently sufficient reasons, Plaintiffs' challenge fails at the outset.

But even on the merits, the patients' motion fails. Congress created the subpoena authority precisely to permit access to patient records in investigations of healthcare offenses, subject to the safeguards it deemed sufficient. Plaintiffs' motion rests almost entirely on a single case, *United States v. Westinghouse Electric Corporation*, 638 F.2d 570 (3rd Cir. 1980), in arguing that the Court should engage in a seven-part balancing test to quash the Government's duly issued subpoena. But *Westinghouse* is irrelevant to a HIPAA subpoena's enforcement. Even if it were relevant, the factors would weigh strongly in the Government's favor: the investigative need is compelling, the requests are directly relevant to the statutory violations under investigation, and

the public interest in protecting patient-consumers—especially children—from potentially dangerous drugs is paramount. The Government routinely seeks—and obtains—patient records in healthcare investigations. There is nothing extraordinary or controversial about a Government subpoena issued to a healthcare provider, and Plaintiffs have provided no plausible basis to effectively veto the Government's ability to investigate certain kinds of healthcare offenses. The motion should be denied as procedurally improper and substantively meritless.

FACTUAL AND LEGAL BACKGROUND

The United States is conducting a nationwide investigation into, among other things, whether off-label promotion and/or unlawful dispensing of puberty blockers and cross-sex hormones for use by children suffering from gender dysphoria violated federal law, including the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, ("FDCA"). This investigation is of major public importance given its implications for the safety of minor patients. *See United States v. Article of Drug … Bacto-Unidisk*, 394 U.S. 784, 798 (1969) (FDCA's "overriding purpose" is "to protect the public health" and "is to be given a liberal construction … to ensure that [drug] products marketed serve the public with 'efficacy' and 'safety'"). *See also United States v. Dotterweich*, 320 U.S. 277, 280 (1943) ("The purposes of [the FDCA] thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection.").

The United States Food and Drug Administration ("FDA") has not found that these drugs are safe and effective to treat gender dysphoria or any other mental disorder. Use of prescription drugs such as these for uses not approved as safe and effective by FDA (*i.e.,* off-label use) can expose patients to unproven and potentially dangerous treatments without adequate evidence of safety or effectiveness. The risks are particularly acute where, as here, the patients are children, which makes them especially vulnerable. Moreover, the widespread off-label use of these

powerful drugs also undermines the regulatory system that Congress established to ensure that drugs are used consistent with sound scientific data. *See Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 619 (1973) (noting that legislative history for portions of FDCA "show a marked concern that impressions or beliefs of physicians [regarding a drug's efficacy], no matter how fervently held, are treacherous.").

The FDCA enumerates many different prohibited acts relating to drugs. Importantly, the statute prohibits not only engaging in certain prohibited acts but also the "causing thereof." 21 U.S.C. § 331. Similarly, an agreement amongst more than one person to do an act that violates the FDCA is also punishable as a conspiracy. 18 U.S.C. § 371. Violations of the FDCA are punishable as strict liability misdemeanors and are felonies if done with the intent to defraud or mislead. 21 U.S.C. § 333(a). The Declaration of Lisa K. Hsiao, the Director of the Department of Justice's ("DOJ") Enforcement and Affirmative Litigation Branch (attached hereto as Exhibit A, "Hsiao Declaration") further explains the relevant FDCA violations implicated by the Government's investigation. *See* Hsiao Declaration, Ex. A.

On June 11, 2025, under a delegation of authority from the Attorney General of the United States, Assistant Attorney General Brett A. Shumate caused the DOJ to issue a subpoena upon the Children's Hospital of Philadelphia ("CHOP"). *See* ECF 1-3, Ex. F. The subpoena was issued in furtherance of the investigation (described in the Hsiao Declaration) of potential violations of the FDCA associated with these drugs pursuant to the authority Congress granted to the Attorney General to issue subpoenas requiring "the production of any records or other things relevant to [any] investigation" of a "Federal health care offense." 18 U.S.C. § 3486(a)(1).[1] The authorizing

[1] A "Federal health care offense" is defined by Section 24(a) of Title 18 as "a violation of, or a criminal conspiracy to violate … section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 331) … if the violation or conspiracy relates to a health care benefit program." 18 U.S.C. § 24(a)(2). The statute further defines "health care benefit program" to mean "any public or private plan or contract, affecting commerce, under which any medical benefit, item,

statute was enacted as part of the HIPAA, and as a result, subpoenas issued under that authority are colloquially known as "HIPAA subpoenas." The Hsiao Declaration further explains how the documents demanded by the subpoena are relevant to the Government's investigation of potential FDCA violations, which are Federal health care offenses. *See* Hsiao Decl., Ex. A. at ¶ 37–41. The subpoena was served upon CHOP on the following day, June 12, 2025, and specified a reasonable return date of July 9, 2025. *See* ECF 1-3, Ex. F.

ARGUMENT

I. Plaintiffs lack standing under 18 U.S.C. § 3486.

Plaintiffs have a threshold problem that—on its own—requires the denial of their motion. Congress specifically limited who may challenge a HIPAA subpoena issued under Section 3486. The statute provides precise direction: "At any time ***before the return date*** specified in the summons, ***the person or entity summoned*** may, in the United States district court for the district in which that person or entity does business or resides, petition for an order modifying or setting aside the summons[.]" 18 U.S.C. § 3486(a)(5) (emphasis added). By the statute's plain terms, **only** "the person or entity summoned" may move to quash or modify the subpoena. Here, the "entity summoned" is CHOP. Plaintiffs—CHOP patients and their parents—are not the subpoenaed entity. They therefore fall outside the statute's express grant of authority to sue, and their motion should therefore be denied out of hand.

If Congress intended to grant standing to patients to challenge a HIPAA subpoena for their records, it would have done so. In other statutes authorizing investigative demands, Congress has

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or service is provided to any individual, and includes any individual or entity who is providing a medical benefit, item, or service for which payment may be made under the plan or contract." 18 U.S.C. § 24(b). Thus, Congress authorized DOJ to issue Section 3486 subpoenas like the one here to investigate violations of the FDCA, as well as conspiracies to violate the FDCA, if the violation or conspiracy relates to products or services that might ultimately be paid for by any type of health insurance plan—whether public or private.

expressly granted notice and standing to third parties whose records are sought. For example, the Right to Financial Privacy Act ("RFPA") requires notice to a customer whose financial records are sought, and expressly provides that such customers may challenge a subpoena calling for disclosure of their records. *See* 12 U.S.C. § 3410; *see also* 18 U.S.C. § 2704(b) (expressly authorizing customer/subscriber challenges as part of Stored Communications Act); *cf.* 47 U.S.C. § 551 (providing that governmental entity can obtain personally identifiable information from cable television service providers through court order only after cable subscriber has opportunity to appear and contest claim). And notably, courts have properly held under RFPA that *only* "customers" have standing to challenge a subpoena—corporations and other third-parties falling outside the statute's definition of "customer" do not. *See Mackey v. SEC*, No. 3:96MC407, 1997 WL 114801, at *1–*2 (D. Conn. Feb. 21, 1997).

That logic straightforwardly applies here. Section 3486 allows only "the person or entity summoned" to challenge a subpoena. This construction is confirmed by other aspects of the statute, including that § 3486 imposes no notice requirement on the Government or the entity summoned to inform patients or other individuals whose records might be implicated. Under the venerable doctrine of *expressio unius est exclusio alterius*, Congress's choice to expressly and exclusively permit HIPAA subpoena recipients to bring challenges must therefore be read to exclude others from doing so. This point is underscored by other provisions of HIPAA that demonstrate Congress recognized potential impact on patients. Indeed, Congress spoke directly to patient privacy interests, and expressly required the Government to adopt rules and regulations to protect those interests.

For instance, in Section 264 of HIPAA Congress directed the Secretary of Health and Human Services ("HHS") to develop recommendations for protecting the privacy of "individually identifiable health information," and if Congress failed to act, to promulgate

regulations on its own. Pub. L. No. 104-191, § 264, 110 Stat. 1936 (1996). Congress also deliberately chose to channel enforcement of those patient privacy protections through regulations and administrative oversight, not private suits by patients.[2] Congress passed Section 264 at the same time as Section 248—the subpoena provision codified at 18 U.S.C. § 3486—which itself expressly authorized nondisclosure orders that could prevent patients from even learning of the subpoena. *See* 18 U.S.C. § 3486(e)(6).[3] Congress's choice to address patient privacy in one HIPAA provision while simultaneously excluding patients from any role in Section 3486 confirms that Congress deliberately deprived them of standing to challenge a HIPAA subpoena unless they themselves are the "person or entity summoned."

That choice makes sense. HIPAA subpoenas are investigative tools that are specifically designed to obtain patient and billing records so that the Government can gather evidence to determine whether (or not) a federal offense relating to the healthcare products or services a patient received has been committed. It is not uncommon for a federal healthcare offense investigation to require the collection of tens of thousands of patient records for review and analysis. *See, e.g., In re Subpoena Duces Tecum*, 228 F.3d 341, 350–51 (4th Cir. 2000) (upholding HIPAA subpoena to physician for patient records and noting that if physician treated 15,000 patients, a suspicion of fraud would justify reviewing all 15,000 patient records). If every patient mentioned in responsive records could move to quash a HIPAA subpoena, the statute's

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[2] *See, e.g., Williams v. GEO Grp.*, No. 24-CV-5860, 2025 WL 2325649, at *8 n.9 (E.D. Pa. Aug. 11, 2025) (stating "[t]here is no federal private right of action under HIPAA" and collecting cases).

[3] The fact that Section 3486(e)(6) authorizes the Government to obtain a nondisclosure order barring the recipient from disclosing the subpoena's existence further demonstrates that Congress did not intend to grant third parties standing to challenge a HIPAA subpoena. A party obviously cannot challenge a subpoena of which it is wholly unaware. Instead, as Congress has done in the other statutes discussed above, it would have at least required notice to patients. Congress's opposite choice here confirms that strangers to the subpoena are not intended to be able to challenge the subpoena.

enforcement scheme would collapse under the weight of collateral third-party litigation. That is not the careful scheme that Congress designed, which expressly and exclusively requires HIPAA subpoena challenges to be brought by "the person or entity summoned." 18 U.S.C. § 3486(a)(1)(5).

Ignoring the statute's clear mandate, Plaintiffs maintain that because the records concern them, they have standing to quash the subpoena. ECF 1-2 at 9–10. Each of the cases cited by Plaintiffs, however, arose outside of the controlling statutory framework of Section 3486. In *Greene v. Phila. Hous. Auth.*, 789 F. Supp. 2d 582, 586 (E.D. Pa. 2011), the administrative subpoena was issued under the Inspector General Act, which—unlike HIPAA—lacked any statutory provision defining who could move to quash or modify the subpoena. In the absence of statutory guidance, the court borrowed Rule 45 of the Rules of Civil Procedure to evaluate standing. *See id.* & n.4.[4] But here, Congress has expressly limited standing to "the person or entity summoned," there is no room to import broader, general subpoena doctrines that arise under Rule 45. *Greene* thus says nothing about Plaintiffs' standing under Section 3486.

Plaintiffs' reliance on *In Re Grand Jury Matter*, 770 F.2d 36 (3d Cir. 1985) and *Wm. T. Thompson Co. v. Gen. Nutrition Corp.*, 671 F.2d 100 (3d Cir. 1982), is equally misplaced. To start, *In re Grand Jury Matter* merely "assume[d], without deciding," the issue of standing, 770 F.2d at 39, and *General Nutrition Corp.* dealt with an intervenor's standing to appeal under Rule 45, which has next to no relevance to this case, 671 F.2d at 103. Rather, those cases illustrate circumstances in which—in the absence of a statutory mandate on standing—third party standing could be had under another statute or rule where the third party has a recognized privilege or

[4] The court looked to Fed. R. Civ. P. 81(a)(5) to conclude that using Rule 45 was permissible. The text of Rule 81 makes it clear that the Civil Rules do not apply where a statute (*e.g.,* 18 U.S.C. § 3486(a)(5)) supplies the rule. *See* Fed. R. Civ. P. 81(a)(5).

property interest in the documents. These cases say nothing about third-party statutory standing under Section 3486.

Plaintiffs' argument fails on its own terms. While patients may have a generalized privacy interest in their medical records, that interest does not confer ownership or legal control. The medical records at issue here are the property of CHOP, and Plaintiffs do not contend otherwise.

Nor is the information contained in their medical records legally privileged (as opposed to having a reasonable expectation of privacy). *See Whalen v. Roe*, 429 U.S. 589, 602 n.28 (1977) ("The physician-patient evidentiary privilege is unknown to the common law."); *Keyes v. Sessions*, 282 F. Supp. 3d 858, 862 (M.D. Pa. 2017) ("Pennsylvania privileges are not applicable in this matter, and 'the federal common law does not recognize a more general physician-patient privilege.'") (citing *Sarko v. Penn-Del Directory Co.*, 170 F.R.D. 127, 131 (E.D. Pa. 1997)). Because Plaintiffs have neither a property interest nor a recognized privilege in the documents, they cannot transform their privacy interests into third-party standing—even in the absence of Section 3486's limitations on who may sue. And, in any event, a mere general or property interest cannot overcome Congress's express decision limiting standing to challenge HIPAA subpoenas.

II. Sovereign immunity principles independently foreclose Plaintiffs' action.

Because Plaintiffs—strangers to the subpoena—have brought an independent action to quash that subpoena, this action is in substance a suit against the United States that seeks to restrain the Government's investigatory powers. Under settled law, however, such suits are barred absent an express waiver of sovereign immunity. *See FDIC v. Meyer*, 510 U.S. 471, 475 (1994) ("Absent a waiver, sovereign immunity shields the Federal Government and its agencies from suit."); *Bah v. United States*, 91 F.4th 116, 120 (3d Cir. 2024) (same). "Because sovereign immunity is jurisdictional in nature, the terms of the Government's consent to be sued in any

court define that court's jurisdiction to entertain the suit." *Id.* (citation modified). Any such waiver "cannot be implied but must be unequivocally expressed." *United States v. Mitchell*, 445 U.S. 535, 538 (1980) (citation modified).

Absent waiver, sovereign immunity bars an action against the Government to quash a subpoena. *See Ponsford v. United States*, 771 F.2d 1305, 1309 (9th Cir. 1985). Section 3486(a)(5) supplies such a waiver, but it is expressly limited to "the person or entity summoned." By authorizing only the recipient to bring a lawsuit against the United States challenging the subpoena, Congress both defined who has standing (*see supra*) and also specified the sole context in which immunity is waived. Plaintiffs here are thus doubly barred. Permitting Plaintiffs to bring this challenge would require the Court to both enlarge standing and expand the Government's limited waiver of sovereign immunity beyond that which Congress authorized. To do so would be to contravene the Supreme Court's command that "a waiver of the Government's sovereign immunity will be strictly construed, in terms of its scope, in favor of the sovereign." *Lane v. Peña*, 518 U.S. 187, 192 (1996).

III. Plaintiffs' motion is also time-barred.

Even if Plaintiffs had standing and even if the Government were not immune, their petition would still be independently barred as untimely. Section 3486 requires any petition to quash or modify a HIPAA subpoena to be filed "before the return date specified in the summons." 18 U.S.C. § 3486(a)(5). Courts strictly enforce statutory deadlines to move to quash a subpoena. *See Ponsford v. United States*, 771 F.2d 1305, 1309 (9th Cir. 1985) (strictly construing statute's 20-day limit to bring proceeding to quash IRS summons; holding statutory deadline is jurisdictional and "is a condition precedent to the waiver of sovereign immunity"); *accord Sarnowski v. United States*, No. 05-242, 2006 WL 2172615, at *2 (W.D. Pa. July 31, 2006) ("A district court … only has jurisdiction over a petition to quash a third party summons if the

petition is filed strictly within the twenty-day filing period mandated by the statute."); *see also Swann v. Secretary, HUD*, No. 05-492, 2006 WL 148738, at *1 (D.D.C. Jan. 19, 2006) (court lacks subject matter jurisdiction where motion challenging administrative subpoena is untimely under statute authorizing challenge); *Turner v. United States,* 881 F. Supp. 449, 451 (D. Haw. 1995) ("government's waiver of its sovereign immunity is conditioned on the timely filing of the motion to quash.").

Here, Plaintiffs filed this action well after the return date specified on the subpoena: August 7, 2025. As a result, they cannot invoke the statute's limited mechanism to challenge the subpoena—and this Court lacks jurisdiction to even hear such a challenge—assuming the Plaintiffs could otherwise satisfy the statute's standing requirement. Again, this scheme makes sense. Congress coupled the subpoena authority in Section 3486 with a firm deadline: any motion to quash must be filed before the return date. That bright line was no accident. To excuse the motion's tardiness would convert a clear statutory command into an open invitation for endless obstruction—paralyzing large-scale healthcare offense investigations by patient challenges brought at will. That is not the law.

IV. Congress anticipated and authorized subpoenas to obtain patient records.

One of the key purposes of HIPAA is to "combat waste, fraud, and abuse in health insurance and health care delivery." HIPAA, Pub. L. 104-191, preamble, 110 Stat 1936 (1996). The legislative history of the statute confirms that Section 3486 was enacted to "establish procedures for the Attorney General to make investigative demands" for "health information about an individual" in health care offense investigations. H.R. CONF. REP. NO. 104-736, at 261 (1996), *reprinted in* 1996 U.S.C.C.A.N. 1990, 2074. Congress thus anticipated and authorized the Government's access to the very sorts of patient and billing records that Plaintiffs seek to shield.

That is why, in the same statutory section, Congress added specific protections governing the use of that information once produced. Section 3486(e) provides that generally, "[h]ealth information about an individual that is disclosed under this section may not be used in, or disclosed to any person for use in, any administrative, civil, or criminal action or investigation directed against the individual who is the subject of the information." 18 U.S.C. § 3486(e)(1). By enacting these safeguards, Congress made clear that HIPAA subpoenas would inevitably reach patient-identifying records—yet it chose not to carve out an exception simply because the records might be highly personal. If subpoenas under Section 3486 could not reach records about mental health, sexual health, or other sensitive topics, then fraud and abuse schemes exploiting those very areas would be insulated from investigation—exactly the opposite of what Congress set out to prevent in enacting the statute. Congress did not overlook the sensitivity of these records. To quash the subpoena here on that basis would be to override a legislative judgment, leaving certain corners of the health care system beyond scrutiny.

V. *Westinghouse* neither governs this case nor undermines the subpoena.[5]

A. Westinghouse *is not the standard for evaluating subpoenas issued under HIPAA*.

Plaintiffs reliance on *Westinghouse* is misplaced. *Westinghouse* addressed a a subpoena issued under a different statute more than fifteen years before HIPAA was enacted. When Congress enacted HIPAA, it directly confronted the medical privacy concerns that animated

[5] In the interests of judicial economy and to avoid unnecessary duplication, the United States provides here only a brief summary of its arguments about *Westinghouse* to chiefly address the specific arguments made here by the CHOP patients, while incorporating by reference the Government's full arguments set out in the related matter brought by CHOP itself. See Government's Mem. in Opposition to CHOP's Mot. to Modify, *In Re: Administrative Subpoena No. 25-1431-014*, No. 25-mc-39-MAK, ECF 13 (E.D. Pa. Aug. 4, 2025). In light of the Court's statement in its September 23, 2025 Order in this matter that it would resolve the patients' motion "consistent with our ongoing review" of the hospital's motion, the United States respectfully submits that extensive re-briefing appears unnecessary. Order, ECF 6.

Westinghouse while simultaneously authorizing the Attorney General to obtain protected health information to investigate federal healthcare offenses. Since Congress created a statutory, constitutionally sound mechanism for obtaining such private information, there is no need—nor room—for *Westinghouse's* judicially crafted, extra-statutory test for subpoenas issued under HIPAA. Courts evaluating challenges to HIPAA subpoenas have thus followed the ordinary administrative subpoena standard: authority, lawful purpose, and reasonable relevance. This Court should follow suit and reject any effort to graft *Westinghouse*-type balancing onto them.

B. *This Court should decline to extend* Westinghouse *beyond its facts.*

The United States acknowledges the *Westinghouse* is binding precedent in this Circuit as to OSHA subpoenas, but it preserves its view that *Westinghouse* was wrongly decided and should not be extended to subpoenas issued under HIPAA. The Court of Appeals crafted a balancing test without grounding in statutory text or Supreme Court precedent, erecting extra-statutory hurdles to the enforcement of otherwise valid administrative subpoenas. Plaintiffs' own briefing underscores the problem: they invoke *Westinghouse* to demand the Court evaluate seven different factors while acknowledging that ordinarily an administrative subpoena is enforceable so long as it falls within the agency's authority, serves a lawful purpose, and seeks information reasonably relevant to that purpose. *See* ECF 1-2 at 9 (citing *United States v. Morton Salt Co.*, 338 U.S. 632, 652 (1950)). Similarly, Plaintiffs argue that because they entrusted sensitive information to health care providers, they reasonably expected it to remain private. *Id.*; Movant Decls. ¶ 14. But the Supreme Court has rejected that premise in the Fourth Amendment context:

> This Court has repeatedly held that the Fourth Amendment does not prohibit the obtaining of information revealed to a third party and conveyed by him to Government authorities, even if the information is revealed on the assumption that it will be used only for a limited purpose and the confidence placed in the third party will not be betrayed.

United States v. Miller, 425 U.S. 443 (1976). The *Westinghouse* court failed to reconcile its balancing test with *Miller's* clear rule, underscoring why *Westinghouse* lacks a sound constitutional foundation. As a result, it should not be extended to HIPAA subpoenas.

C. Even if it applied, *Westinghouse* cuts against Plaintiffs

Even assuming *Westinghouse* applies here—which it does not—the factors support denial of Plaintiffs' motion to frustrate the Government's investigation through quashal of the subpoena.

i. *Factors 6 and 7—government need and public interest —are dispositive and decisively outweigh privacy concerns.*

The Government begins with factors six and seven because they go to the heart of what its investigation is all about: carrying out the FDCA's "overriding purpose to protect the public health," *Bacto-Unidisk*, 394 U.S. at 798, and safeguarding "the innocent public who are wholly helpless," *Dotterweich*, 320 U.S. at 285, to protect themselves from dangerous or fraudulent "products which may affect the health of consumers." *United States v. Park*, 421 U.S. 658, 673 (1975). As detailed in the Hsiao Declaration, the United States is conducting a nationwide investigation involving potential violations of the FDCA relating to puberty blockers and cross-sex hormones when used to treat gender dysphoria and related disorders in minors. Each subpoenaed category of information is relevant and necessary to that inquiry. The records sought bear directly on whether these practices—regarding drugs not proven safe or effective for this use—may violate federal law and endanger children. This off-label use of these powerful drugs may be putting children at significant risk, leaving lifelong mental and physical side effects and consequences—the full extent of which may yet be unknown to science. *See id.* Hsiao Decl. ¶ 22–29.

Depriving the Government of access to these records would undermine the central purpose of the FDCA. Indeed, Plaintiffs concede (ECF 1-2 at 17) that Congress enacted an express

statutory mandate in HIPAA for the Attorney General to issue subpoenas to investigate the FDCA violations at issue here—a mandate that "ranks with the other public interests which have been found to justify intrusion into records and information normally considered private." *Westinghouse*, 638 F.2d at 579.

This dovetails with *Westinghouse* Factor 7, which emphasizes the public interest served by access to the records. The public has an overwhelming interest in ensuring that the drugs they take into their bodies are both safe and effective for their intended uses—an interest only heightened with minor children, who are uniquely vulnerable to long-term, potentially irreversible physical and mental harm from unproven treatments. *See New York v. Ferber*, 458 U.S. 747, 756 (1982) ("It is evident beyond the need for elaboration that a State's interest in safeguarding the physical and psychological well-being of a minor is compelling.") *Westinghouse* itself recognized that "courts and legislatures have determined that public health or other public concerns may support access to [medical] facts an individual might otherwise choose to withhold." 638 F.2d at 578.

ii. *Factors 1, 2, and 3 are outweighed by the need for information.*

Factors one through three—record type, content, and potential harm—essentially collapse into one factor here. Although the subpoena seeks sensitive health information, CHOP maintains these materials in the ordinary course of its business and are exactly the kinds of records Congress expected HIPAA subpoenas to reach. Nothing about these subpoena requests takes them outside the mainstream of law-enforcement inquiries in healthcare offense investigations. *See* Hsiao Decl. at ¶ 10. Plaintiffs' predictions of "serious harm" is not specifically identified except as generalized "embarrassment" in a citation parenthetical and are unsupported by any concrete showing of likely misuse by the Government. *See* ECF 1-2, at 13. Absent evidence of

specific risk, these concerns do not overcome the compelling governmental interest in enforcing the FDCA, particularly where the health and safety of children are implicated.

iii. *Factor 4—injury from disclosure to the relationship—is at least neutral.*

Westinghouse's fourth factor—impact on the provider-patient relationship—adds little here. Concerns that disclosure might erode patient trust arise in virtually every investigation involving medical records. If applied mechanically, as Plaintiffs urge, the scale would always be stacked against enforcement of every Section 3486 subpoena, thus defeating the careful statutory scheme Congress put in place in HIPAA. Courts caution against such bean-counting especially when it interferes with the Government's investigative powers. *See EEOC v. Am. Exp. Centurion Bank*, 758 F. Supp. 217, 221 (D. Del. 1991) ("federal courts are and should be most cautious about interfering with the investigative power delegated by Congress to agencies"). While the investigation—and the use of patient records to advance it—might affect CHOP's relationship with its patients, Plaintiffs neither articulate nor could the Government discern any principled way to measure, much less substantiate, the severity of that effect. Consequently, this factor should be deemed neutral.

iv. *Factor 5: Governmental use of records for law enforcement provides sufficient protection and makes unauthorized disclosure highly unlikely.*

Factor 5 considers the adequacy of safeguards to prevent unauthorized disclosure. Plaintiffs contend that disclosure of their medical records to DOJ for use in carrying out its core function of investigating and prosecuting violations of federal law creates a "catastrophic" risk of violence, discrimination, and harassment if the information were ever misused or leaked to the general public. ECF 1-2 at 14–15. Their concern misapprehends both the nature of the subpoena and the safeguards inherent in the federal investigative process.

Any production would be to the Government—not the public—and Plaintiffs do not claim the Government itself will use the records to harm them. They also never explain how disclosure to DOJ under statutory limits (*e.g.,* the Privacy Act, 5 U.S.C. § 552a) or routine information-sharing with law enforcement partners plausibly would result in **public** dissemination. Federal investigations regularly handle highly sensitive material—secret grand jury matters, confidential-informant information, Title III interceptions, FISA-derived national security intelligence—all under accepted confidentiality regimes. And courts presume that federal officials will honor their obligations. *See, e.g., United States v. Armstrong*, 517 U.S. 456, 464 (1996) ("[I]n the absence of clear evidence to the contrary, courts presume that [federal prosecutors] have properly discharged their official duties."). The leap from confidential disclosure to law enforcement to widespread dissemination of this information is never bridged by Plaintiffs. *Westinghouse* balancing requires more than conjecture; Factor five favors the Government.

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Taken together, the seven *Westinghouse* balancing factors confirm, not undermine, the subpoena's validity. The dispositive considerations here—the Government's compelling need, the paramount public interest in protecting children's health, and the adequacy of safeguards against misuse—tip the balance decisively in favor of disclosure. Protecting children from potentially dangerous, unproven drugs and safeguarding public health are not just compelling interests—they are the very reason Congress armed the Attorney General with this tool. As explained, *supra*, this Court should not apply *Westinghouse* at all; but even assuming it does, the balance tips firmly toward disclosure.

VI. The subpoena properly seeks evidence of adulterated, misbranded, and unapproved new drug violations of the FDCA.

Plaintiffs are both wrong and lack any basis to assert that the subpoena was issued for an improper purpose or in "bad faith." ECF 1-2 at 17–20. Director Hsiao's declaration sets out facts that squarely refute their allegations and confirm the subpoena's legitimate purpose. *See generally* Hsiao Decl. The Supreme Court has long recognized that an administrative subpoena will be enforced if (1) it is issued for a legitimate purpose; (2) seeks information relevant to that purpose; (3) the information is not already within the Government's possession, and (4) the required administrative steps have been followed. *See United States v. Powell,* 379 48, 57–58 (1964). *Accord Chao v. Community Trust Co.*, 474 F.3d 75, 87 (3d Cir. 2007); *EEOC v. Bessemer Group*, 105 Fed. App'x 411, 413 (3d Cir. 2004). Courts have accordingly placed a "heavy burden" on challengers alleging bad faith. *See FDIC v. Wentz,* 55 F.3d 905, 908 (3d Cir. 1995) (citing *United States v. Cortese*, 614 F.2d 914, 919–20 (3d Cir. 1980).

Plaintiffs cannot carry that burden. To the contrary, the subpoena here was issued squarely within the bounds of Section 3486, which expressly authorizes the Attorney General to issue subpoenas in investigations of "Federal health care offense[s]," including violations of the FDCA that involve a health care benefit program. As Director Hsiao's declaration makes clear, that is precisely the purpose the subpoena serves here.

Director Hsiao's declaration sets forth in detail how the subpoenaed records are directly relevant to the Government's ongoing nationwide investigation into possible violations of the FDCA. The investigation concerns the distribution, promotion, and use of puberty blockers and cross-sex hormones in minors for the treatment of gender dysphoria—uses that the FDA has never approved and that raise grave safety concerns. Such inquiries fall squarely within the Government's statutory mandate to protect the public from misbranded, adulterated, and unapproved drugs.

Plaintiffs claim that "animus" against transgender people is the "official policy" of the United States which taints the investigation. ECF 1-2 at 18. But that confuses political rhetoric with legal authority. What matters is whether the subpoena is tethered to a proper statutory inquiry. Here, it plainly is, as the Hsiao declaration, made under penalty of perjury, makes clear. The subpoena was issued to CHOP to aid in a determination as to whether the hospital, its staff, and affiliates are violating the FDCA—either directly or through a conspiracy with others (*e.g.,* with pharmacies, drug manufacturers, and/or distributors)—with the intent to defraud and mislead. Whether the President has a policy goal of ending gender-related pharmaceutical and surgical treatment of minors—a goal that the Supreme Court has recognized is rational, as it explained in *United States v. Skrmetti*, 605 U.S. ___, 145 S. Ct. 1816, 1835–36 (2025)—is not relevant to determining whether the investigation itself is lawful. This is especially true against the backdrop of the presumption of regularity that attaches to the actions of federal prosecutors. *Armstrong*, 517 U.S. at 464. The fact that the President (or other executive branch leaders) have expressed opposition to gender-affirming care in minors does not convert a facially valid investigation into bad faith. If it did, nearly every enforcement effort in controversial areas would collapse under accusations of "animus" and would provide nearly anyone with a veto of HIPAA subpoenas by invoking political controversy.

Finally, Plaintiffs place heavy reliance on the decision in *In re Administrative Subpoena No. 25-1431-019*, No. 25-mc-91324, 2025 WL 2607784 (D. Mass. Sept. 9, 2025). See ECF 1-2 at 18–19. The Government contends the district court erred in that case. But, in any event, like the Plaintiffs, that court did not have the benefit of the Hsiao declaration setting forth in detail the theories and contours of the investigation. The court there clearly stated that it made its finding of improper purpose in the absence of "any affidavits or other evidence to show proper purpose." *Id.* at *5. But such affidavit is present here. Unlike in the Massachusetts proceedings, the court here

has before it a fulsome declaration, made under penalty of perjury, from a senior career official of the DOJ component conducting the investigation; it clearly demonstrates that the subpoena has a proper purpose and articulates a clear nexus between the requested information and an authorized federal investigation.

In short, Plaintiffs cannot meet their "heavy burden" of proving improper purpose. The record demonstrates that this subpoena was issued pursuant to clear statutory authority, in furtherance of an ongoing nationwide investigation into possible violations of the FDCA, and supported by a declaration from a senior DOJ official. This Court has before it direct evidence of proper purpose. That evidence compels enforcement, not quashal, of the Government's subpoena.

VII. The Court cannot quash subpoenas for non-parties.

Should the Court grant any part of Plaintiffs' motion to quash, any order should be limited to the records of these specific individuals. Absent a class action, relief in federal court is confined to the parties actually before it. The Supreme Court has made clear that "injunctive relief should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs before the court." *Califano v. Yamasaki*, 442 U.S. 682, 702 (1979); *accord Trump v. CASA, Inc.*, 606 U.S. 831 (2025) ("the question is not whether an injunction offers complete relief to **everyone** potentially affected by an allegedly unlawful act; it is whether an injunction will offer complete relief *to* **the plaintiffs before the court**." (emphasis in original)). Although quashal is not an injunction in the technical Fed. R. Civ. P. 65 sense, it is still a form of judicial relief that restrains government action, and the same principal applies. *See Gill v. Whitford*, 585 U.S. 48, 73 (2018) ("We caution, however that standing is not dispensed in gross: A plaintiff's remedy must be tailored to redress the plaintiff's particular injury." (citation modified)). Accordingly, any quashal should extend only to the named Plaintiffs, not to non-parties.

CONCLUSION

Plaintiffs lack standing to challenge the subpoena, their petition is untimely, and their privacy arguments fail under both the statute and *Westinghouse*. The subpoena was issued pursuant to Congress's express authorization in Section 3486 of Title 18, United States Code, to investigate potential violations of the FDCA, and it serves a compelling public interest in protecting public health—specifically that of vulnerable children. Plaintiffs' motion should be denied and this action dismissed.

Dated, this 6th day of October, 2025.

Respectfully submitted,

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[6] The Consumer Protection Branch of the Department of Justice's Civil Division is now the Enforcement and Affirmative Litigation Branch ("EALB"); EALB's Enforcement Section holds all legal authorities previously held by the Consumer Protection Branch.

CERTIFICATE OF SERVICE

I, Ross S. Goldstein, certify that on October 6, 2025, I caused the foregoing Government's Memorandum in Opposition to Plaintiffs' Motion to Quash Subpoena to be filed electronically using the Court's CM/ECF system, through which email notice of the filing will be sent to all counsel of record and will be made available for viewing and downloading from the CM/ECF system.

Dated this 6th day of October, 2025.

/s/ Ross S. Goldstein
ROSS S. GOLDSTEIN