IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

In re Administrative Subpoena 25-1431-014	Case No. 25-mc-0039-MAK Assigned To Judge Mark A. Kearney Date Action Filed: July 8, 2025

SUPPLEMENTAL BRIEF IN SUPPORT OF
MOTION TO LIMIT THE *SUBPOENA DUCES TECUM* ISSUED ON JUNE 12, 2025

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

INTRODUCTION

Nearly four months after issuing a subpoena to Children's Hospital of Philadelphia ("CHOP"), and nearly two months after responding to CHOP's Motion to Limit the Subpoena ("CHOP's Motion" or "Motion"), the Government submitted evidence and arguments in a related case that materially alter its Opposition to CHOP's Motion. That new evidence should not be considered because it is not before the Court in this case and is unreliable in any event. But notwithstanding the Government's post-hoc effort to justify its subpoena, the Government (still) cannot establish that its need for extraordinarily sensitive and personal patient information outweighs the highest-order privacy interests on the other side of the ledger. Accordingly, CHOP's Motion to Limit the Subpoena should be granted.

BACKGROUND

On June 12, 2025, the Government issued a subpoena to CHOP pursuant to 18 U.S.C. § 3486 ("the Subpoena"). Before the July 9, 2025, return date, CHOP moved to limit the Subpoena to exclude Requests 11 through 13, which demand patient names, diagnoses, treatment, and informed consent materials, as well as any other Requests to the extent that they call for patient health information. *See* ECF 1. The Government responded to CHOP's Motion on August 4 (ECF 13).

On September 22, a group of CHOP patients and their families filed a Motion to Quash the Subpoena, designating it as related to CHOP's Motion to Limit. *See* ECF 1, No. 25-mc-54 ("the Patients' Motion"). The Court indicated that it would resolve the Patients' Motion consistent with its ongoing review of CHOP's Motion. *See* ECF 6, No. 25-mc-54.

In Opposing the Patients' Motion, the Government presented new evidence in the form of a Declaration from Lisa Hsiao, a lawyer and Acting Director of the Consumer Protection Branch of the Department of Justice ("DOJ"). *See* ECF 16, Ex. 1, 25-mc-54

("Hsiao Declaration"). The Hsiao Declaration describes the theories under which the Government claims to be pursuing potential violations of the Food Drug and Cosmetic Act ("FDCA"), as well as concerns the Government proffers about the safety and efficacy of medications used to treat gender dysphoria.[1] The Declaration also includes allegations specific to CHOP, none of which the Government presented in its prior filings. *Id.* ¶¶ 34-36. Moreover, in its brief, the Government included new arguments about the application of the balancing test articulated in *United States v. Westinghouse Elec. Corp.*, 638 F.2d 570 (3d. Cir. 1980). *See* ECF 16 at 13-14, 25-mc-54 ("Br. in Opp."). In light of the Government's new evidence and arguments, the Court granted CHOP leave to file this Supplemental Brief in Further Support of the Motion to Limit. *See* ECF 32.

ARGUMENT

I. This Court Should Not Consider the Hsiao Declaration

A. The Hsiao Declaration is not properly before the Court

Nearly two months elapsed between the day the Government issued the Subpoena and the day it filed its Opposition to CHOP's Motion to Limit—plenty of time to prepare a declaration or corral any evidence necessary to support its position. The Government did not file the Hsiao Declaration until nine weeks later, after a related subpoena was quashed on the ground that the Government had "not offer[ed] an iota of suspicion" about the

[1] The views expressed in the Hsiao Declaration do not reflect the medical consensus. Almost every mainstream U.S. medical and mental health professional organization endorses the current standard of care for gender dysphoria, including the prescription and administration of puberty blockers and hormone therapy. *See* Proposed Brief of Amici Curiae American Academy of Pediatrics and Additional National & State Medical and Mental Health Organizations, *Washington v. Trump*, No. 2:25-cv-00244, No. 227-1 (D. Wa. Feb. 2, 2025). A systematic review of medical evidence commissioned by the Utah Legislature found that those treatments "are effective in terms of mental health, psychosocial outcomes, and the induction of body changes consistent with the affirmed gender in pediatric patients," and are "safe in terms of changes to bone density, cardiovascular risk factors, metabolic changes, and cancer." *See* Joanne LaFleur et al., *Gender-Affirming Medical Treatments for Pediatric Patients with Gender Dysphoria*, REPORT FOR THE UTAH LEGISLATURE 90 (May 2025).

recipient hospital's conduct. *In re Administrative Subpoena No. 25-14310019*, No. 33 at 12 (D. Mass. Sept. 9, 2025) ("BCH Decision").

Even today, the Government has made no effort to file the Hsiao Declaration on the docket in this matter, attempting instead to shoehorn its new evidence into CHOP's case by virtue of its Opposition to the Patients' Motion. That should not be permitted. Rather, the Government should be held to the burden all litigants must meet to introduce new evidence after briefing has closed—a burden that includes offering "a reasonable explanation for not introducing the evidence earlier." *Bistrian v. Levy*, 448 F. Supp. 3d 454, 485 n.145 (E.D. Pa. 2020). Given the circumstances here, that is a burden the Government cannot meet.

B. The Hsiao Declaration is unreliable

In addition to its untimeliness, the Hsiao Declaration should be rejected because it is unreliable. Apart from the size of CHOP's Gender and Sexuality Development Program (the "Program")—a fact that in no way warrants investigation—the Hsiao Declaration includes two CHOP-specific allegations. Both are threadbare, of dubious origin, and so heavily qualified and caveated as to offer the Court no meaningful information.

First, the Government alleges that, over seven years, almost 250 CHOP patients were diagnosed with precocious puberty at age ten or older. Hsiao Dec. ¶ 35. But the Government provides no support for its contention that "[t]his is well beyond the age at which children are typically diagnosed." *Id.* Moreover, the Government fails to contextualize the findings of its rudimentary analysis, offering no comparator for the use of the code for precocious puberty at peer hospitals, let alone hospitals that, like CHOP, have providers who specialize in treating endocrine disorders.

Even assuming the cited figure is atypically high, the Government's allegation is far too underdeveloped to offer useful information. For one thing, the provenance of the data set is entirely unknown. The Hsiao Declaration does not indicate whether it might include patients who were diagnosed at a younger age by another provider. *See id.* (describing minors "first diagnosed *at CHOP or a CHOP affiliate* . . . at age 10 or older" without saying whether they might have had a prior diagnosis (emphasis added)). And critically, the Declaration does not specify how many patients received treatment for gender dysphoria.

The second CHOP-specific allegation is weaker still. As originally filed on October 6, 2025, the Hsiao Declaration included a statement (made under penalty of perjury) that "the Government is also aware of a lawsuit filed just this year that details very concerning allegations of a minor being put on puberty blockers after his first visit and cross sex hormones after his second." *See* Ex. A ¶ 36. The next morning, however, the Hsiao Declaration was replaced on the docket, *see* ECF 16, 25-mc-54, and the new version did not reference a lawsuit, *see* Hsiao Dec. ¶ 36.

Although the Government did not explain the change to its sworn statement, a simple internet search reveals that in the weeks after the Subpoena was issued, a media report emerged describing an interview with a former CHOP patient.[2] The report indicated that the patient was "suing the hospital," but CHOP is unaware of any such lawsuit and has not been served. The similarities between the report and the allegations in the Hsiao Declaration—including the reference to a lawsuit—raise suspicions that, in looking to justify its investigative interest in CHOP, the Government simply searched the internet for

[2] Chadwick Moore, *Fashion Model Learning To Be a Man After Being Pushed to Transition at Age 15: 'I Was Really Crazy on the Hormones*,' N.Y. POST (July 26, 2025).

stories fitting its narrative and presented the one it found as fact without adequately scrutinizing its veracity.[3]

***

The Hsiao Declaration is nothing more than a post-hoc attempt to justify the Subpoena. Before filing its Opposition to the Patients' Motion, the Government never made any claims against CHOP (and it still has not done so in this case). The Declaration's belated and reverse-engineered allegations cannot provide a foundation for the Government's investigation and should not be considered in adjudicating CHOP's Motion to Limit.

II. The *Westinghouse* Factors Apply in This Case and Weigh in CHOP's Favor

Although the Hsiao Declaration should be rejected, its consideration would not change the outcome here. Rather, the Declaration (along with the Government's new arguments) only highlights why, under the controlling *Westinghouse* test, the extraordinary privacy interests weighing against disclosure easily overcome any countervailing factors.[4]

A. *The Hsiao Declaration does not improve the Government's showing on Factors 6 and 7*

Relying on the Hsiao Declaration, the Government contends that its investigation "involving potential violations of the FDCA relating to puberty blockers and cross-sex hormones" establishes its need for the information demanded by the Subpoena (Factor 6)

[3] Moreover, the Hsiao Declaration does not faithfully relay the contents of the report, which states that the patient was prescribed androgen blockers after his *second* appointment at CHOP (not his first) and hormone therapy at an unspecified "later" time. *See* n.4, *supra*. Of course, CHOP's supposition about the origins of the allegation may be incorrect. But the Government's late-filed and bare-bones allegation invites such speculation, and it is far too late for the Government to salvage its Declaration by adding new facts.

[4] The Government argues for the first time in its Opposition to the Patients' Motion that *Westinghouse* is binding only as to subpoenas from the Occupational Safety and Health Administration ("OSHA") (Br. in Opp. at 12). That is incorrect. *Westinghouse* has been cited more than 30 times by the Third Circuit, and its balancing test has been repeatedly applied outside the OSHA context, including with respect to administrative subpoenas from other entities. *See, e.g.*, *FDIC v. Wentz*, 55 F.3d 905 (3d Cir. 1995) (applying *Westinghouse* to FDIC subpoena for bank records).

and shows that the public interest weighs in favor of enforcement (Factor 7). Br. in Opp. 13-14. In fact, the opposite is true: To the extent the investigation concerns activities with a nexus to patient information, the legal theories on which it is predicated are fatally flawed.[5]

It is well established that, notwithstanding the FDCA's prohibitions on misbranding and distribution of unapproved drugs (21 U.S.C. § 331(a),(b),(d)), physicians may prescribe and administer FDA-approved drugs and devices for off-label uses. That conclusion follows from the fact that "Congress exempted the practice of medicine from the Act so as not to limit a physician's ability to treat his patients." *United States v. Algon Chem. Inc.*, 879 F.2d 1154, 1163 (3d Cir. 1989) (quoting *Chaney v. Heckler*, 718 F.2d 1174, 1179 & n.13 (D.C. Cir. 1983), *rev'd on other grounds*, 470 U.S. 821 (1985)). "'Congress would have created havoc in the practice of medicine had it required physicians to follow the expensive and time-consuming procedure of obtaining FDA approval before putting drugs to new uses.'"[6] *Id.* (quoting *Chaney*, 718 F.2d at 1179).

The conclusion that the FDA does not regulate physicians' off-label prescription and administration of medication has been affirmed by numerous courts. *See Wash. Legal Found. v. Henney*, 202 F.3d 331, 333 (D.C. Cir. 2001) ("A physician may prescribe a legal drug to serve any purpose that he or she deems appropriate, regardless of whether the drug has been approved for that use by the FDA."); *United States v. Caronia*, 703 F.3d 149, 153

[5] While CHOP records might be relevant to an investigation into potential off-label violations by manufacturers, patient-identifying information would be immaterial to that inquiry. *See* BCH Decision at 12 (noting "tenuous link" between patient-identifying information and off-label promotion).

[6] That is particularly true in the pediatric context where off-label usage is exceedingly common. *See, e.g.*, H. Christine Allen *et al.*, *Off-Label Medication Use in Children, More Common than We Think: A Systematic Review of the Literature*, 111 J. OKLA. STATE MED. ASSOC. 776, 181 (2018) ("Our study and literature review demonstrate that off-label use of medications in pediatric patients is a common practice, with a significant number of children, inpatient and outpatient, receiving an off-label medication.").

(2d Cir. 2012) ("[P]rescription drugs can be prescribed by doctors for both FDA-approved and -unapproved uses; the FDA generally does not regulate how physicians use approved drugs."); *United States v. Evers*, 643 F.2d 1043, 1048 (5th Cir. 1981) ("FDA has at no point contended . . . that the misbranding provisions of the Act prohibit a doctor from prescribing a lawful drug for a purpose for which the drug has not been approved by the FDA"); *cf. Buckman Co. v. Plaintiffs' Legal Cmte.*, 531 U.S. 341, 350 (2001) ("'[O]ff-label' usage 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."); *Shuker v. Smith & Nephew PLC*, 885 F.3d 760, 773-74 (3d. Cir. 2018) ("[T]he statutory scheme contemplates that physicians will prescribe or administer components outside of a system with which the FDA approved their use." (citations omitted)); 21 U.S.C. § 396 ("Nothing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device.").

The FDA and DOJ's Office of Legal Counsel ("OLC") agree. According to the FDA, once the agency "approves a drug, healthcare providers generally may prescribe the drug for 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). Or, as OLC put it, "[a]s a general matter, FDA does not regulate the practice of medicine, which includes 'off-label' prescribing." 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). "While 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.*

The Hsiao Declaration gestures at this universally recognized limitation on the reach of the FDCA, conceding that "physicians are permitted to prescribe an FDA-approved drug for an unapproved use." Hsiao Dec. ¶ 12. But in the very next sentence the Declaration asserts that, "depending on the circumstances, prescribing for unapproved purposes can itself involve FDCA violations—for example, where the physician is engaged in the distribution or labeling of an unapproved drug." *Id.* From there, the Hsiao Declaration suggests a theory of liability that would implode the practice-of-medicine exemption and upend the FDCA: "[H]ealthcare providers" are "place[d] …in the chain of distribution" when they deliver puberty blockers and hormone therapy via implant or injection. *Id.* ¶ 23.

That theory is fundamentally unsound. "Choosing what treatments are or are not appropriate for a particular condition"—including gender dysphoria—"is at the heart of the practice of medicine." *Judge Rotenberg Educ. Ctr., Inc. v. FDA*, 3 F.4th 390, 400 (D.C. Cir. 2021). In Pennsylvania, the use of puberty blockers and hormone therapy to treat that condition is lawful. *See United States v. Skrmetti*, 145 S. Ct. 1816, 1836 (2025) ("We afford States 'wide discretion to pass legislation in areas of medical and scientific uncertainty.'"). Accordingly, in the collective view of the courts, the FDA, and OLC, such conduct falls *outside* the scope of the FDCA and cannot form a basis for liability under its provisions.[7]

[7] Critically, the Hsiao Declaration fails to raise even a hint of suspicion that CHOP physicians are engaging in the kinds of activities that could trigger liability under the prevailing view of the FDCA, which limits enforcement to scenarios in which physicians are operating outside accepted medical practice and/or acting as manufacturers of unapproved products. *See e.g.*, Press Release, DOJ, *Bluefield Doctor Pleads Guilty to Misbranding* (Aug. 2020) (doctor dispensed drugs "outside the usual course of professional practice" to patients who were not examined and did not pay for visits); Press Release, DOJ, *Georgia Doctor Pleads Guilty to Distributing Misbranded Weight Loss Drug Product* (Apr. 2023) (doctor sold sublingual form of drug approved as injectable where drug was produced in unregistered facility and bore inaccurate label); *United*

Once the flaws in the Government's theory are understood, its justification for demanding patient information falls apart. The Government cannot ground its demand in the need to "establish[] . . . the scale of potential FDCA violations" (Hsiao Dec. ¶ 41) when the underlying conduct does not violate the statute. Likewise, "clinical record[s]" linked to "billing and insurance claims,"[8] "disclosure of off-label use", and "informed consent" cannot show "fraudulent intent" (*id.*) sufficient to "transform[] a misdemeanor FDCA violation into a felony" where there is no potential violation to "transform" (*id.* ¶ 20). And interrogating families about conversations with providers cannot illuminate potential FDCA violations when those interactions occurred outside the bounds of the statute. *See id.* ¶ 41.

B. *The Government's new argument does not improve its showing on Factor 5*

In response to CHOP's Motion, the Government contended that the protections against disclosure of information gathered pursuant to the Subpoena were adequate because HIPAA "broadly prohibits the government from using or disclosing 'health information about an individual' that is obtained via subpoena." *See* ECF 13 at 8-9 (quoting 18 U.S.C. § 3486(e)(1)). The Government abandons that argument in its Opposition to the Patients' Motion, relying instead on the general terms of the Privacy Act, 5 U.S.C. § 552a, and the presumption that officials honor their obligations to maintain confidentiality over sensitive material. *See* Br. in Opp. at 16.

The Government's new argument gets it no further than its old one. As CHOP explained in its Motion, the Privacy Act allows disclosure to entities that are *not* foreclosed

States v. Merlino, 627 F. Supp. 3d 450 (E.D. Pa. 2022) (retired doctor sold industrial chemical as weight loss drug); *U.S. v. Regenerative Sciences*, LLC, 741 F.3d 1314, 1319-20 (D.C. Cir. 2014) (rejecting "practice of medicine defense" in civil misbranding case where physicians produced a substance FDA deemed unsafe).

[8] The Hsiao Declaration does not indicate that the Government is investigating False Claims Act violations and cites a delegation limiting the investigation to "violations of the FDCA." Hsiao Declaration ¶ 5.

from disseminating that information to the public. ECF 1 at 18-19 (citing 5 U.S.C. § 552a(b)(9)). The secrecy regimes the Government cites (Br. in Opp. 16)—applicable to grand-jury material, Title III intercepts, and FISA-generated information—are vastly different. Unlike section 3486, each of those statutes or rules *itself* bars disclosure, often under threat of civil and criminal penalties. *See* FED. R. CRIM P. 6(e)(2)(B)(vi),(7) ("Rule 6(e)"); 18 U.S.C. § 2520(a),(f),(g); 50 U.S.C. § 1809(a)(3),(c). And unlike the Privacy Act, those regimes limit the uses to which entities that receive authorized disclosures may put the information. *See*, *e.g.*, Rule 6(e)(3)(B), (E)(iii)-(v); 18 U.S.C. § 2517(1),(6),(7),(8); 50 U.S.C. § 1801(h)(1)-(4). Absent similar guardrails, the risk of disclosure is intolerably high.

C. *The privacy-focused factors far outweigh any countervailing interest*

The Government's new evidence and arguments do nothing to undercut CHOP's showing on Factors 1, 2, and 4, which weigh heavily against disclosure. With respect to Factor 3—the potential harm from disclosure—the Hsiao Declaration validates CHOP's concerns. The Declaration confirms that the Government will use patient records to query witnesses about confidential communications with their healthcare providers in service of assessing whether those providers offered "false or misleading information" in connection with treatment. Hsiao Dec. ¶ 41. As CHOP explained, if patients are "questioned about [their] care" and "made to feel that their statements could call into question the actions of" their doctors, they could have "feelings of guilt and fear that would be very damaging to [their] mental health." ECF 1, Ex. B. ¶ 16. Even absent further dissemination, then, disclosure of patients' health information to the Government threatens significant harm.

CONCLUSION

The Motion to Limit the Subpoena should be granted.

Dated: October 20, 2025

Respectfully submitted,

/s/ Lawrence G. McMichael
Lawrence G. McMichael (Pa. ID 28550)
Nina C. Spizer (Pa. ID 82443)
Timothy J. Ford (Pa. ID 325290)
Dilworth Paxson LLP
1650 Market Street, Suite 1200
Philadelphia, PA 19103
(215) 575-7000

Martine E. Cicconi
Charles F. Connolly
Raphael R. Prober
Akin Gump Strauss Hauer & Feld
2001 K ST, N.W.
Washington, D.C., 20006
Tel: 202-887-4024
mcicconi@akingump.com
cconnolly@akingump.com
rprober@akingump.com

Attorneys for Respondent, The Children's Hospital of Philadelphia

CERTIFICATE OF SERVICE

I, Lawrence G. McMichael, Attorney for Respondent, hereby certify that I have served the foregoing *Reply in Support of Motion to Limit the Subpoena* upon the below Attorneys for Requestor via electronic mail on this day, October 20, 2025.

Brett Shumate, Assistant Attorney General -- Brett.a.shumate@usdoj.gov

Ross Goldstein – Ross.goldstein@usdoj.gov

Patrick Runkle – Patrick.r.runkle@usdoj.gov

Francisco Unger – Francisco.l.unger@usdoj.gov

Tiara Johnson – Tiara.a.johnson@usdoj.gov

Jordan Campbell – Jordan.c.campbell@usdoj.gov

/s/ Lawrence G. McMichael
Lawrence G. McMichael

EXHIBIT A

DECLARATION OF LISA K. HSIAO

Pursuant to 28 U.S.C. § 1746, I, Lisa K. Hsiao, hereby declare as follows:

GENERAL BACKGROUND

1. I am the Acting Director of the Enforcement and Affirmative Litigation Branch ("EALB") within the United States Department of Justice.

2. EALB's Enforcement Section ("Enforcement") is the successor to the Consumer Protection Branch ("CPB") and is vested with all of CPB's legal authorities, including handling investigations and litigation arising under federal statutes that protect consumers' health, safety, economic security, and identity integrity. Enforcement, as the successor to CPB, is authorized to oversee and conduct all civil and criminal matters arising under the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301, *et seq*. *See* 28 C.F.R. § 0.45(i) and Justice Manual 4-8.000.

3. Through Presidentially-appointed, Senate-confirmed officers of the Department of Justice, Enforcement is authorized to undertake appropriate investigations of any violations of the Food, Drug, and Cosmetic Act (FDCA) relating to the on- or off-label use by manufacturers and distributors of drugs, including puberty blockers, sex hormones, or any other drug used to facilitate a child's so-called "gender transition." *See* AG Bondi Memo dated April 22, 2025.

4. The Attorney General may authorize other officers of the Department of Justice to perform certain functions of the Attorney General. *See* 28 U.S.C. § 510. In any investigation of a federal health care offense, the Attorney General may issue in writing and cause to be served a subpoena requiring the production and testimony described in 18 U.S.C. § 3486(a)(l)(B). *See* 18 U.S.C. § 3486(a)(l)(A).

5. Pursuant to Attorney General Order Number 3591-2015, dated November 10, 2015, the Attorney General authorized the Assistant Attorney General for the Civil Division to issue and serve administrative subpoenas pursuant to 18 U.S.C. §§ 3486(a)(l)(A) and (a)(l)(B) to investigate violations of the FDCA that relate to a health care benefit program.

6. The subpoena to Children's Hospital of Philadelphia ("CHOP"), No. 25-1431-014 was lawfully issued and authorized by Brett A. Shumate, Assistant Attorney General for the Civil Division, in connection with a valid investigation being conducted in my office.

7. The facts in this Declaration come from my personal observations, my training and experience, and information obtained from other government personnel. This Declaration is intended to demonstrate that the administrative subpoena discussed herein was issued in the furtherance of an investigation authorized by law, and that the records and other things the subpoena seeks are relevant to that investigation. Accordingly, this Declaration does not set forth all my knowledge about this matter.

LEGAL BACKGROUND

8. The overriding purpose of the FDCA is to protect the public health. *United States v. Article of Drug … Bacto-Unidisk*, 394 U.S. 784, 798 (1969). The FDCA's purpose should "infuse construction of the [FDCA]" so that courts give the FDCA a liberal construction that furthers protection of the public health, including in criminal enforcement of the FDCA. *Id. United States v. Dotterweich*, 320 U.S. 277, 280 (1943); *See also United States v. Park*, 421 U.S. 658, 672–73 (1975). This consideration applies even more strongly where the Government seeks to enforce the FDCA to protect the health of children.

9. A "federal healthcare offense" for purposes of a subpoena issued under 18 U.S.C. § 3486 is defined by 18 U.S.C. § 24(a) 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 benefit program." 18 U.S.C. § 24(a). The statute defines "health care benefit program" to mean "any public or private plan or contract, affecting commerce, under which any medical benefit, item, 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). A subpoena issued under Section 3486 (commonly referred to as a "HIPAA subpoena") may be used to investigate both substantive 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 a private or public health insurance program.

10. Administrative subpoenas issued under 18 U.S.C. § 3486 are routinely used to obtain categories of medical, billing, and related information in federal healthcare offense investigations. The materials requested by the subpoenas issued in this investigation fall within that framework and include the same kinds of records—patient files, insurance submissions, treatment documentation, and communications (such as emails)—that federal investigators typically review to determine whether a federal health care offense may have occurred.

FDA'S APPROVAL OF DRUGS

11. The FDCA regulates the development, manufacturing and distribution of drugs in the United States. For a "new drug" to enter interstate commerce, the manufacturer must first demonstrate to the United States Food and Drug Administration ("FDA") that the drug is both safe and effective for each of its intended uses. 21 U.S.C. §§ 331(d), 355(a). The introduction into interstate commerce of an unapproved new drug violates the FDCA. 21 U.S.C. § 331(d).

12. A drug manufacturer obtains FDA approval for a new drug through a new drug application ("NDA") that demonstrates that its drug is safe and effective for each of its intended uses. 21 U.S.C. § 355(a). As part of the approval process, FDA reviews the proposed labeling for

the drug in the NDA, which must include adequate directions for how to use the drug for each of its intended uses. 21 U.S.C. § 352(f); 21 C.F.R. § 201.5. When FDA approves an NDA, it determines that the drug is safe and effective **for the specific use or uses identified in the application.** As part of that approval, FDA also approves the product's proposed labeling, including prescribing information, as providing adequate directions for use for those approved indications. FDA's approval of a drug for one or more particular uses does **not** mean that the drug is safe and effective for unapproved uses, nor does approval mean that the labeling provides adequate directions for unapproved uses. While physicians are permitted to prescribe an FDA-approved drug for an unapproved use, such prescribing may warrant investigation because it may provide evidence of FDCA violations. Also, depending on the circumstances, prescribing for unapproved uses can itself involve FDCA violations—for example, where the physician is engaged in the distribution or labeling of an unapproved drug.

MISBRANDING OF DRUGS PRESCRIBED FOR UNAPPROVED USES THROUGH ILLEGAL LABELING

13. A drug is misbranded if its labeling does not have adequate directions for the use of the drug. 21 U.S.C. § 352(f). FDA-approved labeling contains directions only for the drug's approved uses. If a drug manufacturer or other person distributes an approved drug for an unapproved use, the manufacturer or other person could be charged with misbranding the drug or distributing a misbranded drug with labeling that lacks adequate directions for its intended uses.[1] 21 U.S.C. §§ 331(a), 331(b), 331(c), 331(k), and 352(f)(1). CPB has participated in successful prosecutions of drug manufacturers for such illegal conduct. *See, e.g.*, *United States v. Pharmacia & Upjohn Co.*, Case No. 09-CR-10258-DPW (D. Mass. 2009); *United States v. Eli Lilly & Co.*, Case No. 09-CR-00020-RK (E.D. Pa. 2009).

[1] As noted above, it is possible for doctors to prescribe an approved drug for an unapproved use without violating the FDCA.

14. A drug is also misbranded if its labeling is false or misleading in any particular. 21 U.S.C. § 352(a).

15. Under the FDCA, drug labeling is broadly defined as any "written, printed, or graphic matter … *accompanying*" the drug. 21 U.S.C. § 321(m) (emphasis added). The term "accompanying" is interpreted broadly and includes materials that are separate from the drug but nonetheless related to it, including any material that supplements, explains, or is designed for use with the drug. *See* 21 U.S.C. § 321(m); 21 C.F.R. § 1.3(a); *Kordel v. United States*, 335 U.S. 345 (1948); *United States v. Urbuteit*, 335 U.S. 355 (1948); *United States v. 47 Bottles … Jenasol RJ Formula 60*, 320 F.2d 564, 569 (3d Cir. 1963) (literature shipped by company to sales agent and then stored in agent's bedroom closet was labeling: "[I]t cannot be said that … the Court promulgated or intended to promulgate a requirement that there be an actual use in order that the literature constitute labeling."). Labeling can include promotional materials, advertisements, brochures, flyers, instruction sheets, posters, and similar materials.

16. If a drug manufacturer or other person distributes (or causes the distribution of) an approved drug with false or misleading labeling for an unapproved use, the manufacturer or other person could possibly be charged with misbranding the drug or distributing a misbranded drug. 21 U.S.C. §§ 331(a), 331(b), 331(c), 331(k), and 352(a). CPB has participated in successful prosecutions of manufacturers for false and misleading labeling. *See, e.g., United States v. Avanos Medical, Inc.*, Case No. 21-CR-0307-E (N.D. Tex. 2021) (deferred prosecution agreement for false and misleading labeling for medical device).

ILLEGAL DISTRIBUTION OF AN UNAPPROVED NEW DRUG

17. A "new drug" is any drug that is "not generally recognized, among [qualified] experts . . . as safe and effective for use under the conditions prescribed, recommended, or suggested in the *labeling* thereof … ." 21 U.S.C. § 321(p)(1) (emphasis added). Even if a substance has been

on the market for years, it can be a "new drug" if used for an indication that has not been approved by FDA and is not generally recognized as safe and effective for that indication. The vast majority of prescription drugs on the market are "new drugs" under the FDCA.

18. If a drug manufacturer or other person distributes (or causes the distribution of) an approved drug for an unapproved use with labeling for that unapproved use, the manufacturer or other person could be charged with distributing an unapproved new drug in violation of the FDCA. 21 U.S.C. § 331(d).

INTENT IN FDCA CRIMES

19. A violation of 21 U.S.C. § 331 is a federal criminal offense that is punished as a strict liability misdemeanor without any proof of criminal intent. *See Park*, 421 U.S. at 672–73; *United States v. Wiesenfeld Warehouse Co.*, 376 U.S. 86, 91 (1964). Through its strict liability misdemeanor provision, the FDCA imposes rigorous criminal accountability on companies and individuals involved with drugs that affect the health of consumers in circumstances where consumers realistically cannot protect themselves. *See Weisenfeld*, 376 U.S. at 91; *Dotterweich*, 320 U.S. at 280–81. This heightened accountability is even more acute when the consumers at risk are children. Consequently, any violation of Section 331, including the causing of any prohibited act listed in Section 331, is a federal crime, even in the absence of any criminal intent.

20. A felony FDCA violation requires the same conduct as the strict liability misdemeanor, but with the added element of an intent to defraud or mislead. 21 U.S.C. § 333(a). Evidence of intent to defraud or mislead—whether directed at a government agency, a patient, or an insurance company—thus transforms a misdemeanor FDCA violation into a felony offense. Evidence of an intent to defraud or mislead a government agency or another third-party, such as a patient or insurer, in connection with an FDCA violation is sufficient to establish a felony FDCA

offense. Efforts to conceal a violation or evade detection also can demonstrate the requisite intent to defraud or mislead.

THE DRUGS AT ISSUE IN THIS INVESTIGATION

21. This investigation focuses on prescription drugs typically used in gender-related care for children and adolescents suffering from a recognized mental disorder known as gender identity disorder or, as the most recent version of the American Psychiatric Association's DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS refers to it, gender dysphoria. Included in this group of prescription drugs are (1) drugs used to suppress the production of sex hormones to delay puberty—the most common being gonadotropin-releasing hormone agonists ("GnRH agonists"), commonly referred to as "puberty blockers;" and (2) cross-sex hormones meant to induce physical changes to alter the child's secondary sexual characteristics to resemble those typically seen in the opposite sex and less like the individual's biological sex. Testosterone, a Schedule III controlled substance under the Controlled Substances Act, is included in this latter group.

22. FDA has not determined these drugs to be either safe or effective for the treatment of gender dysphoria. Nor has FDA approved any of these drugs for the treatment of gender dysphoria or any other psychiatric disorder. While these prescription drugs are FDA-approved for other indications (e.g., precocious puberty, prostate cancer, hypogonadism, etc.), FDA has not approved any NDA that establishes the safety and efficacy of these drugs for use in minors with gender dysphoria. As explained above, introducing a such "new drug" into interstate commerce without an FDA-approved indication is unlawful. Thus, to the extent these drugs are intended to treat gender dysphoria in minors, they constitute unapproved new drugs under federal law, and their distribution for that unapproved indication violates the FDCA and is a federal crime.

23. Some of these drugs, including puberty blockers, are not administered orally. Rather, they are typically administered by injection by a medical professional or through an outpatient surgical procedure to implant the drug. Puberty blockers are typically implants or injectables that require administration by a physician or nurse in a medical facility that must purchase, store, and administer the drug, placing healthcare providers in the chain of distribution of that drug. Similarly, testosterone may be, and often is, administered by injection.

24. The United States Government is aware of credible, publicly available evidence relating to the widespread practice of prescribing cross-sex hormones and puberty blockers to treat gender dysphoria in minors that casts doubt on the safety and efficacy of this practice. The United States Department of Health and Human Services ("HHS"), of which FDA is a component agency, has determined that the evidence for the safety and efficacy of these drugs for the treatment of gender dysphoria in minors is weak. *See generally*, U.S. Dep't of Health & Human Svcs., *Treatment for Pediatric Gender Dysphoria: Review of Evidence and Best Practices* (May 2025), https://opa.hhs.gov/gender-dysphoria-report. Specifically, HHS found that some of the pharmacologic interventions under investigation here "carry risk of significant harms including infertility/sterility, sexual dysfunction, impaired bone density accrual, adverse cognitive impacts, cardiovascular disease and metabolic disorders, [and] psychiatric disorders." *Id.* at 10. HHS further determined that "the overall quality of [scientific] evidence concerning the effects of any intervention on psychological outcomes, quality of life, regret, or long-term health is **very low**." *Id.* at 13 (emphasis added).

25. The Government is also aware of other major scientific publications and national health authorities that have questioned the strength and quality of the evidence base for the efficacy of puberty blockers and other medical interventions to treat youth for gender dysphoria. In the United Kingdom, for example, the British National Health Service ("NHS") commissioned

an independent review led by Dr. Hilary Cass, a pediatrician and the former President of the Royal College of Pædiatrics and Child Health, to evaluate how NHS was providing care for children experiencing gender-related distress. *See generally* NHS England, *Independent Review of Gender Identity Services for Children and Young People: Final Report* (Apr. 10, 2024), https://cass.independent-review.uk/home/publications/final-report/ ("*Cass Review*"). Dr. Cass's review concluded: "This is an area of remarkably weak evidence, and yet results of studies are exaggerated or misrepresented by people on all sides of the debate to support their viewpoint. The reality is that we have no good evidence on the long-term outcomes of interventions to manage gender-related distress." *Cass Review* at 13.

26. With regard to puberty blockers, Dr. Cass reported that a systematic review conducted by the University of York "found no evidence that puberty blockers improve body image or dysphoria" while "a known side effect of puberty blockers on mood is that it may reduce psychological functioning." *Id.* at 179. Regarding cross-sex hormones, the *Cass Review* agreed with another systematic review that concluded that:

> There is a lack of high-quality research assessing the outcomes of hormone interventions in adolescents with gender dysphoria/incongruence, and few studies that undertake long-term follow up. No conclusions can be drawn about the effect on gender dysphoria, body satisfaction, psychosocial health, cognitive development, or fertility. Uncertainty remains about the outcomes for height/growth, cardiometabolic and bone health.

Id. at 184.

27. As a result of the *Cass Review's* findings, in December 2024, the United Kingdom banned puberty blocker treatment for gender dysphoria. *See* Press Release, U.K. Dep't of Health & Soc. Care, *Ban on Puberty Blockers to be Made Indefinite on Experts' Advice* (Dec. 11, 2024), https://www.gov.uk/government/ news/ban-on-puberty-blockers-to-be-made-indefinite-on-experts-advice (stating that "there is currently an unacceptable safety risk in the continued prescription of puberty blockers to children"). Press reports indicate that Great Britain is

similarly considering banning cross-sex hormones for minors. *See* Alison Holt, *Cross-Sex Hormones for Under 18s Could be Restricted or Banned*, BBC NEWS (May 22, 2025), https://www.bbc.com/news/articles/cg711xevd89o.

28. Other European countries have likewise enacted restrictions on the use of these pharmacologic interventions for treating gender-related disorders in minors, or are considering them. *See, e.g., Sweden Puts Brakes on Treatments for Trans Minors*, FRANCE 24 (Aug. 2, 2023), https://www.france24.com/en/live-news/20230208-sweden-puts-brakes-on-treatments-for-trans-minors; Siobhan Harris, *Europe and the Puberty Blocker Debate*, MEDSCAPE MED. NEWS (Apr. 25, 2024), https://www.medscape.com/viewarticle/europe-and-puberty-blocker-debate-2024a1000831 (reporting on European countries' practices and findings including France's National Academy of Medicine recommendation that the "greatest reserve" be used in puberty blockers and/or hormones in children and adolescents; Sweden's conclusion that risks of puberty blockers and hormones currently outweigh potential benefits).

29. Both the HHS review and the UK's independent *Cass Review*—along with numerous other systematic reviews of the evidence that the Government is aware of—justify questioning the scientific foundation for prescribing puberty blockers and cross-sex hormones for minors as limited and potentially problematic. It is far from certain, therefore, that prescribing these drugs—that have not been approved by FDA for treating minors with gender-related disorders—would ever be considered by the agency as safe and effective for that indication. To the contrary, the available public record suggests there is serious potential for harm.

EVIDENCE OF FDCA AND HEALTH CARE FRAUD VIOLATIONS IN PEDIATRIC GENDER-RELATED CARE

30. From testimonies of public whistleblowers and leading national medical experts on the subject matter, the Government is aware of potential violations of federal law in connection

with the provision of gender-related treatments for minors occurring at healthcare providers across the country.

31. This includes allegations and evidence of fraudulent billing practices to secure insurance coverage/payment. Such practices include, but are not limited to, providers (i) using the incorrect diagnosis and/or billing code (e.g., "endocrine disorder, unspecified" instead of "gender dysphoria" to prescribe cross-sex hormones, or "precocious puberty" instead of "gender dysphoria" to prescribe puberty blockers) because they know that certain insurance plans may not cover the off-label prescription of puberty blockers or cross-sex hormones for gender-related treatment[2]; (ii) changing or misrepresenting a patient's sex in the medical records and coding and billing for "endocrine imbalance," which is supported by accompanying bloodwork showing endocrine levels atypical of the incorrectly documented sex (but consistent with the patient's actual sex); and (iii) fraudulently making a gender dysphoria diagnosis where patients do not meet the DSM-5 diagnostic criteria, but the providers know that the carrier or plan will cover off-label prescription of cross-sex hormones or puberty blockers to treat gender dysphoria.

32. The Government also knows of evidence and allegations of many cases where providers failed to provide adequate labeling and to provide the information necessary to obtain informed consent, actively deceived patients and parents with false claims and statements regarding the drugs' effectiveness or alternatives, and misrepresented to minor patients and their parents the risks associated with and the science claimed to support taking the drugs described herein for gender dysphoria.

33. The Government has also reviewed evidence (including transcripts and video recordings) from national conferences on treating transgender patients, including minors,

[2] In fact, one nonprofit organization has published guidance to health care providers advising them of "coding alternatives for trans healthcare," which detailed "codes that are commonly rejected by insurance providers" and "codes that are commonly accepted by insurance providers."

wherein presenters describe and encourage attendees to engage in the provision of purely patient-driven care (or "embodiment goals"), with little regard for gender dysphoria diagnoses, assessment, or clinical criteria. These recommendations include prescribing cross-sex hormones and puberty blockers to minors. The Government is concerned that such facially deficient care may be accompanied by facially deficient or misleading labelling.

34. CHOP's Gender & Sexuality Development Clinic is one of the largest pediatric gender clinics in the country. Given the significant number of children treated at CHOP's gender clinic, combined with its knowledge that potential federal healthcare offenses may systematically be occurring in the provision of gender-related medical care for minors, the Government has ample reason to suspect that such offenses may be occurring at CHOP. Beyond that, the Government is aware of information particular to CHOP that raises concern that federal healthcare offenses may be occurring there.

35. This includes extensive anonymized insurance claims data analyses of claims submitted by clinicians at CHOP, which is being conducted by a Government contractor. Based on diagnosis codes, it appears that between 2017 and 2024, there were almost 250 minors first diagnosed at CHOP or a CHOP affiliate with central precocious puberty at age 10 or older, including numerous teenagers aged 14 to 18. This is well beyond the age at which children are typically diagnosed with precocious puberty.

36. The Government is also aware of a lawsuit filed just this year that details very concerning allegations of a minor being put on puberty blockers after his first visit and cross-sex hormones after his second with no meaningful assessment, as well as failure to provide him the necessary information regarding the risks of taking such medications. That is, the allegations of a former CHOP patient support the Government's suspicion that CHOP may be engaging in exactly the types of practices the Government is investigating.

THE SUBPOENA SPECIFICATIONS SEEK INFORMATION RELEVANT TO THE INVESTIGATION

37. The fifteen requests in the investigative HIPAA subpoena issued to CHOP seek to further the investigation described above. The requests can be broadly broken down into four main categories: (1) requests related to personnel and corporate oversight (Request 1); (2) requests related to billing, coding, and reimbursement practices (Requests 2–6); (3) requests related to the practice's relationships with drug manufacturers, distributors, and pharmacies (Requests 7–10); and (4) requests regarding clinical practices and drug safety (Requests 11–15). All the subpoenaed records and documents are relevant to the federal healthcare investigation described herein. *See* 18 U.S.C. § 3486(a)(1).

38. Request 1 seeks information to identify who had authority to direct prescribing, billing, or marketing practices to determine liability. Under strict liability doctrines, including the responsible corporate officer doctrine, officers and responsible personnel can be held criminally liable for FDCA violations even without direct participation. Personnel files also show financial incentives, disciplinary history, and/or training which can establish knowledge and intent.

39. The requests in the second group (regarding billing, coding, and reimbursement practices) are necessary to determine whether the clinic disguised treatment for gender-related mental disorders as another, physical illness (*e.g.,* endocrine disorder) to secure health benefit program reimbursement. Such practices are especially important to demonstrate an "intent to defraud or mislead" under 21 U.S.C. § 333(a)(2) if the clinic misrepresented the intended use of the drugs. Moreover, training materials and internal discussions can reveal whether improper coding was a deliberate strategy.

40. The third group of requests (relating to relationships with drug manufacturers, distributors, and pharmacies) are probative of an intent to market or promote drugs for unapproved uses. If CHOP, or one of its affiliated healthcare providers, received promotional

materials, "scientific exchange information," or payments to encourage prescribing of puberty blockers or cross-sex hormones, such information would support a FDCA theory (including conspiracy) involving unlawful off-label promotion. Similarly, information regarding financial arrangements (consulting agreements, sponsorships, speaking honoraria) may suggest improper influence to reinforce a showing an intent to misbrand, including with intent to defraud or mislead.

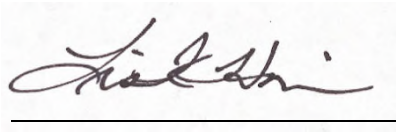
41. The final group of requests (relating to patient-level clinical practices and drug safety) will permit the United States to evaluate the scope of prescribing the drugs described herein (including the number and age range of patients treated), and consistency of diagnoses. It also establishes the scope of interstate distribution and the scale of potential FDCA violations. Linking each patient's clinical record to corresponding billing and insurance claims can demonstrate whether diagnoses were miscoded, which can prove fraudulent intent. Documentation of clinical justification, informed consent, and disclosure of off-label use is key to assessing whether the clinic (and/or potential co-conspirators) concealed or downplayed risks associated with using these drugs in a manner not approved by FDA. Absence or minimization of such warnings could establish the intent to mislead. Patient charts also typically capture adverse outcomes, side effects, and complications of drug use. By reviewing multiple patient records, the investigative team may reveal systemic use of the same masking codes, fraudulent informed consent documents, etc. This enables investigators to distinguish between mere errors and an institutionalized practice. Finally, providing patient records, including patient identities, can provide essential investigative leads. Parents may be witnesses about what disclosures were made. Patients (depending on age and circumstances) may provide information about the informed consent process, side effects, or other false or misleading information about the drugs conveyed during treatment. Health benefit programs tied to identified patients could provide

additional information, including claim records, creating a triangulated evidentiary record. In sum, without this information, the Government 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).

GOVERNMENT INVESTIGATIVE RESOURCES

42. This is a bona fide, high-priority, and substantial national investigation of potential FDCA violations in the provision of gender-related care for minors. Substantial government resources have been assigned to it. It is being handled by several veteran, career prosecutors with many decades of experience in healthcare fraud and FDCA enforcement between them, supported by a team of document analysts and other forensic specialists. The Federal Bureau of Investigation has assigned agents and analysts to assist with various field activities and is employing advanced data analytics to identify prescribing patterns, potential unlawful off-label promotion, and patterns in reimbursement. The scope and coordination of these efforts reflect the seriousness with which the Government is pursuing potential violations of federal law.

I declare under penalty of perjury that the foregoing is true and correct. Executed on this 6th day of October, 2025.



LISA K. HSIAO
Acting Director
Enforcement & Affirmative Litigation Branch
United States Department of Justice