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

IN RE: SUBPOENA NO. 25-1431-014	**:**	**MISCELLANEOUS ACTION**
	:	
	:	**NO. 25-39**

MEMORANDUM

KEARNEY, J. **November 21, 2025**

Our elected Congresspersons granted the Department of Justice limited authority in 1996 to investigate federal health care offenses involving the labeling and distribution of prescription drugs. The Department of Justice is now investigating the labeling and distribution of prescribed clinically authorized puberty blockers and hormone therapy. It subpoenaed fifteen categories of records from The Children's Hospital of Philadelphia including billing and insurance records, communications with manufacturers and sales representatives, and the names and complete medical and psychological records of children receiving gender-affirming care. The Hospital agrees to produce most of the requested materials. But it objects to producing the identities of its child patients and their families along with their confidential medical files. Its objection requires we study two questions: whether Congress authorized a subpoena for the children's confidential medical records, and, if so, whether the children's privacy interests outweigh the Department of Justice's need for these confidential medical records under the Food, Drug, and Cosmetic Act.

We find the answer to both questions is "no." We strike the three requests for these child-identifying and treatment and disclosure records as beyond the authority granted by Congress. We also find, even if this private information could be relevant, the heightened privacy interests of children and their families substantially outweighs the Department's need to know the children's names, addresses, and treatment along with disclosures for gender-affirming care at The Children's Hospital of Philadelphia.

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We review three document requests demanded under a subpoena issued by the United States Department of Justice to The Children's Hospital of Philadelphia seeking the identity of child patients and their medical treatment under the Hospital's long-established program offering gender-affirming medical care. We appreciate the Department of Justice enforces the Food, Drug, and Cosmetics Act. It should do so by ensuring compliance with the Act's requirements governing the manufacturing, distribution, and labeling of drugs in interstate commerce and by prosecuting violations of those requirements. But it remains governed by law and its conduct is subject to the scrutiny of judges and juries. The three document requests to the Hospital before us today seek the identity of transgender children and their treatment seeking the most confidential of medical information in an environment where the described policy of the United States is to end this prescribed medical care notwithstanding Pennsylvania's exclusive authority to allow it.

The Commonwealth retains the police power to supervise medical procedures and care.

The three requests warrant a return to fundamentals set by our Framers and the persons we elect to Congress. The Framers reserved the police power, and with it the authority to set standards of medical care, to the states such as Pennsylvania.[1] Pennsylvania regulates the practice of medicine through its exercise of state police powers to protect public health and safety. It exercises its traditional police powers to protect vulnerable groups against discrimination and to ensure equal access to care. The Commonwealth, for example, has long adopted civil rights protections for transgender people in areas such as education, employment, housing, and public accommodations.[2] Pennsylvania Governor Shapiro confirms gender-affirming medical care is legal in the Commonwealth.[3] The Commonwealth covers gender-affirming care through its Medicaid program and bars state-regulated health insurance plans from denying coverage based on gender identity or gender dysphoria.[4] No Pennsylvania professional licensing board has ever found gender-affirming

care when provided consistent with the Commonwealth's standard of care to be inappropriate.[5] But this does not reflect an unwillingness to police harmful medical practices including in sexual identity. For example, several Pennsylvania licensing boards adopted policies condemning conversion therapy as harmful and unprofessional conduct, subject to administrative discipline, due to its discredited pseudoscientific basis and significant emotional and psychological harm it inflicts on children.[6]

The Hospital offers medical care for transgender children for the last eleven years.

The Commonwealth through its police powers closely supervises the Hospital.[7] The Hospital opened its Gender and Sexuality Development Program in 2014 consistent with Pennsylvania law.[8] The Program "offers psychosocial and medical support for transgender children, adolescents, young adults and their families" and "provides services based on individual and family needs, including comprehensive assessments, monthly support groups, connections to community resources, and, where appropriate, medical care."[9] Patients describe the Program as a "safe space to share their experience without fear of repercussions" and characterize the medical care they receive "as a lifeline."[10]

Families guide the medical care decisions for their transgender children under the Program.[11] Each child begins with an assessment by a mental health provider involving the child and their parent or guardian.[12] The assessment process then includes a "comprehensive psychosocial evaluation" if gender dysphoria is under consideration.[13] The psychosocial evaluation "typically involves patients sharing intimate and extremely sensitive personal details, often touching on such subjects as discomfort with specific body parts, sexual history, past trauma, interfamilial dynamics, use of self-harm or other negative coping mechanisms that may risk their health and well-being such as disordered eating, and experiences of harassment and bullying."[14]

The evaluation also considers the patient's "cognitive abilities, executive function skills, communication skills, emotional functioning, self-awareness/social cognition, and capacity for decision-making."[15] If gender dysphoria is diagnosed, the care plan is tailored to the patient's age, development, and specific needs.[16] Treatment proceeds if the family and care team agree on the plan and after a discussion of risks, benefits, and alternatives.[17] Treatment can include puberty blocking medication and hormone therapy.[18] Medical care requires parental informed consent and the child's assent. [19] Care under the Program "is and has always been consistent with standards of care supported by leading medical organizations."[20]

The United States Government decided in January 2025 to end gender-affirming medical care.

President Trump issued Executive Order 14168 on his Inauguration Day, January 20, 2025, titled "Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government."[21] The President declared "[i]t is the policy of the United States to recognize two sexes, male and female[, and t]hese sexes are not changeable and are grounded in fundamental and incontrovertible reality."[22]

The President issued a second Executive Order 14187 on January 28, 2025 titled "Protecting Children From Chemical and Surgical Mutilation."[23] The President, through Executive Order 14187, pronounced "medical professionals are maiming and sterilizing a growing number of impressionable children under the radical and false claim that adults can change a child's sex through a series of irreversible medical interventions."[24] The President proclaimed "this dangerous trend" is "a stain on our Nation's history" and "it must end."[25] The President further declared "it is the policy of the United States that it will not fund, sponsor, promote, assist, or support the so-called 'transition' of a child from one sex to another, and it will rigorously enforce all laws that prohibit or limit these destructive and life-altering procedures."[26] The President defined "chemical

and surgical mutilation," which "sometimes is referred to as 'gender-affirming care'" as "the use of puberty blockers . . . to delay the onset or progression of normally timed puberty in an individual who does not identify as his or her sex; the use of sex hormones . . . to align an individual's physical appearance with an identity that differs from his or her sex; and surgical procedures that attempt to transform an individual's physical appearance to align with an identity that differs from his or her sex or that attempt to alter or remove an individual's sexual organs to minimize or destroy their natural biological functions."[27]

The President, through Executive Order 14187, directed federal agencies funding research or education at medical institutions to "immediately take appropriate steps to ensure that institutions receiving Federal research or education grants end the chemical and surgical mutilation of children."[28] The President ordered the Department of Justice to "prioritize investigations and take appropriate action to end deception of consumers, fraud, and violations of the Food, Drug, and Cosmetic Act by any entity that may be misleading the public about long-term side effects of chemical and surgical mutilation."[29]

The United States Senate confirmed the President's nominee Pamela Bondi as Attorney General on February 4, 2025.[30] Attorney General Bondi issued a memorandum on April 22, 2025 titled "Preventing the Mutilation of American Children."[31] Attorney General Bondi described a "radical ideological agenda" of "teach[ing] children to deny biological reality" and issued "guidance to all Department of Justice employees to enforce rigorous protections and hold accountable those who prey on vulnerable children and their parents."[32]

Attorney General Bondi claimed her authority through Congress's prohibitions in the Food, Drug, and Cosmetic Act focusing on manufacturers and distributors promoting off-label uses for approved drugs. She directed federal prosecutors must now "act decisively to protect our children

and hold accountable those who mutilate them under the guise of care" and to "undertake appropriate investigations of any violations of the Food, Drug, and Cosmetic Act by manufacturers and distributors engaged in misbranding by making false claims about the on- or off-label use of puberty blockers, sex hormones, or any other drug used to facilitate a child's so-called 'gender transition.'"[33] "Even if otherwise truthful, the promotion of off-label uses of hormones—including through informal campaigns like those conducted by sales reps or under the guise of sponsored continuing medical education courses—run afoul of the [Food and Drug Administration]'s prohibitions on misbranding and mislabeling."[34] Attorney General Bondi further described gender-affirming care as "an unconscionable ideology" and pledged "the Department of Justice will bring these practices to an end."[35]

Congress regulates drug manufacturing, labeling, and distribution through the Food, Drug, and Cosmetic Act.

The Department of Justice based its investigation on perceived violations of the Food, Drug, and Cosmetic Act. Congress, through the Act, sets the mandates governing the development, manufacture, labeling, and interstate distribution of drugs and medical devices.[36] Congress empowered the Food and Drug Administration to ensure drugs and devices are safe and effective for their intended uses before they may be introduced into interstate commerce.[37] A drug manufacturer must obtain Food and Drug Administration approval to market a prescription drug in the United States through the New Drug Application Process.[38] "[T]he manufacturer must demonstrate the drug's safety and effectiveness," meet manufacturing and facility requirements, and "obtain [Food and Drug Administration approval] of the drug's labeling.[39]

"Labeling" is defined broadly to include "all labels and other written, printed, or graphic matter" on or accompanying a drug.[40] This encompasses materials travelling with the product or supplementing its description—not only packaging materials but also promotional pieces

distributed by the manufacturer.[41] The Food and Drug Administration regulations treat a wide array of materials supplied by the manufacturer, packer, or distributor of the drug and which are disseminated by or on behalf of its manufacturer, packer, or distributor as labeling.[42]

Congress through Section 331 of the Act identifies the unlawful conduct and the section serves as the "heart of the enforcement provisions."[43] Congress acknowledges these "prohibitions have been described as a catalogue of definitions elaborating two basic concepts: 'adulteration' and 'misbranding,'" the Act's two principal categories of violations.[44] It is unlawful to introduce an adulterated or misbranded product into interstate commerce and violations carry criminal penalties, including strict-liability misdemeanors and felonies when committed with intent to defraud or mislead.[45]

Adulteration relates to a product's physical condition and can include contamination, improper manufacturing processes, or failure to meet established quality standards.[46] Misbranding concerns the accuracy and adequacy of a product's labeling and promotional representations and can include false or misleading labeling or inadequate directions for use.[47] Congress through the Act prohibits a manufacturer from selling a misbranded drug and from promoting or advertising a drug for any use not included in its Food and Drug Administration-approved labeling.[48] A drug is also misbranded if it lacks "adequate directions for use," meaning instructions allowing a layperson to use the drug safely for its intended purposes.[49] The drug's "intended use" is determined by the objective intent of the manufacturer or other entity responsible for the labeling, as reflected in its labeling, advertising, and statements by the manufacturer or its representatives.[50] Prescription drugs are exempt from the "adequate directions for use" requirement if dispensed by a licensed practitioner through a prescription.[51]

The Department of Justice further defines the scope of its investigation under the Food, Drug, and Cosmetic Act.

Attorney General Bondi's prosecutors set out to enforce her mandate to "act decisively to protect our children and hold accountable those who mutilate them under the guise of care."[52] Assistant Attorney General for the Civil Division Brett Shumate followed with a June 11, 2025 memorandum titled "Civil Division Enforcement Priorities."[53] Assistant Attorney General Shumate echoed the Executive Orders and Attorney General Bondi's views confirming the Department of Justice: "will use all available resources to prioritize investigations of doctors, hospitals, pharmaceutical companies, and other appropriate entities consistent with these directives."[54] Assistant Attorney General Shumate promised "these efforts will include, but will not be limited to, possible violations of the Food, Drug, and Cosmetic Act and other laws by (1) pharmaceutical companies that manufacture drugs used in connection with so-called gender transition and (2) dealers such as online pharmacies suspected of illegally selling such drugs."[55] Assistant Attorney General Shumate did not direct the Department of Justice to obtain children's and their families' identities or their confidential medical files.

The Department of Justice subpoenas the Hospital for records including the children's names, treatment records, and disclosures to their guardians.

The United States Department of Justice wasted no time implementing Attorney General Bondi's directives to investigate misbranding by manufacturers and distributors promoting off-label uses of puberty blockers and hormones. Assistant Attorney General Shumate issued more than twenty subpoenas to medical centers around the Nation "to investigate [f]ederal health care offenses" on the same day as his June 11, 2025 memorandum.[56] The Department served the Subpoena upon the Hospital the following day under the authority granted by Congress in 1996 under the statute commonly referred to as "HIPPA" (Health Insurance Portability &

Accountability Act of 1996).[57] Although Congress defines a "federal health care offense" more broadly, the Department limits its reliance here to "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."[58] Congress defines a "'[h]ealth 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.'"[59]

The Department of Justice in looking for a federal health care offense tied to misbranding by manufacturers and distributors promoting off-label uses under the Act demanded the Hospital produce records consistent with fifteen identified requests.[60] It demanded the Hospital produce broad categories of records including, among other things, complete personnel files for executives, prescribing providers, and billing staff; all documents concerning International Classification of Diseases coding and billing practices for gender-related care; internal and external communications regarding coding strategies; insurance communications; training materials; and correspondence with pharmaceutical manufacturers and representatives.[61] The Hospital groups the fifteen requests into four categories: (1) "files for any personnel responsible for directing [the Hospital]'s affairs and personnel who prescribe medication;" (2) "documents regarding the promotion of off-label uses of puberty blockers and cross-sex hormones;" (3) "documents related to billing records and practices, insurance claims, diagnosis codes, and the use of puberty blockers and hormones in connection with gender related care;" and (4) "documents related to any adverse event connected with such care."[62]

Counsel for the Hospital met with the Department of Justice on July 7, 2025.[63] The Hospital agreed to produce many categories of records responsive to the Subpoena but told the Department "it could not compromise the privacy of its patients by providing their confidential health information."[64] The Hospital objected to "all parts of the Subpoena calling for health information of [its] patients, including but not limited to Requests 11, 12, and 13,"[65] which seek:

> 11. Documents sufficient to identify each patient (by name, date of birth, social security number, address, and parent/guardian information) who was prescribed puberty blockers or hormone therapy.
>
> 12. For each such patient identified in Subpoena specification 11, *supra*, documents relating to the clinical indications, diagnoses, or assessments that formed the basis for prescribing puberty blockers or hormone therapy.
>
> 13. All documents relating to informed consent, patient intake, and parent or guardian authorization for minor patients identified in Subpoena specification 11, *supra*, including any disclosures about off-label use (*i.e.*, uses not approved by the United States Food and Drug Administration) and potential risks."[66]

The Hospital timely moved to limit the Subpoena as to Requests 11, 12, and 13.[67] The Department of Justice issued a press release the day after the Hospital's motion titled "Department of Justice Subpoenas Doctors and Clinics Involved in Performing Transgender Medical Procedures on Children."[68] The Department touted sending "more than [twenty] subpoenas to doctors and clinics involved in performing transgender medical procedures on children" and the "investigations include health[ ]care fraud, false statements, and more."[69] Attorney General Bondi proclaimed "[m]edical professionals and organizations that mutilated children in the service of a warped ideology will be held accountable by this Department of Justice."[70]

Patients, states, and other medical institutions seek relief here and in other Districts.

Several patients and former patients who received gender-affirming care at the Hospital and their parents also moved to limit the Subpoena before us on September 22, 2025.[71] The Department of Justice responded with a sworn Declaration of Lisa K. Hsiao, the Director of the

Department of Justice's Enforcement and Affirmative Litigation Branch to show the basis for the Department's investigation.[72] Director Hsiao purports to explain "the relevant [Federal Food, Drug, and Cosmetic Act] violations implicated by the Government's investigation" and "how the documents demanded by the [S]ubpoena are relevant to the Government's investigation" of those potential violations, "which are [f]ederal health care offenses."[73]

We ordered the Department to supplement the record by submitting joint *in camera* letters apprising us of related challenges, reporting on the status of the more than twenty other subpoenas issued to health care providers nationwide, and attaching docket sheets, orders, and opinions entered to date.[74] At least five other districts—including the United States District Courts for the Western District of Pennsylvania, the Western District of Washington, the District of Massachusetts, the District of Maryland, and one additional matter under seal—are addressing or addressed parallel motions to limit or quash.

Sixteen jurisdictions, led by Pennsylvania Governor Josh Shapiro and joined by Massachusetts, California, Colorado, Connecticut, Delaware, the District of Columbia, Illinois, Maryland, Minnesota, Nevada, New Jersey, New York, Oregon, Vermont, and Washington, filed an amicus curiae brief three weeks ago in support of the Hospital's motion to limit the Subpoena.[75] The Department of Justice opposed the Amici earlier this month.[76]

II. Analysis

The Hospital moves to limit the Subpoena to strike Requests 11, 12, 13, and "[a]ny and all other Requests enumerated in the Subpoena (Request 1 through Request 15) to the extent that such Requests or sub-Requests call for the production of health information of [its] patients."[77] The Hospital argues these three requests violate its child-patients' privacy rights and disregard the exceptionally sensitive nature and special character of the records sought.[78] It argues the seven factors established by our Court of Appeals forty-five years ago in *United States v. Westinghouse*

Elec. Corp. warrant limiting the Subpoena by striking Requests 11, 12, and 13 and other requests to the extent they seek the same information.[79] The Hospital "does not categorically contest [the Department of Justice]'s authority to review its conduct or to initiate an investigation through a subpoena issued under [Section] 3486" and does not seek to quash "the Subpoena in its entirety."[80]

The Department of Justice is not interested in limiting these three requests; it wants the intimate, individualized, and personally identifying medical files of every child seeking gender-affirming care permitted under Pennsylvania law.[81] It argues our Court of Appeals's *Westinghouse* analysis is either inapplicable to the Subpoena, wrongly decided, or, alternatively, the factors weigh in its favor requiring we deny the Hospital's Motion.[82]

We expect the Department of Justice agrees we do not have the ability to disregard precedent in a nation of laws. The Subpoena before us (as well as one in the Western District of Pennsylvania) is the only Section 3486 subpoena (disclosed to us) governed by our Court of Appeals for the Third Circuit's longstanding *Westinghouse* framework, notice of which the Department of Justice has had for over forty-five years. We are guided by Congress's mandate the requested information must be relevant to be authorized and our Court of Appeals's established guidance. We find the three requests are not statutorily authorized and, even if they are, our Court of Appeals's balancing test in *Westinghouse* is controlling precedent. We further find a balancing of the defined *Westinghouse* factors overwhelmingly weigh in favor of protecting the privacy interests of the Hospital's child patients given the Department of Justice's stated purpose of examining alleged misbranding arising from false or misleading claims under the Act about the on- or off-label use of puberty blockers and hormone therapy. We limit enforcement of the Subpoena to exclude Requests 11, 12, and 13.

But we cannot venture into a speculative declaration about records not before us. We deny the Hospital's broader request to exclude "[a]ny and all other Requests enumerated in the Subpoena (Request 1 through Request 15) to the extent that such Requests or sub-Requests call for the production of health information of [its] patients" without prejudice. The request as to "health information" is too indefinite to permit relief on the present record, but the Hospital may seek more specific protection if future disputes arise after experienced counsel confer on their obligations.

A. The Hospital enjoys standing to challenge the three requests.

We must first ensure the Hospital can object to the three requests regarding the child-patients' names and medical records. Standing is a threshold issue under Article III.[83] The Department of Justice claims (at least in response to the Hospital's Motion) it is "highly skeptical" whether the Hospital enjoys standing to raise a Fourth Amendment challenge to this subpoena on behalf of all its patients.[84] We must determine whether the Hospital has constitutional standing to object to disclosing its child-patients' identities and medical information. We find the Hospital enjoys standing.

The Department of Justice's position on standing is belied by its admissions before us. It argued in opposition to the related patients' motion: "Congress specifically limited who may challenge" a subpoena under Section 3486—only the Hospital.[85] The Department of Justice also emphasizes Congress imposes no notice requirement to patients, meaning they receive no opportunity to assert their own interests.[86] The Department's theory precludes anyone from challenging its wishes. Such a reading would leave the Department of Justice's administrative subpoena power untethered to any check and place it beyond meaningful judicial review.

Our Court of Appeals applying the rule of law rejects this result. Parties seeking to challenge an administrative subpoena "must assert their own legal interests and show . . . their

interests are within the zone of interests the statute is intended to protect."[87] We look to whether Congress provides an "express right to challenge the subpoenas issued under it."[88] The Department of Justice (given its lawyers' professional obligations) must concede "by [Section 3486's] plain terms, *only* 'the person or entity summoned' may move to quash or modify the subpoena. Here, the 'entity summoned' is [the Hospital]."[89]

Our Court of Appeals confirmed in *Westinghouse* the Hospital may assert its patients' privacy interests because it has "the necessary concrete adverseness."[90] The subpoena in *Westinghouse* targeted the employer, compelled production of documents in its possession, and exposed it to contempt if it refused.[91] The employer has "an ongoing relationship with its employees" and "an adverse decision on the merits of the constitutional claim regarding employee privacy may adversely affect the flow of medical information which it needs from them."[92] "[T]he absence of any notice . . . of the subpoena means that no person other than [the movant] would be likely to raise the privacy claim."[93]

The Hospital stands in the same posture. The Department of Justice targets it and demands records in its custody. It faces the burden of compliance and the risk of contempt. It relies on patient trust in maintaining sensitive medical information and has a direct interest in preserving its child-patients' willingness to share such information. Patients receive no notice of the Subpoena but for the Department of Justice's press releases touting Attorney General Bondi's efforts to end this Pennsylvania-approved medical treatment (which she considers a warped and radicalized ideology) irrespective of whether the subpoenaed records come close to showing manufacturers and distributors are violating the Food, Drug, and Cosmetic Act. The Department of Justice's theory would create precisely the vacuum our Court of Appeals in *Westinghouse* rejected. The Constitution does not tolerate such an unreviewable subpoena power and neither does Congress.

The Hospital enjoys standing to challenge the Subpoena.

B. The Department of Justice lacks statutory authority to compel the Hospital produce documents responsive to Requests 11, 12, and 13.

We, like the Department of Justice and Hospital, are bound by the rule of law. Our task is not to evaluate whether Attorney General Bondi's view—casting Pennsylvania-approved gender-affirming medical care as mutilating children in service of a warped and radicalized ideology and yielding a mandate to end such care—is good for our Nation or a fair policy. We instead must focus on our respect for Congress allowing the Department of Justice to prosecute federal health care offenses under the Food, Drug, and Cosmetics Act.

We are first mindful "[j]udicial review of administrative subpoenas is 'strictly limited.'"[94] Our Court of Appeals instructs we enforce an administrative subpoena if the Department of Justice can show: (1) "the investigation will be conducted pursuant to a legitimate purpose;" (2) "the inquiry is relevant;" (3) "the information demanded is not already within the [Department of Justice's] possession;" and, (4) "the administrative steps required by the statute have been followed."[95] Our Court of Appeals explains the same standard as requiring enforcement "if the subpoena is for a proper purpose, the information sought is relevant to that purpose, and statutory procedures are observed."[96] "The demand for information must not be unreasonably broad or burdensome."[97]

This mandate is not new or responsive to the President's or Attorney General Bondi's views now manifested in demands for children's identities and their medical and psychological records from their doctors. The Supreme Court has articulated the same principle for more than seventy years: "it is sufficient if the inquiry is within the authority of the agency, the demand is not too indefinite and the information sought is reasonably relevant."[98] "The gist of the protection is in the requirement . . . that the disclosure sought shall not be unreasonable."[99] "It is contrary to

the first principles of justice to allow a search through all [of a party's] records, relevant or irrelevant, in the hope that something will turn up."[100] "[R]easonableness, including particularity in describing the place to be searched, and the persons or things to be seized . . . comes down to [whether] specification of the documents to be produced [is] adequate, but not excessive, for the purposes of the relevant inquiry. Necessarily, . . . this cannot be reduced to formula; for relevancy and adequacy or excess in the breadth of the subpoena are matters variable in relation to the nature, purposes and scope of the inquiry."[101]

"The ultimate inquiry . . . is whether the enforcement of the administrative subpoena would constitute an abuse of the court's process."[102] "The subpoenaed party bears the heavy burden of establishing [such] abuse."[103] Enforcing an administrative subpoena "for an improper purpose, such as to harass the [investigation's target] or to put pressure on him to settle a collateral dispute, or for any other purpose reflecting on the good faith of the particular investigation" would be an abuse of the court's process.[104] Federal judges are entrusted by the Framers and the people to ensure the unparalleled power of a Department of Justice subpoena is not abused; our role is "not that of a mere rubber stamp, but of an independent reviewing authority called upon to insure [sic] the integrity of the proceeding."[105] We "must insist that the [Department of Justice] not act arbitrarily or in excess of its statutory authority."[106]

This inquiry leads us back to the first principles and to the authority vested by the Framers in our elected persons representing us in Congress. The authority to issue administrative subpoenas is not inherent in the Executive Branch—it is a delegation from Congress. Congress permitted the Department of Justice, through Section 3486, to issue subpoenas only to investigate a "[f]ederal health care offense" and only to seek "records or other things relevant to the investigation" of such an offense.[107] The scope of this power extends only as far as Congress allows. And Congress ties

the authority directly to relevance—the Department of Justice may not use a federal court subpoena to demand specific records if they are not relevant to a federal health care offense.[108]

So our task today is to determine whether Congress authorized the Department of Justice to compel the documents demanded in Requests 11, 12, and 13. We find the Department of Justice lacks statutory authority because these three requests seek information which bear no relevance to the investigation Congress permitted or to the investigation the Department of Justice tells the world it is pursuing under the Act. Enforcing these requests would transform Congress's 1996 grant of authority in Section 3486 from a tool of legitimate inquiry into a license for intrusion Congress never granted. The Department of Justice must operate within the limits set by our elected representatives in Congress.[109]

1. The Department, absent demonstrating relevance of Requests 11, 12, and 13, lacks statutory authority to demand the children's identities and files.

The Hospital does not challenge most of the Subpoena's broad categories of requests. Those categories—Requests 1–10 and 14–15—seek billing data, insurance-claim submissions, coding guidance, communications with insurers, materials exchanged with manufacturers and compounding pharmacies, and safety-related communications.[110] They could plausibly bear on the commercial conduct the Department describes in its investigative purposes under the Act.

The dispute today instead centers on a narrower set of requests of a fundamentally different character. Requests 11, 12, and 13 seek child-patients' identities and highly sensitive medical information: psychosocial evaluations, diagnoses, treatment rationales, informed-consent forms, intake assessments, and family-authorization documents.[111] These materials reflect individualized clinical care and deeply personal medical disclosures.[112] They do not speak to how products were labeled, marketed, introduced into interstate commerce, or billed to health care benefit plans. We cannot discern how such information is *relevant* to an inquiry into a "federal health care offense"

as Congress defined it or as the Department of Justice describes it here—potential violations of Section 331 of the Food, Drug, and Cosmetic Act relating to a health care benefit program.

The Department asserts the child-patient-specific files are relevant to a Section 331 investigation because "[l]inking each patient's clinical record to corresponding billing and insurance claims can demonstrate whether diagnoses were miscoded, which can prove fraudulent intent" and "[d]ocumentation 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 [the Food and Drug Administration]."[113] It further contends "[a]bsence or minimization of such warnings could establish the intent to mislead" and "reviewing multiple patient records . . may reveal systemic use of the same masking codes, fraudulent informed consent documents," or other "institutionalized practice[s]."[114] It argues "providing patient records, including patient identities, can provide essential investigative leads" because "parents may be witnesses about what disclosures were made" and "patients . . . may provide information about the informed-consent process, side effects, or other false or misleading information about the drugs conveyed during treatment."[115]

These explanations do not withstand scrutiny. As we explained, Congress, through the Act, regulates the introduction, labeling, and distribution of drugs in interstate commerce; it does not govern how physicians diagnose patients, obtain consent, document treatment, or communicate with them.[116] The conduct the Department of Justice describes—miscoded diagnoses, allegedly incomplete disclosures, or purportedly misleading consent forms—concerns how drugs are used in practice, not how they are labeled, promoted, or distributed in commerce. Alleged deficiencies in those areas may implicate state informed-consent or professional-discipline standards, but they

do not establish a Section 331 violation "relating to" a health care benefit program within the meaning of Section 3486.

Linking individualized clinical narratives to billing data does not transform clinical narratives into statutorily relevant material. If coding accuracy or billing irregularities exist, the relevant evidence lies in the Hospital's coding guidance, claim forms, insurer correspondence, and internal communications—precisely the information captured in Requests 2–6. Likewise, the Department of Justice's own later-articulated theories, which shift toward examining manufacturer marketing, consulting arrangements, or broader supply-chain conduct, underscore the relevant evidence for such commercial practices lies in Requests 7–10, 14, and 15. Those requests seek communications with manufacturers and compounding pharmacies, promotional or "scientific exchange" materials, contracts, and safety-related documents.

The Department of Justice's Requests 11, 12, and 13 seek none of this information. These requests concern how clinicians treated individual children and intimate clinical details shedding no light on whether the Hospital introduced a misbranded or unapproved drug into interstate commerce under the Act and Section 331. And the "fraudulent intent" and "intent to mislead" language the Department of Justice cites enhances the penalty for an existing Section 331 violation; it does not create one where none exists.[117] We agree with Judge Joun the connection between child-patient-identifying information and potential fraudulent billing codes or unlawful off-label promotion is tenuous at best and cannot shoulder the weight of compelled disclosure of a child's medical files.[118]

The Department of Justice's reliance on children's identities, social security numbers, and addresses as "investigative leads" underscores the speculative nature of Requests 11, 12, and 13. Congress in Section 3486 authorizes the Department of Justice to compel documents *relevant* to

an investigation—not to conduct open-ended discovery in search of witnesses or narratives to support a theory. "The requirement that subpoenas be used only for a legitimate and authorized governmental purpose prohibits the government from engaging in arbitrary fishing expeditions and from selecting targets of investigation out of malice or an intent to harass."[119]

The Supreme Court long ago recognized the need to balance the Department's investigatory authority with the individual's right to be free from unreasonable intrusion. The Court described this balance as a "basic compromise" designed to secure the public interest in effective investigation "and at the same time to guard the private ones affected against the only abuses from which protection rightfully may be claimed."[120] Those private interests are "the interests of men to be free from officious intermeddling, whether because irrelevant to any lawful purpose or because unauthorized by law, concerning matters which on proper occasion and within lawfully conferred authority of broad limits are subject to public examination in the public interest. Officious examination can be expensive, so much so that it eats up men's substance. It can be time consuming, clogging the processes of business. It can become persecution when carried beyond reason."[121] Administrative subpoenas, including those issued under Section 3486, must remain tethered to lawful authority and reasonable relevance, lest the investigatory process itself become the abuse Congress forbids. The breadth and intrusiveness of Requests 11, 12, and 13 surpass the boundary set by the Court.

The Department of Justice has not offered a factual basis (rather than investigative speculation) to find the personally identifying and clinical child-patient records sought in Requests 11, 12, and 13 are relevant to an authorized investigation of a *federal health care offense* within the meaning of Section 3486. Those children's records concern lawful medical practice governed by Pennsylvania law, not potential Section 331 violations involving a health care benefit program.

The Department of Justice lacks statutory authority for a rambling exploration of the Hospital's files to learn the names and medical treatment of children.

2. We are not persuaded by the Department of Justice's later evolving theories of relevance for statutory authority.

The Department of Justice has shifted its explanations for the investigation before us as our colleagues across the Nation have identified problems with the Department's numerous subpoenas. These shifts reinforce why the specific child-patient-identifying and clinical records demanded in Requests 11, 12, and 13 fall outside Congress's grant of authority in Section 3486. The Department's latest characterizations of its inquiry vary widely and do not establish a connection between an authorized investigation into a federal health care offense and the intimate individualized medical files of a child patient.

The Department—varying over the weeks following Attorney General Bondi's mandate and Assistant Attorney General Shumate's admissions—described its purposes over the last few months into: (1) hospitals' and clinicians' off-label dispensing and billing practices where insurance claims related to off-label use "could constitute a federal health care offense";[122] (2) whether the Hospital itself "is violating the [Food, Drug, and Cosmetic Act]—either directly or through a conspiracy with others (*e.g.*, with pharmacies, drug manufacturers, and/or distributors)—with the intent to defraud and mislead";[123] (3) drug manufacturers' "market[ing of] puberty-blocker drugs and cross-sex hormones directly to pediatric transgender programs" and "consulting agreements" with prescribing clinicians;[124] and (4) a broad "supply-chain" theory encompassing "entities in the drug supply chain, including hospitals, manufacturers, and distributors," alleged to have "caused the introduction of misbranded or unapproved drugs into interstate commerce (or have misbranded them while held for sale)."[125] These categories concern commercial practices, billing practices, and interactions with manufacturers or distributors. The

Department of Justice does not explain why the Hospital needs to personally identify children entrusted by their families to its care along with diagnoses, psychosocial histories, clinical rationales, or informed-consent disclosures. The Department of Justice has not shown statutory authority with its latest theories.

a. The Hospital's experience is not evidence of a federal health care offense.

The Department of Justice admits seeking these records because the Hospital managed its Program under Pennsylvania law with some renown over the past eleven years. Director Hsiao swears the Department's investigation ties directly to the Hospital because its eleven-year Program is "one of the largest pediatric gender clinics in the country" and thus—simply because it has more children patients—the Department of Justice can jump to a conclusion of having "ample reason to suspect" federal health care offenses "may be occurring at [the Hospital]."[126] Director Hsiao cites an ongoing review of anonymized insurance claims data and one patient complaint as the basis for this suspicion.[127] Her sworn explanation suggests a long-standing medical program with one patient complaint over eleven years is somehow the basis to assume fraud. But Director Hsiao does not articulate a reason why or how the identities and individualized medical files of children patients bear on these theories. The Hospital's meaningful role in more children's lives than other medical providers is not a federal crime to our understanding. More patients do not mean there could be more fraud.

b. Commercial practices of others is not statutory authority for producing the children's identities, diagnoses, or authorizations.

The Department of Justice recast these three requests as "targeted for information bearing on commercial practices involving federally-regulated drugs."[128] This belated explanation differs markedly in both *scope* and *subject*—shifting from potential provider-level billing or dispensing irregularities—to manufacturer-level marketing relationships and, most recently, to a nationwide

supply-chain inquiry encompassing actors far beyond the Hospital and its child patients. The Department of Justice insists the requested three categories of documents are "plainly" "tethered to a proper statutory inquiry . . . as [Director] Hsiao['s] [D]eclaration, made under penalty of perjury, makes clear."[129] It concludes Congress gave it subpoena authority whenever the Department of Justice concludes documents are "plainly tethered" to the limited inquiries authorized by Congress. Its wayward reasoning makes it difficult to identify a consistent statutory basis or investigative target within the limits Congress imposed in Section 3486 and leaves uncertain whether the present three requests (for personally identifying and highly confidential and sensitive medical records of children) remains confined to the "federal health care offense" Congress authorized the Department of Justice to investigate for the stated purposes under the Food, Drug, and Cosmetics Act. This explanation is not credible.

c. Congress did not authorize demanding children's records when investigating fraud in distribution or promotion of puberty blockers and cross-sex hormones under the Act.

The Department of Justice invokes sweeping needs for the children's identities far removed from those claimed purposes granted by Congress. It describes its investigation over the past few months as focusing on "the distribution, promotion, and use of puberty blockers and cross-sex hormones in minors for the treatment of gender dysphoria—uses that the [Food and Drug Administration] has never approved and that raise grave safety concerns."[130] The Department of Justice is investigating "expressly prohibited potential misconduct in the health[ ]care field . . . involving lifelong consequences to vulnerable minors."[131] It concludes, without anything more than its belief, the records "bear directly" on whether prescribing puberty blockers and cross-sex hormones to treat gender dysmorphia—"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."[132] Even taken at face value, these concerns describe policy disagreements about the propriety of medical care left to the Commonwealth since the Nation's founding and not a federal crime under the Act. They do not establish statutory relevance of child-patient-specific files.

The Department of Justice's evolving rationales expose a uniquely misplaced view of its ability to expand the limits Congress imposed in Section 3486 and the investigation it claims to be pursuing. We remind the Department Congress authorized this investigation of a federal health care offense, which—when the Department of Justice relies on the Act—means a violation of Section 331 relating to a health care benefit program. Congress never authorized a roving mandate to regulate and alter state-licensed medical care. States retain "wide discretion to pass legislation in areas of medical and scientific uncertainty" and the use of puberty blockers and hormone therapy to treat gender dysmorphia is legal in Pennsylvania as confirmed by Governor Shapiro.[133]

Attorney General Bondi's and Assistant Attorney General Shumate's mantra of concern for child welfare, however genuine, is not a substitute for the limited authority granted to them by the elected representatives. The Department of Justice's subpoena power extends only to information relevant to a Section 331 offense relating to a health benefit program, not to generalized policy objections about medical treatment decisions. Congress, through Section 3486, does not authorize a federal investigation into lawful medical practice simply because the President or current Attorney General disapproves of the care provided regardless of Pennsylvania's approval in the exercise of its police powers.

d. The Department of Justice misreads Congress's mandate in the Food, Drug, and Cosmetic Act.

The Department of Justice's theory rests on an admittedly unprecedented interpretation of the Food, Drug, and Cosmetic Act. The Department seeks to transform Congress's regulation of

the manufacture, distribution, and labeling of drugs into a vehicle for federal oversight of how physicians diagnose, treat, and counsel child patients. And then to go a step further and obtain the identity of those children. This view misstates the conduct Section 331 reaches. This theory cannot supply the statutory relevance needed to justify Requests 11, 12 and 13 under Section 3486.

Congress, through the Act, regulates *commerce*, not *care*. Both the Food and Drug Administration and our colleagues long recognized off-label prescribing—the use of an approved drug for an unapproved indication—is lawful and beyond the Act's reach.[134] "Although the Act regulates a manufacturer's distribution of drugs, it does not go further by regulating a doctor's practice of medicine."[135] Congress likewise expressly preserved state authority over medical practice, providing in part, "[n]othing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease."[136] The Food and Drug Administration "can only regulate the marketing and labelling of devices. It cannot regulate what physicians do with the devices with respect to their patients."[137] The United States Office of Legal Counsel agrees: "As a general matter, [the] [Food and Drug Administration] does not regulate the practice of medicine, which includes 'off-label' prescribing."[138] "Federal regulation of medical products is grounded in the introduction of [articles] in interstate commerce for commercial distribution, not use by physicians. This concept forms the basis for the 'practice of medicine' doctrine, which maintains that [the Food and Drug Administration] lacks authority under the [the Act] to regulate patient treatment decisions made by licensed physicians."[139]

Director Hsiao blurs these fundamental distinctions. She swears "a drug manufacturer or other person distributes" a misbranded or unapproved drug simply by prescribing or administering an approved drug for an unapproved indication and "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 [Act] and is a federal crime."[140]

The Director's assertion is wrong as a matter of law. The practice of off-label prescribing and administering puberty blockers and cross-sex hormones to children with gender dysphoria is lawful in Pennsylvania and clinicians "are free to exercise their professional judgement [sic] to prescribe [Food and Drug Administration]-approved drugs for any use they see fit."[141] Director Hsiao further stretches the concept of "labeling" to suggest ordinary clinical documents may qualify as "false or misleading labeling."[142] But "labeling" under the Act refers to written or graphic materials accompanying a drug in commerce—materials disseminated by *manufacturers, packers, or distributors* to describe or promote the product—not to internal medical records, informed consent forms, or physician–patient communications.[143] Director Hsiao finally suggests health care providers become part of the "chain of distribution" of a drug when a drug must be administered by a physician or nurse at a medical facility purchasing and storing the drug.[144] This theory has no cognizable bounds; it defies both law and logic. Accepting this interpretation would transform every act of treatment into a potential federal offense. And be directly contrary to Congress's mandate.

The Department of Justice belatedly disclaimed an intent "to criminalize routine, non-fraudulent off-label prescribing" yet simultaneously contends the Act and "its implementing regulations make it unlawful to distribute drugs in interstate commerce when the intended use . . . is not a [Food and Drug Administration]-approved indication and/or where the drug does not have adequate directions for that intended use."[145] But the first clause simply restates Director Hsiao's assertion using an approved drug for an unapproved indication renders it an "unapproved new drug" and the second echoes the misbranding provision which requires manufacturer labeling to

include "adequate directions for use." Neither theory governs physicians acting within their state-regulated scope of practice—prescribing or administering Food and Drug Administration-approved drugs in the exercise of professional medical judgment. Misbranding liability, as Congress structured it, attaches to those who design, control, or disseminate a drug's labeling—such as manufacturers and distributors—not to physicians engaged in patient-specific treatment.[146] Clinicians neither create a drug's labeling nor define its "intended use" under the Act, and the statutory exemption for prescription drugs removes a requirement they provide "adequate directions for use" when prescribing Food and Drug Administration-approved drugs to individual patients.[147] The prescription-drug framework rests on licensed practitioners exercising medical judgment rather than layperson-directed labeling. Nothing in the Act treats a physician's diagnosis, counseling, or prescription decisions as misbranding. The Department of Justice's disavowal of criminal intent thus conflicts with (and does not cure) the premise underlying Director Hsiao's sworn belief off-label medical practice itself violates the Act. We again cannot fathom where Director Hsiao's theory would lead in prosecutions of clinicians who exercise their learned judgment to find these drugs will help their child patients and the Commonwealth agrees with them. The Director may, of course, pursue legitimate violations of the Act (such as the interstate distribution of unapproved drugs or the misbranding of manufacturer labeling) but she offers no basis for compelling disclosure of child-patient identities and intimate medical records absent any showing those records could reveal a federal health care offense relating to a health care benefit program as Section 3486 requires. We find no such showing possible on the theories Director Hsiao advances here.

The Department of Justice further reasons "Congress . . . did not intend to insulate from scrutiny every transaction that happens to involve a licensed practitioner" and relies heavily on a

decision from another Circuit over a decade ago in *United States v. Regenerative Sciences, LLC*.[148] But the Court of Appeals for the District of Columbia's analysis in *Regenerative Sciences* offers no basis for the Department's attempt to classify ordinary prescribing of approved drugs as actionable under the Act or to justify obtaining the identities of children patients. The Court of Appeals for the District of Columbia reviewed a fact pattern with physicians who manufactured and administered an unapproved stem cell mixture—a drug the Food and Drug Administration had "*not approved* . . . as safe for *any use*" and "hence challenge[d the physicians'] right to prescribe [it] *at all*."[149] "[T]he focus of the [Food and Drug Administration]'s regulation [was] the Mixture. That is, the [Food and Drug Administration did] not claim that the procedures used to administer the Mixture [were] unsafe; it claim[ed] that the Mixture itself [was] unsafe."[150] The Court of Appeals for the District of Columbia's limited discussion of the Act's scope as it applied to physicians recognized doctors who step into the manufacturing or compounding role cannot rebrand conduct prohibited under the Act as the "practice of medicine" to evade oversight because doing so would "create an enormous gap in the Act's coverage."[151] The Department of Justice's reasoning has no bearing here where physicians prescribe approved drugs already in lawful commerce and subject to state regulation of medical practice. The Department of Justice's reliance on two other out-of-Circuit citations fare no better.[152] Neither supports treating prescribing and administering a Food and Drug Administration-approved drug as "distribution" or "misbranding." And they do not come close to requiring disclosure of children's identities and clinical files to investigate misbranding concerns under the Act.

The Department of Justice hopes to reinterpret Congress's longstanding mandate in the Act to reach lawful clinical care. Extending it so far would subvert Congress's design, erase the long-recognized boundary between drug regulation and the practice of medicine, and intrude upon

Pennsylvania's sovereign authority to oversee the medical profession in the Commonwealth guaranteed under the Tenth Amendment. Such an interpretation would seem to disregard the limits of Congress's intent and risk undermining the physician-patient relationship and open, evidence-based communication about care—a result at odds with both Congress's direction in Section 3486 and sound medical practice set by the Commonwealth. As a bottom line, the subpoena authority granted by Congress does not reach lawful off-label prescribing or internal clinical documentation requiring we find the patient-specific materials in Requests 11, 12 and 13 cannot be relevant to investigating a Section 331 "federal health care offense."

C. Our Court of Appeals's *Westinghouse* analysis requires we balance the child's privacy interests with the Department of Justice's need for the children's records in Requests 11, 12, and 13.

The Hospital offers an alternative even if we found Requests 11, 12, and 13 satisfy the criteria for judicial enforcement (which we do not). The Hospital alternatively argues we must strike Requests 11, 12, and 13 after balancing the seven factors set by our Court of Appeals when evaluating whether "an intrusion into an individual's privacy is justified."[153] Our Court of Appeals defines these seven factors ("*Westinghouse* factors"): (1) "the type of record requested;" (2) "the information it does or might contain;" (3) "the potential for harm in any subsequent nonconsensual disclosure;" (4) "the injury from disclosure to the relationship in which the record was generated;" (5) "the adequacy of safeguards to prevent unauthorized disclosure;" (6) "the degree of need for access;" and, (7) "whether there is an express statutory mandate, articulated public policy, or other recognizable public interest militating toward access."[154]

The Department of Justice argues the *Westinghouse* factors do not apply to the Subpoena because Congress in Section 3486 "superseded the *Westinghouse* test by addressing the concerns about medical privacy that animated the *Westinghouse* decision" and "*Westinghouse* was wrongly decided."[155] We disagree with the Department on both fronts.

1. Congress in Section 3486 does not supersede *Westinghouse.*

The Department of Justice maintains Congress establishes a narrow set of procedural requirements for issuing and enforcing a subpoena and includes no reference to the *Westinghouse* balancing test.[156] Congress addressed medical privacy when it enacted the Health Insurance Portability and Accountability Act of 1996 (including Section 3486) by limiting disclosure of protected health information and granting the Department of Justice a distinct, constitutionally sound subpoena power to obtain such information.[157] The Department of Justice argues compliance with Section 3486's procedural requirements automatically resolves all constitutional privacy concerns.[158] It relies on our Court of Appeal's analysis in *In re KB Toys Inc.* to argue statutory text alone controls.[159] It also cites three out-of-Circuit decisions and concludes "[t]he only circuit courts to have considered [Section 3486] subpoenas have upheld them over Constitutional challenges that attempt to place privacy-based, *Westinghouse*-like additional restrictions on their use."[160]

The Hospital counters Section 3486 does not define constitutional boundaries and Congress through Section 3486(a)(7) preserved legal standards recognized by federal courts.[161] Congress in Section 3486(a)(7) confirms the Subpoena cannot compel the production of materials protected under standards governing federal court subpoenas and those standards in our Circuit at the time Congress enacted Section 3486(a)(7) included privacy balancing under *Westinghouse*.[162] Congress is presumed to legislate with knowledge of existing law leading the Hospital to argue Congress incorporated those limits into Section 3486.[163] It also distinguishes the Department's out-of-Circuit authorities.[164]

We will not disregard binding precedent. The *Westinghouse* analysis is binding precedent in our Circuit. The Department of Justice's contrary and unsupported position is unpersuasive. The Department reaches to suggest a subpoena issued under Section 3486 stands beyond constitutional

review because the Department's asserted interest always outweighs privacy interests.[165] But a court enforcing a federal statute must do so in a manner consistent with the Constitution. Statutory authorization—whether broad or silent—does not displace constitutional limits or insulate executive action from judicial review. Our Supreme Court directs even in areas where Congress exercises its most expansive authority, courts must still ensure executive action complies with fundamental constitutional protections.[166] Section 3486 cannot override the constitutional privacy framework set by *Westinghouse*.

The Department of Justice's claim is belied by the viability of the *Westinghouse* analysis after Congress enacted Section 3486 almost thirty years ago. Our Court of Appeals applied the *Westinghouse* factors in *F.D.I.C. v. Wentz* to assess privacy interests in personal financial records and explained "[w]hen personal documents of individuals, as contrasted with business records of corporations, are the subject of an administrative subpoena, privacy concerns must be considered" and again cited the *Westinghouse* factors.[167] It emphasized "[p]ersonal financial records have never been as tightly guarded as 'information concerning one's body'" and found the defendants failed to "produce[] any evidence to show that the information contained in their personal financial records 'is of such a high degree of sensitivity that the intrusion could be considered severe or that the [directors] are likely to suffer any adverse effects from disclosure to [government] personnel.'"[168] It concluded the "strong public interest in safeguarding the [Federal Deposit Insurance Corporation]'s legislative mandate outweighs the minimal intrusion into the privacy that surrounds the directors' personal financial records."[169] Our Court of Appeals in *United States v. Oncology Servs. Corp.* distinguished the situation where the defendant raised no privacy claim but reaffirmed "agency requests for medical records implicate[] privacy rights" under *Westinghouse*.[170] Judge Shapiro reiterated in *Matter of Delaware River Stevedores* "privacy,

breadth, potential for harm from subsequent, non-consensual disclosure, adequacy of safeguards, and the burden of production" are relevant considerations.[171] And Judge Padin confirmed last year in *CMA CGM S.A. v. CIS Dev. Found., Inc.* "courts must also consider privacy concerns when 'personal documents of individuals, as contrasted with business records of corporations, are the subject of an administrative subpoena.'"[172] None of these cases involved Section 3486 subpoenas for child medical records, but each applied or reaffirmed *Westinghouse* as controlling precedent in our Circuit and confirmed privacy remains a constitutional consideration in administrative subpoena cases involving personal or medical information.[173]

The Department of Justice reaches to avoid this precedent in our Circuit. Its reliance on our Court of Appeals's reasoning *In re KB Toys Inc.* is misplaced. It cites the case for the proposition "[i]f the text [of a statute] is clear and unambiguous, this Court must simply apply it."[174] But our Court of Appeals in *In re KB Toys Inc*. addressed when legislative history may be used to interpret ambiguous statutory text.[175] The Hospital does not claim Section 3486 is ambiguous or rely on legislative history. It argues statutory compliance alone does not displace constitutional limits.[176] We agree with the Hospital finding Congress through Section 3486(a)(7) underscores this deference to the highest law in the land by preserving legal standards recognized by federal courts when evaluating subpoenas.[177]

The Department of Justice's out-of-Circuit cases involving constitutional challenges to Section 3486 subpoenas fare no better. None foreclose application of *Westinghouse* in a case where patients' privacy interests in sensitive and identifying medical records are squarely presented. Its reliance on these decisions overstates both their holdings and their relevance. The subpoena in *Whispering Oaks* sought financial and business documents, such as invoices, tax returns, personnel files, and communications with state agencies about the residential care facility's operations.[178]

The subpoena did not seek children patients' medical records and the facility never raised a constitutional privacy concern.[179] The Court of Appeals for the Eighth Circuit simply applied only the traditional administrative subpoena enforceability framework (statutory authority, lawful purpose, relevance, and reasonableness) and found the subpoena enforceable without considering possible privacy interests in financial records (including the type of records the Hospital agrees to produce in response to other requests).[180]

The subpoena in *Doe* sought various records from a physician under investigation for an alleged kickback arrangement.[181] The requests most comparable to those here concerned "all documents and patient files evidencing Doe's referral of patients for *certain* electrodiagnostic tests" and "referral of patients to a *specific* medical testing laboratory for *certain* diagnostic ultrasound tests."[182] Those requests involved limited referral information, not comprehensive or identifying medical records, and the Court of Appeals for the Sixth Circuit "did not address this aspect of the subpoena" because the physician "no longer dispute[d] the reasonableness of the government's request for patient documents."[183] The physician did not raise a constitutional privacy claim.[184] The Court of Appeals for the Sixth Circuit similarly applied only the traditional administrative subpoena enforceability framework and observed "the primary point of contention [was] whether the [other] documents requested [were] relevant to the investigation."[185] The characterization of *Whispering Oaks* and *Doe* as cases "uph[olding Section 3486 subpoenas] over Constitutional challenges that attempt to place privacy-based, *Westinghouse*-like additional restrictions on their use" is misleading.[186] Neither case presented a constitutional privacy challenge, leaving the Courts of Appeals for the Sixth and Eighth Circuits no reason to go beyond the traditional administrative subpoena enforceability framework and consider *Westinghouse* or a similar balancing test.

Judge Jones's analysis, as affirmed by the Court of Appeals for the Fourth Circuit in *In re Subpoena*, reflects a case-specific balance of interests, not a determination Section 3486 inherently provides constitutionally sufficient privacy protection for all subpoenaed medical records "as a matter of law."[187] The subpoena before Judge Jones sought extensive patient materials, "including "medical files, patient appointment books, patient billing records, office sign-in sheets, and telephone messages" for services billed to various federal and private programs.[188] The physician and medical practice moved to quash the subpoena and argued the "patients' privacy interests in their medical files outweigh the government's interest in those files."[189] The Department of Justice offered to seek only those "patient files which remain relevant to [the] investigation after [its] review of the initial production" which excluded patient treatment files. [190] So Judge Jones did need to face the question of the Department of Justice seeking patient treatment files now before us. Judge Jones recognized the "express statutory mandate and articulated public policy" and "safeguards against further disclosure" under Section 3486 but also acknowledged "the personal nature of the information sought" and prohibited disclosure "to anyone other than the employees and representatives of the Department of Justice" or "to a grand jury or court in any subsequent proceeding."[191] Judge Jones found the public interest in combating health care fraud outweighed the individual privacy interest given the limited scope of requested production.[192] The Court of Appeals for the Fourth Circuit affirmed holding the Department of Justice's "compelling interest in identifying illegal activity and in deterring future misconduct" outweighed "the privacy rights of those whose records were turned over to the government" under the facts presented.[193] Both courts expressly considered privacy interests and balanced them against the Department of Justice's asserted need for redacted records—an approach consistent with, not contrary to, *Westinghouse*. We face a much greater privacy interest of children and their families receiving

physician-recommended gender-affirming care at a time when their Attorney General describes their medical care as a warped ideology. And the Department of Justice today has not shown the specific need to investigate the children.

The Department of Justice also references *United States v. Hertel & Brown Physical & Aquatic Therapy* as the only decision in our Circuit discussing a Section 3486 subpoena and emphasizes Judge Baxter did not mention *Westinghouse* but instead cited and quoted from the Court of Appeals for the Sixth's Circuit's decision in *Doe.*[194] But Judge Baxter's analysis in *Hertel* arose in the context of motions to suppress in a criminal prosecution after the Federal Bureau of Investigations already issued requests and obtained patient data from third-party health insurers.[195] The insurers voluntarily complied with the requests in the *Hertel* ongoing criminal case, which sought billing and claims information including patient names, social security numbers, diagnosis codes, dates of service, and amounts billed and paid.[196] Judge Baxter addressed only whether the defendants could assert their own expectation of privacy in those insurer records sufficient to establish standing for a Fourth Amendment challenge, not whether the patients held a constitutional privacy interest of the kind established in *Westinghouse*.[197] The "protected privacy interest in medical data generally concern[s] an individual's privacy interest in his own medical data, which is not at issue here."[198] Judge Baxter cited *Doe* only to describe Section 3486's broad investigatory authority.[199] Judge Baxter did not address the constitutional privacy question and did not address *Westinghouse* or its relevance to Section 3486 subpoenas. Judge Baxter's analysis in *Hertel* provides no support for the Department of Justice's suggestion *Westinghouse* does not apply to our review of Requests 11, 12, and 13 seeking the identity of child patients and their treatment files.

The Department of Justice's unprecedented reading of Section 3486 requires us to find Congress removed a federal court's power to protect medical privacy, no matter its sensitivity or scope, and turn a procedural statute into a shield against constitutional review. Such an outcome conflicts with both *Westinghouse* and the principle federal statutes yield to constitutional protections. Statutory compliance does not dissolve privacy interests. We must weigh those interests against the Department's asserted need. *Westinghouse* remains binding precedent in this Circuit, and we apply its factors.

2. We do not find our Court of Appeals wrongly decided *Westinghouse*.

The Department of Justice next urges us to disregard *Westinghouse* on the theory our Court of Appeals "wrongly decided" it because the court identified no statutory or Supreme Court basis for its holding.[200] It expresses skepticism about "an affirmative, free-floating right to control the disclosure of medical records in whatever context they may be found" given what it views as the "lack of historical grounding for such a right."[201]

This is not a legal argument—it is an invitation to ignore precedent. We may not ignore controlling law to accommodate a party's skepticism. Our Court of Appeals's *Westinghouse* guidance remains binding precedent in this Circuit unless and until our Court of Appeals or the Supreme Court says otherwise. We have found no authority to the contrary and the Department offers none. We will apply the *Westinghouse* factors in balancing the children's privacy interests with the Department of Justice's demands for their identities and medical treatment records in Requests 11, 12, and 13.

D. The *Westinghouse* factors weigh in favor of protecting the most sensitive information regarding a child's gender-affirming care.

We next weigh our Court of Appeals's seven *Westinghouse* factors to determine whether the Department of Justice's demands for the children's identities and medical treatment records

justify "intrusion into an individual's privacy."[202] We weigh the competing interests and the scale weighs in favor of protecting the privacy of children's identities and treatment in an investigation into whether medical professionals are using false billing codes or misbranding the puberty blockers and hormone therapy. The Department's asserted need falls short of justifying an intrusion of this magnitude. The Department through Requests 11, 12, and 13 seeks intensely personal and sensitive medical information warranting the highest level of protection. The Department of Justice can pursue its investigation into federal health care offenses without forcing disclosure of these records, particularly given the breadth of other information the Hospital already agreed to produce. The exceptional privacy interests at stake compel limiting the Subpoena to exclude Requests 11, 12, and 13.

1. The type of medical records requested and information they do or might contain weighs in favor of protecting the children's privacy.

The first two *Westinghouse* factors require we study the type of record requested and the information the record contains or might contain. We address and weigh the first and second *Westinghouse* factors together because they both concern the sensitivity of the information sought and are closely intertwined. Both the Hospital and the Department of Justice likewise group these factors together.[203]

The Hospital emphasizes the extraordinary sensitivity of the requested information regarding its child patients.[204] The Department of Justice in Requests 11, 12, and 13 demand assessments, diagnoses, and informed consent records underlying medical decisions to prescribe puberty blockers and hormone therapy and documents identifying the patients associated with those records by name.[205] These records reflect comprehensive psychosocial and medical evaluations and often involve intimate disclosures about "discomfort with specific body parts, sexual history, past trauma, interfamily dynamics, use of self-harm or other negative coping

mechanisms . . . such as disordered eating, and experiences of harassment and bullying."[206] The Hospital argues such information sits at the core of patient privacy and has long been recognized as such by courts and federal regulators.[207] It maintains these records are far more sensitive than the "results of routine testing, such as X-rays, blood tests, pulmonary function tests, hearing and visual tests" at issue in *Westinghouse*.[208] It also underscores the compounded intrusion created by the Department of Justice's demand for child-patient identifiers and our Court of Appeals recognition linking highly personal medical information to specific individuals substantially magnifies the privacy stakes.[209]

The Department of Justice "does not quibble with the sensitivity of the patient information involved" but rejects the Hospital's "characterization and balancing" of the factors.[210] It portrays the Hospital as having "cho[sen] to bankroll and run a specialty clinic" in a "controversial" field and argues the Hospital cannot insulate sensitive medical practices from investigation simply by invoking the "sensitivity of [the] information" at the outset.[211] It suggests the Hospital's reliance on privacy concerns would effectively create a "zone of impunity" for providers operating in areas of medicine the Hospital labels "sensitive."[212] The Department of Justice offers its inability to investigate "the provision of pharmaceuticals to minors without obtaining records of pharmaceuticals provided to minors" as an example.[213]

The Department of Justice further asserts the sensitivity of these records "actually militates in favor of disclosure, not against it—because the consequences to children of unlawful practices in gender-related care practices are potentially so severe" and cites Justice Thomas' recent concurrence in *United States v. Skrmetti* as "evidence suggesting that gender-related care for minors in the United States is rife with potential consumer-protection violations."[214] It argues the

Hospital's showing on these factors "is entirely outweighed by the need for the records and the [Department of Justice's] interest in preventing potential lifelong consequences to children."[215]

The sensitivity of the requested records is beyond dispute. Our Court of Appeals has long recognized "[t]here can be no question . . . medical records, which may contain intimate facts of a personal nature, are well within the ambit of materials entitled to privacy protection."[216] This protection squarely extends to prescription records.[217] One can "look[] at an individual's prescription records to determine [their] illnesses" or "to ascertain such private facts," including "whether a woman is attempting to conceive a child through the use of fertility drugs"—"precisely the sort [of information] intended to be protected by penumbras of privacy."[218] It likewise extends to information regarding sexuality and sexual orientation, and disclosures entailing "stigma, potential for harassment, and risk of much harm from non-consensual dissemination of the information," such as an individual's HIV-positive status or a minor's pregnancy.[219] When highly sensitive medical information is linked to an identified individual—such as pairing a patient's name with HIV-specific medications—the resulting information is a "private matter" into which intrusion may occur only upon a showing of "sufficient cause."[220] The governing principle is straightforward: "[t]he more intimate or personal the information, the more reasonable the expectation is that it will remain confidential."[221]

The records sought here fall at the highest end of the intimate and personal spectrum. They contain comprehensive psychosocial evaluations and deeply personal disclosures by children about their bodies, sexuality, trauma, family dynamics, self-harm, mental-health history, and cognitive and emotional functioning. They also include the diagnoses, clinical reasoning, and informed-consent discussions underlying treatment decisions. This level of detail places the information among the most personal and sensitive a medical provider can hold and squarely

within the class of intimate material our Court of Appeals has long regarded as warranting the strongest constitutional protection. The Department of Justice seeks to pair these disclosures with the names, dates of birth, addresses, and social security numbers of the children involved. Linking such intimate material to identified children—across assessments, diagnoses, psychosocial histories, and consent discussions—invokes the strongest privacy protections recognized in *Westinghouse* and applied for forty-five years.

We are not persuaded in the least by the Department of Justice's attempt to invert these factors by claiming the sensitivity of the information "militates in favor of disclosure . . . because the consequences to children of unlawful practices in gender-related care practices are potentially so severe."[222] Its stated investigation concerns potential federal health care offenses premised on a violation of Section 331 only to the extent the violation relates to a health care benefit program.[223]The focus of such an inquiry is conduct involving a "public or private plan or contract, affecting commerce"—not clinical risks, potential medical consequences to individual children, or the adequacy of informed-consent discussions.[224] Invoking patient welfare to justify disclosure therefore misdirects the inquiry. The underlying medical care does not become subject to compelled disclosure simply because it is sensitive or controversial; sensitivity cannot be transformed into a reason to compel disclosure when the authorized (and represented) investigative purpose concerns only a potential Section 331 offense relating to a health care benefit program, not patient safety or medical judgment governed by the Commonwealth's police power.

The Department of Justice's reliance on Justice Thomas's concurrence does not strengthen its position. A concurrence about consumer-protection concerns is not evidence of a Section 331 violation nor does it supply the "sufficient cause" required to intrude into constitutionally protected medical information.

The *Westinghouse* factors one and two weigh heavily in the Hospital's favor. But we do not treat them as dispositive. We simply find the Department of Justice's stated rationale does not diminish the highest level of privacy interests inherent in these records or convert their sensitivity into a basis for compelled disclosure.

2. Potential for harm in subsequent nonconsensual disclosure weighs in favor of the child's privacy interests.

The third *Westinghouse* factor considers the potential for harm in subsequent nonconsensual disclosure. The Department of Justice offers little to address the privacy concerns; it instead confirms it is seeking the records to investigate further including the children and their families and risks including turning parents into witnesses against their child's doctors regarding the most private and sensitive medical care.

The Hospital describes the potential harm as severe.[225] It points to the "embarrassment, humiliation, and trauma" its patients could face if their records and exceptionally sensitive information "were somehow made public" through leaks or other disclosure.[226] The records contain intimate details about patients, their families, friends, and others in their lives and the Hospital stresses the harm would reach beyond its patients to people named in the records "who have little or no connection to the Program and no idea that information concerning them is at issue."[227] Awareness of the Requests 11, 12, and 13 heightened fears of surveillance and exposure among patients and families.[228] The Hospital warns these fears of future disclosure will deter some patients from seeking care and engaging in daily life, with serious health and psychological consequences.[229] It further explains the Department of Justice's intent to obtain identifiable records creates a risk of direct contact between federal investigators and patients.[230] The Hospital describes such potential encounters as distressing, potentially outing patients and increasing their risk of harassment, discrimination, and violence.[231]

The Department of Justice gives this factor little attention. It groups it with the first two factors and offers one response—it is "willing to work with [the Hospital] to minimize the impact on vulnerable patients, such as by accepting anonymized records as a first pass with the potential for obtaining more information on specific records should the need arise."[232] The third factor concerns harm if nonconsensual disclosure occurs, not the likelihood of disclosure. The Department's cursory statement does not meaningfully address the potential harms the Hospital describes.

The Hospital makes a detailed and unrebutted showing of the harm and consequences to follow even from the slightest disclosure of a child's sensitive medical records. Such disclosures would strip patients of control over their most personal information, expose intimate details about their bodies and lives, and risk public outing and lasting stigma. The disclosures would inflict deep emotional harm, destroy trust in medical care, and spread the damage to families, peers, and many others.

We must also be realistic when recognizing disclosure of certain medical conditions—particularly those burdened with political controversy or public misunderstanding—can inflict extraordinary harm on the patient and their family. Judge Brotman in *Doe v. Borough of Barrington* described how profound harms can follow revelation of an individual's AIDS status and emphasized "the privacy interest in one's exposure to the AIDS virus is even greater than one's privacy interest in ordinary medical records because of the stigma that attaches with the disease."[233] "The potential for harm in the event of a nonconsensual disclosure is substantial."[234] Judge Brotman ultimately found "[t]he government's interest in disclosure here does not outweigh the substantial privacy interest involved."[235]

We do not suggest, in any respect, gender-affirming care for transgender children is comparable in medical gravity to the once-fatal HIV/AIDS disease. We reference the history for a far narrower purpose: to illustrate how the disclosure of highly sensitive medical information can expose individuals to stigma, misunderstanding, or hostility—particularly in political climates where those charged with protecting the public's welfare have taken an adversarial view of certain medical care based on ideology rather than deferring to Pennsylvania's police power to regulate medical care at the Hospital. Gender-affirming medical care, like HIV-AIDS care not too long ago, has become a flashpoint of national political conflict, saturated with name-calling, fear, and hostility. In such an environment, disclosure of children's identities and treatment details (when they wish to keep them confidential) would expose them and their families to the same kinds of stigma, harassment, and social injury Judge Brotman recognized as both foreseeable and intolerable when intimate medical information becomes public.

And the harm to the Hospital's patients is not hypothetical. The Department of Justice already described the very disclosures this factor exists to guard against. It intends to use patient identities as "essential investigative leads."[236] "Parents may be witnesses" and "[p]atients (depending on age and circumstances) may provide information."[237] This is not a distant privacy concern. It is a plan to intrude on the most private sphere of vulnerable children and their families and to investigate them. The harm is grave, foreseeable, and—by the Department of Justice's own admission—imminent in an area of medical care the President and Attorney General claim are "a stain on our Nation's history" and "a warped ideology." In pressing forward while acknowledging this consequence, the Department effectively confirms the very harm the third *Westinghouse* factor exists to prevent. The potential, and apparent forthcoming, harm from nonconsensual disclosure of these records is extraordinary and weighs decisively against enforcement.

The third factor weighs in the Hospital's favor.

3. Injury to the physician–child-patient relationship from disclosure favors the children's privacy interests.

The fourth factor considers the injury to the relationship between the child patient and the medical provider creating the records.[238] The Hospital argues this factor weighs heavily against disclosure. It describes the physician–patient relationship as a cornerstone of effective care with confidentiality at its core.[239] Patients share deeply personal information expecting their records to remain private and not open to unfettered access by federal investigators based on the care they received.[240] The Hospital warns disclosure through Requests 11, 12, and 13 would discourage families from seeking treatment, deter open communication with providers, and erode trust needed for accurate diagnosis and effective care.[241] It distinguishes the employer-employee relationship in *Westinghouse* where disclosure carried little risk of deterrence and argues the chilling effect here is real and far-reaching with public health consequences beyond just the patients in the Program.[242] It cautions patients and families may avoid seeking care at the Hospital if they fear their records will be shared with federal investigators.[243]

The Department of Justice "does not doubt that the relationship between [the Hospital] and its patients might be somehow affected by" the investigation but dismisses the Hospital's concerns as speculative and essentially universal.[244] It argues any medical provider could make the same claim and this factor "is similar to the first three in that it will almost always militate against disclosure" in nearly every investigation.[245] It further laments the first four *Westinghouse* factors will always weigh against it "before subpoena enforcement even begins" in sensitive medical cases, creating an exception to Section 3486 broad enough to "swallow the rule."[246] It urges us to treat this factor "as neutral here, as it should in any Government investigation of a medical provider."[247]

The Department's argument on this factor misses the mark. Disliking how the first four *Westinghouse* factors often favor nondisclosure in sensitive medical contexts is not a legal basis to declare the fourth factor "neutral." Our Court of Appeals in *Westinghouse* directs us to assess the injury to the physician–child-patient relationship creating the records and weigh it against the other factors, not to rewrite the framework. And these are not x-rays. The Department of Justice describes the care as controversial. There is no basis for a slippery-slope theory on this reach. We today face a unique challenge in a charged environment where the child's medical care is disparaged by the highest levels of law enforcement. The *Westinghouse* factors remain binding in our Circuit. We apply the test as it exists.

The Hospital makes a persuasive and unchallenged showing of harm to the physician–child-patient relationship. Patients and families who believe their medical records can be turned over to federal investigators will understandably hesitate to seek care, withhold critical information from their doctors, or avoid treatment for gender-affirming concerns (given the present attacks on this care by the highest levels of law enforcement). This is not speculation; it is a rational response to a legitimate risk particularly given the rhetoric from federal law enforcement about persons seeking this care. The Department offers no evidence to the contrary. Its sole argument—any medical provider for any medical concern could make the same claim—does not neutralize the factor. It is an admission the harm the fourth factor recognizes is real and recurring in highly sensitive medical contexts as opposed to financial or commercial records or information about knee injuries or diabetes medicines. Disclosure in this context harms the physician–child-patient relationship. The Department of Justice gives us no reason to find otherwise. This factor weighs against disclosure.

The fourth factor weighs in the Hospital's favor.

4. The undefined adequacy of safeguards to prevent unauthorized disclosure in this uniquely public attack on children's gender identities and their doctors' medical care slightly favors the children's privacy absent the Department of Justice offering specific sanctions or prohibitions for unauthorized disclosure.

Factor five of the *Westinghouse* balancing test considers the adequacy of safeguards to prevent unauthorized disclosure. The Hospital argues this factor weighs against disclosure because no statutory or regulatory provision broadly prohibits the Department of Justice from further disseminating patient-specific information obtained under a Section 3486 subpoena.[248] It emphasizes the "limitation on use" under Section 3486(e)(1) protects only against using or disclosing information "in any administrative, civil, or criminal action or investigation directed against the individual who is the subject of the information"—the patient here—but does not restrict disclosure for any other purpose by its terms.[249] The Hospital also points to the Department of Justice's public statements committing to "partner" with state officials to "share intelligence" and "build cases against hospitals and practitioners" and contends nothing in Section 3486 prevents the Department of Justice from providing patient-specific information to state law-enforcement agencies.[250] The Hospital argues these possibilities heighten the risk of both authorized and unauthorized disclosures.[251] We are also mindful of Attorney General Bondi and Assistant Attorney General Shumate's repeated public denouncement of this medical care. We cannot compare the production of routine medical records for adults to medical records in areas where the Attorney General has now essentially condemned the doctors helping the children.

The Department of Justice responds courts of appeals repeatedly find the Section 3486 statutory safeguards adequate to protect patient privacy.[252] It contends the Hospital misunderstands those statutory protections: Congress through Section 3486(a)(8) requires the Department of Justice return records if the investigation does not ripen into an enforcement action and Congress "broadly prohibits" the Department from using or disclosing information obtained under the

Subpoena.[253] The Department dismisses concerns about potential disclosure to state officials because such sharing would be authorized by statute and the fifth factor concerns only *unauthorized* disclosure.[254] It also notes additional protections such as a protective order, sealing, or a written agreement could further limit dissemination.[255]

The Department of Justice's reliance on Section 3486(e)(1) to claim the statute "broadly prohibits" the disclosure or use of patient information obtained under a Section 3486 subpoena is misleading. Congress in Section 3486(e)(1) restricts only the use or disclosure of a patient's health information in actions or investigations directed against that individual and even then allows disclosure upon a judicial finding of good cause.[256] Congress imposes no general bar on further sharing of patient information obtained under a Section 3486 subpoena, including with state officials where authorized. Congress does require the Department of Justice to return or destroy materials if its investigation does not proceed to enforcement.[257] But the provision concerns return and not disclosure. It does not itself provide a nondisclosure safeguard.

The Hospital's remaining broader concerns would, in an ordinary case, drift into speculation. Federal officials' general enforcement rhetoric or policy statements are not, by themselves, proof of an imminent unauthorized leak. We appreciate courts of appeals to consider the question have found the statutory safeguards associated with Section 3486 adequate and the Department correctly notes protective orders, sealing, and similar mechanisms can further mitigate risks of disclosure.

But we are in a different posture. This investigation has a significant public shaming (for some) component following on public condemnation of persons seeking gender-affirming care. The Department has not offered examples of similar situations, but we only need to look a few years back to the shaming of persons with HIV-related illnesses as Judge Brotman ably reviewed.

The President described this medical care as a stain on our history and the Attorney General pronounced this gender-affirming care mutilates children in service of a radicalized and warped ideology. The Department of Justice offers nothing to mitigate a concern for these children and their families given these pronouncements. And we do not find a basis to risk harm absent concrete assurances from the Department of protections and penalties for those who disclose this information without authorization, and who might share the Attorney General's condemnation of these patients.

Factor five slightly weighs in favor of the Hospital.

5. The Department's stated needs for access are outweighed by the children's privacy interests given the Hospital is not today contesting the other twelve requests tied to the Department's investigative purposes.

The sixth factor our Court of Appeals identified in *Westinghouse* requires we balance the degree of the Department of Justice's need for access to the children's and their family's identification and treatment records. The Hospital argues the Department of Justice "has multiple avenues to investigate health care offenses without intruding on patient privacy."[258] It emphasizes the Department already possesses numerous alternative investigative tools—such as subpoenaed billing records, the Program's policies and practices for informed consent, and solicited whistleblower tips—none of which require the patient-identifying and clinical information demanded in Requests 11, 12, and 13.[259]

The Department of Justice counters its need for access to the children's identity and treatment records is "extremely heightened" because: (1) it is investigating statutory violations routinely examined under the Act and the records requested are "common in such investigations;" (2) subpoena recipients cannot dictate what evidence an investigator may obtain and the Hospital does not offer a "compelling reason" to restrict the Department's approach here; and (3) the secrecy surrounding gender-affirming care makes patient records essential.[260] It further claims factor six

is "essentially dispositive" because "the investigation relates to potential misconduct committed against vulnerable children, leaving lifelong mental and physical side effects and consequences."[261] The Department's view is a "compelling interest in investigating health care offenses involving children outweighs, as a matter of law, an individual's privacy interest in medical records" and "[t]he Constitution cannot reasonably be interpreted to divest the Government of its ability to protect children and combat offenses committed against them."[262]

The Hospital responds its position is supported by "specific, credible, and *uncontested* evidence" showing compelled disclosure of these patient records would itself inflict serious psychological harm on the very children the Department of Justice claims to protect.[263] It stresses recognizing the force of "the four privacy-focused *Westinghouse* factors" does not divest the Department of Justice of its "ability to protect children" as the Department of Justice suggests.[264] The Hospital reiterates the Department retains numerous investigative options "without enforcing a dragnet-style subpoena for sensitive patient records."[265] It also argues the Department's reliance on Director Hsiao's Declaration does little to establish "need" because "[t]o the extent the investigation concerns activities with a nexus to patient information, the legal theories on which [the Declaration] is predicated are fatally flawed."[266]

Our studied examination confirms the records sought in Requests 11,12, and 13 do not meaningfully advance the Department of Justice's stated investigative purposes. We are also persuaded the unchallenged Requests 1–10 and 14–15 should already capture the relevant evidence without requiring disclosure of the children's and their families' identities and most sensitive personal information. The Department of Justice identifies four broad areas of inquiry across its multiple filings.[267] These categories concern commercial practices, billing practices, and interactions with manufacturers or distributors. None of these areas of inquiry inherently requires

access to children's and their families' identities, psychosocial histories, sexual-development disclosures, family dynamics, trauma histories, or other intimate clinical details sought in Requests 11, 12, and 13.

Off-label dispensing is addressed directly through Requests 2–6, which seek the entire universe of billing records, insurance claims, internal protocols and guidance regarding International Classification of Diseases codes, communications about coding, training materials, and communications with insurers.[268] These requests capture the documents bearing on how medical professionals coded diagnoses and how they submitted claims. We then contrast the child patients' psychosocial evaluations, intimate clinical narrative, or informed-consent materials and their personal identities; we have no basis to find this information would shed light on whether a medical professional miscoded a diagnosis. Potential violations of Section 331 (the Department's second investigative purpose) concern introduction, labeling, and distribution of drugs in interstate commerce as it relates to a health care benefit plan. The Department of Justice's theories of downplayed risks, off-label use, and "masking" codes instead concern clinical practice and internal documentation. Congress through Section 331 does not regulate clinical practice. Even taking the Department of Justice's theory at face value, the relevant evidence would appear in Requests 7–10 and 14, which seek communications with manufacturers and compounding pharmacies, communications with sales representatives or medical-science liaisons, "scientific exchange" materials and promotional documents, contracts or consulting agreements, and communications about drug safety.[269] Whether manufacturers improperly marketed puberty blockers or hormones or whether clinicians entered into consulting agreements (the Government's third investigative purpose) is likewise fully addressed through Requests 7–10.[270] Contrast once again Requests 11, 12, and 13 which do not seek information about marketing practices, financial relationships, or

promotional conduct. A child's diagnosis, consent form, or identity does not reveal whether a manufacturer reached out to clinicians, sponsored programs, paid honoraria, or encouraged off-label use. The supply-chain theories involving manufacturers and distributors (the Department's fourth investigative purpose) would be reflected, if at all, in Requests 7–10 and 14–15, which seek communications with manufacturers and compounders, safety-related communications, and documents concerning adverse events, side effects, or medically unfavorable consequences.

The unchallenged Requests collectively capture every category of evidence relevant to the Department of Justice's stated investigations. We face a different analysis in reviewing Requests 11, 12, and 13 which concern how clinicians treated individual patients and contain no information about marketing conduct, upstream distribution protocols, billing protocols, coding policies, financial arrangements with manufacturers, or supply-chain transactions.

The Department of Justice's attempts to explain Requests 11, 12, and 13 by appealing to the seriousness of its investigation and arguing the sensitivity of the information "heightens" the Department of Justice's need misdirects the inquiry. Congress through Section 3486 authorizes Requests 11, 12, and 13 only for investigating potential Section 331 offenses relating to a health care benefit program consistent with the stated investigation purposes. The Department of Justice cannot expand its purposes by reframing Requests 11, 12, and 13 as an instrument to "protect children" nor by invoking generalized concerns about "misconduct against vulnerable minors." The need analysis must remain tethered to the purpose Congress identified. The Department of Justice's reliance on *New York v. Ferber* for the proposition "[i]t 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" is misplaced.[271] The facts reviewed in *Ferber* involved criminal prohibitions on the distribution of child sexual-abuse materials, a context in which the Court recognized a

compelling state interest wholly distinct from the administration of health care benefit programs.[272] Invoking *Ferber* in this context conflates two entirely different spheres of regulatory authority. It does not bear on whether children's constitutionally protected medical records are needed for an investigation into a potential Section 331 offense relating to a health care benefit program.

The Department of Justice's theory factor six is "essentially dispositive" and overrides all others cannot be squared with *Westinghouse*. Our Court of Appeals has long emphasized a balancing test, not a hierarchy or sliding scale on which the governmental need presumptively eclipses medical privacy. Treating factor six as dispositive would nullify decades of *Westinghouse* precedent and collapse the analysis into a single governmental-need inquiry. Nothing in Section 3486 or judicial guidance supports this reaching result.

Nothing in the present record establishes a need—within the meaning of *Westinghouse* or Congress's grant in Section 3486—for the patient-identifying clinical files demanded in Requests 11–13. The investigative purposes are fully addressed by the unchallenged requests. The personal and intimate material sought in Requests 11–13 does not advance an inquiry into a potential Section 331 offense relating to a health care benefit program. This factor favors nondisclosure.

Factor six weighs in the Hospital's favor.

6. The President's and Attorney General's articulated public policy weighs in favor of disclosure.

The final *Westinghouse* factor considers whether there is an express statutory mandate, articulated public policy, or other recognizable public interest militating toward access. The Hospital does not dispute Section 3486 grants the Department of Justice investigative authority over health care offenses.[273]

The *Westinghouse* seventh factor weighs in favor of disclosing the children's identities and medical treatment under strict protocols.

III. Conclusion

Congress granted the United States Department of Justice in 1996 the ability to subpoena documents from medical professionals relevant to investigating the labeling and distribution of prescription puberty blockers and hormone therapy under the Food, Drug, and Cosmetic Act. The Department of Justice now invokes this power twenty-nine years later to demand doctors and hospitals governed by Pennsylvania law disclose the identities of transgender child-patients and the medical and psychological care records documenting their gender-affirming care. The Department of Justice is following the President's January 2025 executive order announcing the policy of the United States is to recognize only two sexes and the United States will now pursue a policy of ending puberty blockers or hormone therapy to children although prescribed by doctors consistent with an individual state's authority to supervise medical care. Attorney General Bondi announced in April 2025 the Department of Justice will investigate false or misleading claims about the on- or off-label use of puberty blockers and hormone therapy to transgender children under the Food, Drug, and Cosmetic Act. The Department of Justice then issued subpoenas to twenty medical providers across the Nation including The Children's Hospital of Philadelphia seeking fifteen categories of records. The Department of Justice touted its stated investigative purpose of protecting children "mutilated" in "the service of a warped ideology."

The Hospital has treated children facing these gender identity issues for the last eleven years consistent with Pennsylvania citizens approving the legality of gender-affirming medical care. The Hospital agreed to produce defined financial, insurance, and billing records consistent with the Department's stated purposes.

But the Department of Justice, following the President's and Attorney General's specific direction to only recognize two sexes and end the use of puberty blockers and hormone therapy notwithstanding a state's view under its police powers, also demanded the Hospital produce three

categories of records beyond internal financial and billing records. It demands (subject to contempt of court for failing to do so) the Hospital's Gender and Sexuality Development Program now produce documents: (1) identifying the names, addresses, and social security numbers of its child patients prescribed puberty blockers and hormone therapy and their families' identifying information; (2) the child's medical treatment records including diagnoses; and, (3) describing each child's informed consent, patient intake, parent or guardian authorization, and use of medicine not approved by the Food and Drug Administration. The Hospital objects to producing child-patients' confidential medical records.

We asked for briefing to understand how these three requests fit within Congress's authorization to obtain information relating to a violation of the Food, Drug, and Cosmetic Act. We studied several rounds of briefing including from Amici Pennsylvania Governor Shapiro and several other states addressing two questions: whether Congress authorized the production of the children's confidential medical records; and, if so, whether the children's privacy interest outweigh the Department of Justice's need for these confidential medical records for the stated investigative purposes under the Food, Drug, and Cosmetic Act. The Department of Justice shifted much of its focus during our study admittedly in response to other Judges precluding the production of records by medical centers outside of Pennsylvania.

We find the Department of Justice has not shown Congress granted it authority to compel information relevant to its defined investigation under the Food, Drug, and Cosmetic Act. It offers no basis to compel the Hospital to identify the children (and their families), their treatment records, and disclosures made to them. We further find, even if the information responsive to these three requests is relevant (and thus authorized by Congress for a subpoena), the children's and their families' privacy interests in their highly sensitive and confidential medical and psychological

treatment in an charged political environment which considers their medical treatment to a radicalized warped ideology far outweigh the Department of Justice's shifting need for the information specifically identified in the three challenged requests. We grant the Hospital's motion in part striking the three challenged requests and all information contained in responses to other requests disclosing the same information.

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[1] The Tenth Amendment reserves to the states powers not delegated to the federal government. U.S. CONST. amend. X. These police powers include the authority to protect public health and safety. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996); *Slaughterhouse Cases*, 83 U.S. 36, 62 (1873).

[2] 43 P.S. § 955; 16 Pa. Code §§ 41.204, 41.206; Commonwealth of Pennsylvania, Pennsylvania's Human Relations Commission's Guidance on Discrimination on the Basis of Sex Under the Pennsylvania Human Relations Act (PHRA), https://www.pa.gov/content/dam/copapwp-pagov/en/phrc/documents/Sex%20Discrimination%20Guidance%20PHRA-3-3-2021.pdf (last visited Nov. 18, 2025).

[3] ECF 36 at 9.

[4] Pennsylvania Dep't of Human Servs., *Children's Health Insurance Program (CHIP) Eligibility and Benefits Handbook* 54 (Apr. 5, 2017), https://www.pa.gov/content/dam/copapwp-pagov/en/dhs/documents/chip/eligibility-and-benefits/documents/CHIP%20Eligibility%20and%20Benefits%20Handbook%202017_May2021.pdf; Pennsylvania Dep't of Human Servs., Medical Assistance Bulletin No. 99-16-11, *Federal Final Rule, "Nondiscrimination in Health Programs and Activities" and Implication for Coverage of Services Related to Gender Transition* (July 18, 2016), https://www.pa.gov/content/dam/copapwp-pagov/en/dhs/documents/docs/publications/documents/forms-and-pubs-omap/c_233793.pdf.

[5] ECF 36 at 9.

[6] 49 Pa. Code §§ 16.63, 21.416, 25.218, 41.62, 47.5; Commonwealth of Pennsylvania, *Shapiro Administration Announces Five State Boards Have Adopted New Policies Making Clear That Conversion Therapy on LGBTQ+ Minors is Harmful and Unprofessional* (May 2, 2024), https://www.pa.gov/governor/newsroom/2024-press-releases/shapiro-administration-announces-five-state-boards-have-adopted-. The Commonwealth defines the scope of medical practice, sets licensure requirements, and oversees professional discipline through state licensing boards. ECF 36 at 7–8. The State Boards of Medicine and Osteopathic Medicine in Pennsylvania hold exclusive authority to license, regulate, and discipline medical and osteopathic physicians and other health

professionals. *See* 63 P.S. §§ 422.1–422.51a; *id.* §§ 271.1–271.19. Physicians must meet education, training, and examination requirements before receiving a license and must be licensed to practice medicine in the Commonwealth. *See id*. §§ 422.22, 271.6. The State Board of Medicine adopts regulations "defin[ing] the accepted standard of care." *Id.* § 422.41(8)(ii). The standard in the absence of a regulation is care "normally exercised by the average professional of the same kind in [the] Commonwealth under the circumstances." *Id.* The Boards discipline physicians who deliver care below the accepted standard or engage in incompetence, gross negligence, or repeated negligence. *Id.* §§ 422.41, 271.15; 49 Pa. Code § 16.61. Regulation of the practice of medicine rests with the states and in the Commonwealth the authority lies with its Boards.

[7] The Hospital opened in 1855 as the first hospital in the United States dedicated exclusively to pediatric care. ECF 1 at 4; Children's Hosp. of Phila., *A History of Breakthroughs,* https://www.chop.edu/about-us/our-history (last visited November 18, 2025).

[8] ECF 1 at 4.

[9] *Id.* at 5; *see also id.* at 61–66 ("Hawkins and Dowshen Decl.").

[10] *Id.* at 63–64 (Hawkins and Dowshen Decl. ¶¶ 12, 16).

[11] *Id.* at 62 (Hawkins and Dowshen Decl. ¶ 4).

[12] *Id.* (Hawkins and Dowshen Decl. ¶¶ 4–5).

[13] *Id.* (Hawkins and Dowshen Decl. ¶ 6).

[14] *Id.* at 64 (Hawkins and Dowshen Decl. ¶ 14).

[15] *Id.* at 62 (Hawkins and Dowshen Decl. ¶ 6).

[16] *Id.* (Hawkins and Dowshen Decl. ¶ 7).

[17] *Id.* at 62 (Hawkins and Dowshen Decl. ¶¶ 8–9).

[18] *Id.* at 6.

[19] *Id.* at 63 (Hawkins and Dowshen Decl. ¶ 10).

[20] *Id.* at 5.

[21] Exec. Order No. 14168, 90 Fed. Reg. 8615 (Jan. 20, 2025).

[22] *Id.* § 2.

[23] Exec. Order No. 14187, 90 Fed. Reg. 8771 (Jan. 28, 2025).

[24] *Id.* § 1.

[25] *Id.*

[26] *Id.*

[27] *Id.* § 2(c).

[28] *Id.* § 4.

[29] *Id.* § 8(c).

[30] PN11-2 — Pamela Bondi — Department of Justice, 119th Congress (2025-2026), https://www.congress.gov/nomination/119th-congress/11/2.

[31] Memorandum from Pamela Bondi, Attorney General to Select Component Heads, *Preventing the Mutilation of American Children* (Apr. 22, 2025), https://www.justice.gov/ag/media/1402396/dl.

[32] *Id.* at 1, 3.

[33] *Id.* at 3–4.

[34] *Id.* at 4 (citing 21 U.S.C. §§ 321(m)–(n), 331, 352(a), (t); 21 C.F.R. §§ 201.100, 201.128, 202.1(1)(2)).

[35] *Id.* at 6.

[36] 21 U.S.C. § 301 *et seq*.

[37] *See id.* §§ 331, 355.

[38] Agata Dabrowska & Susan Thaul, How FDA Approves Drugs and Regulates Their Safety and Effectiveness, Congressional Research Services (May 8, 2018), https://www.congress.gov/crs-product/R41983.

[39] *Id.*

[40] 21 U.S.C. § 321(m).

[41] *Kordel v. United States*, 335 U.S. 345, 349–50 (1948).

[42] *See* 21 C.F.R. § 202.1(l)(2) (These materials include "[b]rochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips, lantern slides, sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio, or visual matter descriptive of a drug and references published (for example, the 'Physicians Desk Reference') for use by medical practitioners, pharmacists, or

nurses, containing drug information supplied by the manufacturer, packer, or distributor of the drug and which are disseminated by or on behalf of its manufacturer, packer, or distributor are hereby determined to be labeling as defined in section 201(m) of the act."). "In essence, virtually all communication with medical professionals concerning a drug constitutes labeling." 21 C.F.R. § 202.1(l)(2). *In re Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 RAs) Prods. Liab. Litig.*, No. 24-3094, 2024 WL 4520117, at *9 (E.D. Pa. Oct. 17, 2024) (citing 21 C.F.R. § 202.1(l)(2)) (collecting cases).

[43] Jennifer A. Staman, Enforcement of the Food, Drug, and Cosmetic Act: Select Legal Issues, Congressional Research Service (Feb. 9, 2018), https://www.congress.gov/crs-product/R43609 (citing Peter Barton Hutt, Richard A. Merrill, and Lewis A. Grossman, Food and Drug Law 12-16, 1196 (Foundation Press, 3d ed. 2007)). Section 301 is codified at 21 U.S.C. § 331.

[44] *Id.* (internal citation and quotations omitted); *see also* 21 U.S.C. § 331.

[45] 21 U.S.C. §§ 331, 333.

[46] *See id.* § 351.

[47] *See id.* § 352.

[48] *Id.*

[49] 21 U.S.C. § 352(f); 21 C.F.R. § 201.5.

[50] 21 C.F.R. § 201.128.

[51] 21 U.S.C. § 353(b)(2). Congress in Section 353(b)(2) exempts "[a]ny drug dispensed by filling or refilling a . . . prescription of a practitioner licensed by law to administer such drug" if basic labeling requirements are met. *Id.* The prescription must "bear[] a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber, and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription." *Id.* A parallel regulatory exemption applies to prescription drugs at any stage of distribution. *See* 21 C.F.R. § 201.100.

[52] *See supra* note 33.

[53] Memorandum from Brett A. Shumate, Assistant Attorney General to All Civil Division Employees, *Civil Division Enforcement Priorities,* U.S. Dep't of Just., Civ. Div. (June 11, 2025), https://www.justice.gov/civil/media/1404046/dl.

[54] *Id.* at 2.

[55] *Id.* at 2–3 (citing [2]1 U.S.C. § 301 *et seq*.). Neither the President nor Attorney General Bondi ever mentioned exposing the names and diagnoses of children of the people who elected President Trump a few months earlier.

[56] The Assistant Attorney General for the Civil Division is authorized through Attorney General Order Number 3591-2015 dated November 10, 2015 to issue and serve administrative subpoenas to investigate possible violations of the Food, Drug, and Cosmetic Act relating to a health care benefit program. ECF 42-1 at 2.

[57] 18 U.S.C. § 3486(a)(1)(A)(i)(I) (commonly referred to as "Section 3486"); ECF 1 at 34 (Subpoena).

[58] *In re: Administrative Subpoena No. 25-1431-014*, No. 25-mc-54 (E.D. Pa. Oct. 6, 2025) ("Patients' Case"), ECF 16 at 3 n.1 (quoting 18 U.S.C. § 24(a)(2)); *see also* Patients' Case, ECF 16-1 at 2 (Declaration of Lisa K. Hsiao ("Hsiao Decl.") ¶ 5).

[59] Patients' Case, ECF 16 at 3-4 n.1 (quoting 18 U.S.C. § 24(b)); *see also* Patients' Case, ECF 16-1 at 2 (Hsiao Decl. ¶ 9).

[60] ECF 1 at 39 (Subpoena Section III).

[61] *See id.* (Subpoena Request No. 1) ("Complete personnel files for each employee, contractor, or affiliate of the Company in the following categories: (a) executives, management employees, or board members with authority to direct any aspect of the Company's affairs; (b) employees, contractors, or affiliates who have authority to prescribe medications or perform medical evaluations; and (c) employees, contractors, or affiliates who are engaged in billing activities."); *id.* (Subpoena Request No. 2) ("All documents, including billing records, insurance claims, internal protocols, or guidance, concerning the use of ICD (i.e., International Classification of Diseases) diagnosis codes in connection with the treatment of minor patients receiving gender-related care."); *id.* at 40 (Subpoena Request No. 4) ("All documents reflecting communications among Company employees (including physicians, billing staff, and administrators), or between the Company and any third party, relating to whether or how to code or bill for treatment of gender dysphoria by using alternative diagnoses or alternative ICD codes."); *id.* (Subpoena Request No. 5) ("All communications with public or private health care benefit programs or plans regarding the use of [International Classification of Diseases] codes for gender-related care, including any inquiries, denials, or appeals related to claims for such care."); *id.* (Subpoena Request No. 6) ("Any training materials, coding manuals, presentations, or communications relating to billing or coding practices for gender-related care, puberty blockers, or hormone therapy."); *id.* (Subpoena Request No. 7) ("All documents relating to communications between You and any pharmaceutical manufacturer of puberty blockers or hormones, or any compounding pharmacy providing puberty blockers or hormones, relating to the use of such drugs in gender-related care for minors."); *id.* (Subpoena Request No. 8) ("All documents relating to communications with pharmaceutical sales representatives, marketing departments, or medical science liaisons regarding the use of puberty

blockers or hormones for gender-related care or the treatment of gender dysphoria, including with regard to the safety and efficacy of such drugs for those uses.").

[62] *Id.* at 7–8.

[63] *Id.* at 8.

[64] *Id*.

[65] *Id.*

[66] ECF 1 at 40 (Subpoena Request Nos. 11–13).

[67] ECF 1.

[68] U.S. Dep't of Just., Off. of Pub. Affairs, *Department of Justice Subpoenas Doctors and Clinics Involved in Performing Transgender Medical Procedures on Children* (July 9, 2025), https://www.justice.gov/opa/pr/department-justice-subpoenas-doctors-and-clinics-involved-performing-transgender-medical.

[69] *Id.*

[70] *Id.*

[71] Patients' Case, ECF 1.

[72] Patients' Case, ECF 16-1 (Hsiao Decl.). The Enforcement and Affirmative Litigation Branch is the successor to the Consumer Protection Branch. *Id.* at 1 (Hsiao Decl. ¶ 2). It is authorized as the successor "to oversee and conduct all civil and criminal matters arising under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, *et seq*." *Id.* (citing 28 C.F.R. § 0.45(i); Justice Manual 4-8.000).

[73] Patients' Case, ECF 16 at 3-4 (citing Patients' Case, ECF 16-1 at 13-15 (Hsiao Decl. ¶¶ 37–41)). We told the Department of Justice we would address the patients' and former patients' argument as part of our study of the Hospital's arguments. Patients' Case, ECF 6.

[74] ECF 22.

[75] ECF 36.

[76] ECF 38.

[77] ECF 1 at 4.

[78] *Id.* at 1, 9.

[79] *Id.* at 9; *United States v. Westinghouse Elec. Corp.,* 638 F.2d 570, 577 (3d Cir. 1980).

[80] ECF 1 at 4.

[81] *See* ECF 13.

[82] *Id.* at 2.

[83] *Wayne Land & Min. Grp., LLC v. Delaware River Basin Comm'n*, 959 F.3d 569, 574 (3d Cir. 2020) (citing *Va. House of Delegates v. Bethune-Hill*, 587 U.S. 658, 663 (2019)).

[84] ECF 13 at 6. It is worth noting the Department of Justice relies on *United States v. Miller,* 425 U.S. 435 (1976) for the proposition the Fourth Amendment does not protect information voluntarily shared with a third party, even if the individual expected the information to remain confidential. *See id.* (citing *Miller*, 425 U.S. at 443) ("[T]he 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."). But *Miller* is a far cry from the information sought here. *Miller* concerned an individual defendant who sought to suppress his own bank records obtained through subpoenas issued to two banks after indictment on federal charges. *Id.* at 436. The bank records at issue were "not confidential communications but negotiable instruments to be used in commercial transactions" and the Supreme Court found no "legitimate 'expectation of privacy'" in those documents. *Id.* at 442. Reliance on a case involving routine bank records to justify compelled disclosure of sensitive medical information ignores the profound difference between commercial transactions and the most private details of a person's life.

[85] *See* Patients' Case, ECF 16 at 4; *see also id.* at 8 ("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 [the Hospital].").

[86] *See id.* at 5 ("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.").

[87] *United States v. Brooks*, 841 F. App'x 346, 351 (3d Cir. 2020) (citing *Davis ex rel. Davis v. Phila. Hous. Auth.*, 121 F.3d 92, 96 (3d Cir. 1997)).

[88] *Id.* (internal citation omitted).

[89] Patients' Case, ECF 16 at 4 (quoting 18 U.S.C. § 3486(a)(5)) (emphasis in original).

[90] *Westinghouse,* 638 F.2d at 574; *cf. Singleton v. Wulff,* 428 U.S. 106, 118 (1976) (allowing physician to assert privacy rights of his patients); *Griswold v. Connecticut,* 381 U.S. 479, 481 (1965) (same).

[91] *Id.*

[92] *Id.*

[93] *Westinghouse,* 638 F.2d at 574.

[94] *University of Med. & Dentistry of New Jersey v. Corrigan*, 347 F.3d 57, 64 (3d Cir. 2003).

[95] *Id.* (quoting *F.D.I.C v. Wentz*, 55 F.3d 905, 908 (3d Cir. 1995); *see also United States v. Powell*, 379 U.S. 48, 57-58 (1950), *United States v. Morton Salt Co.,* 338 U.S. 632, 652 (1950))

[96] *See, e.g., CMA CGM S.A. v. CIS Dev. Found., Inc*., No. 24-364, 2024 WL 3964322, at *2 (D.N.J. Aug. 28, 2024) (quoting *N.L.R.B. v. Frazier*, 966 F.2d 812, 815 (3d Cir. 1992)); *In Matter of Petition for Enf't of Subpoenas of Fed. Mar. Comm'n Issued to Jose Diaz/Tioga Fruit Terminal, Inc., Chilean Line, Inc.*, No. 97-21, 1997 WL 414944, at *2 (E.D. Pa. July 22, 1997).

[97] *Wentz*, 55 F.3d at 908 (quoting *United States v. Westinghouse Elec. Corp.,* 788 F.2d 164, 166 (3d Cir. 1986)).

[98] *Morton Salt Co.*, 338 U.S. at 652.

[99] *Id.* (quoting *Oklahoma Press Publ'g Co. v. Walling*, 327 U.S. 186, 208 (1946)).

[100] *Fed. Trade Comm'n v. Am. Tobacco Co.*, 264 U.S. 298, 306 (1924).

[101] *Oklahoma Press Publ'g Co., 327 U.S. at 209 (footnote and internal quotation marks omitted).*

[102] *Univ. of Med. & Dentistry of New Jersey*, 347 F.3d at 64 (quoting *SEC v. Wheeling-Pittsburgh Steel Corp.*, 648 F.2d 118, 125 (3d Cir. 1981)).

[103] *Wentz*, 55 F.3d at 908 (citing *United States v. Cortese*, 614 F.2d 914, 919 (3d Cir. 1980)).

[104] *Wheeling-Pittsburgh Steel Corp.*, 648 F.2d at 128 (quoting *Powell,* 379 U.S. at 58); see also *United States v. Westinghouse Elec. Corp*., 788 F.2d 164, 166-67 (3d Cir. 1986) (first citing *Pickel v. United States*, 746 F.2d 176, 185 (3d Cir. 1984); and then citing *Wheeling-Pittsburgh Steel Corp.*, 648 F.2d at 125 ("[I]f a subpoena is issued for an improper purpose . . . its enforcement constitutes an abuse of the court's process.").

[105] *Wearly v. F.T.C.*, 616 F.2d 662, 665 (3d Cir. 1980)

[106] *N.L.R.B. v. Frazier*, 966 F.2d 812, 815 (3d Cir. 1992) (cleaned up).

[107] 18 U.S.C. §§ 3486(a)(1)(A)(i), (a)(1)(B)(i); *see also* Patients' Case, ECF 16 at 3 ("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.'").

[108] *See, e.g., Doe v. United States*, 253 F.3d 256, 266 (6th Cir. 2001) ("Because § 3486 authorizes subpoena requests for documents 'which *may be relevant* to an authorized law enforcement inquiry,' . . . the question of the relevance of the documents requested is inherently a question of whether the [Department of Justice] had the statutory authority to issue this subpoena.") (emphasis in original).

[109] We are aware of two publicly available decisions by our colleagues quashing similar administrative subpoenas upon medical centers for exceeding the Department of Justice's statutory authority. We are also aware of cases where the Department of Justice and the subpoenaed medical provider are not allowing public access to their arguments but are sharing them with us given our Order to do so but we do not describe those cases in deference to the parties' wishes in those cases.

The Department of Justice served Boston Children's Hospital with an identical administrative subpoena seeking records related to the hospital's provision of gender-affirming care. *In re: Administrative Subpoena No. 25-1431-019*, No. 25-91324, 2025 WL 2607784, at *1 (D. Mass. Sept. 9, 2025). The Department of Justice purportedly issued the subpoena to "investigate whether [the hospital] engaged in unlawful off-label promotion of puberty blockers and cross-sex hormones in violation of the [Act] and other false claims that may have been submitted to federal health[ ] care programs." *Id.* at *1. The hospital challenged the subpoena, arguing the Department of Justice issued the subpoena in bad faith and courts must not enforce administrative subpoenas issued in bad faith. *Id.* at *5 (citing *United States v. Powell*, 379 U.S. 48 (1964)). Judge Joun noted courts enforce administrative subpoenas if the agency shows: "(1) the subpoena is issued for a congressionally authorized purpose, the information sought is (2) relevant to the authorized purpose and (3) adequately described, and (4) proper procedures have been employed in issuing the subpoena." *Id.* at *4 (citation omitted). Judge Joun first considered whether the Department of Justice made a prima facie showing of proper purpose and then considered whether the hospital demonstrated an improper purpose. *Id.* at *5 (citing *United States v. Comley*, 890 F.2d 539 (1st Cir. 1989)). Judge Joun found the Department failed to make a prima facie showing of proper purpose because it had not submitted affidavits or other evidence tying the "broad array" of subpoenaed material to a legitimate investigation. *See id.* at *5–6. Judge Joun emphasized the Department did not adduce evidence the hospital engaged in billing fraud or unlawful off-label promotion of puberty blockers and requested documents unrelated to these practices. *Id.* at *6. Judge Joun reasoned the context of the President's executive orders challenging gender-affirming care and the lack of evidence supporting the Department's stated reasons for the subpoena showed improper purpose. *Id.* at *7. Judge Joun granted the hospital's motion to quash. The Department of Justice moved to alter or amend Judge Joun's opinion on October 7, 2025 followed by a notice of appeal to the United States Court of Appeals for the Court of Appeals on November 7, 2025. *In re: Administrative Subpoena No. 25-1431-019*, 25-91324, ECFs 35, 46. Judge Joun did not rule on the Department's motion to alter or amend before it appealed.

Judge Whitehead similarly granted a motion to quash a few weeks ago. The Department of Justice issued an identical administrative subpoena to QueerDoc, a telehealth provider of gender-affirming care. *QueerDoc, PLLC v. U.S. Dep't of Just.*, No. 25-42, 2025 WL 3013568, at *1–2 (W.D. Wash. Oct. 27, 2025). As in the Boston case, the Department of Justice argued our elected officials in Congress gave it authority under Section 3486 to request documents which would aid in its

investigation of "billing fraud" and "whether off-label promotion and/or unlawful dispensing of puberty blockers and cross-sex hormones for use by minors violated federal law, including the Food, Drug, and Cosmetic Act." *Id.* at *2. Judge Whitehead granted QueerDoc's motion to quash. Judge Whitehead found the Supreme Court held in *Powell* government agencies must not issue administrative subpoenas "for an improper purpose, such as to harass the [recipient] or to put pressure on [it] to settle a collateral dispute, or for any other purpose reflecting on the good faith of the particular investigation." *Id.* at *4 (quoting *United States v. Powell*, 379 U.S. 48, 58 (1964)). Judge Whitehead further relied on his governing Court of Appeals's guidance subpoenas may be challenged "on any appropriate grounds, including failure to satisfy the *Powell* requirements or abuse of the court's process," *id.* at *5 (quoting *Crystal v. United States*, 172 F.3d 1141, 1144 (9th Cir. 1999)), and courts in his Circuit "both can and do examine whether subpoenas are issued in bad faith." *Id.* Judge Whitehead concluded the record revealed improper purpose and emphasized the Department of Justice issued the subpoena shortly after President Trump expressed his views through executive orders challenging gender-affirming care and the stated reasons for the investigation (to investigate drug manufacturers, distributors, and providers submitting false insurance claims) did not match QueerDoc's actual operations, because it did not manufacture or distribute puberty blockers, nor did it submit insurance claims for patients. *Id.* at *5–6. Judge Whitehead reasoned "the breadth of the subpoena requests" suggested the Department "issued the subpoena first and searched for a justification second." *Id.* at *6. He found the record established the Department of Justice issued the subpoena "for a purpose other than to investigate potential violations of the [Food, Drug, and Cosmetic Act] or [False Claims Act]." Judge Whitehead granted QueerDoc's motion to quash. *Id.* at *7. The Department of Justice has not moved to alter or amend Judge Whitehead's opinion nor yet appealed to the United States Court of Appeals for the Court of Appeals.

We are also aware of another case which remains entirely under seal. Our colleague also quashed the subpoena in its entirety for similar statutory authority reasons.

[110] ECF 1 at 4; *id.* at 39–41 (Subpoena Requests).

[111] *Id.* at 4, 10–12.

[112] *See supra* notes 12–15.

[113] Patients' Case, ECF 16-1 at 14 (Hsiao Decl. ¶ 41).

[114] *Id*.

[115] *Id.*

[116] *See generally* 21 U.S.C. § 331; *see also supra* notes 36–51.

[117] *See* 21 U.S.C. § 333(a)(2).

[118] *In re Admin. Subpoena No. 25-1431-019*, No. 25-91324, 2025 WL 2607784, at *6 (D. Mass. Sept. 9, 2025).

[119] *In re Subpoena Duces Tecum*, 228 F.3d 341, 349 (4th Cir. 2000) (citing *United States v. R. Enter., Inc.*, 498 U.S. 292, 299 (1991) (cleaned up); *see also U.S. E.P.A. v. Alyeska Pipeline Serv. Co.*, 836 F.2d 443, 447 (9th Cir. 1988), *abrogated by, McLane Co. v. E.E.O.C.*, 581 U.S. 72 (2017) ("[W]hile the 'investigatory powers . . . should be interpreted broadly,' 'the subpoena cannot be so broadly stated as to constitute a fishing expedition.'") (citation omitted); *In re Sealed Case (Admin. Subpoena)*, 42 F.3d 1412, 1418 (D.C. Cir. 1994) (quashing subpoena to the extent that the agency sought "unfettered authority to cast about for potential wrongdoing"); *United States v. Theodore*, 479 F.2d 749, 754 (4th Cir. 1973) ("The Government cannot go on a 'fishing expedition' . . . and where it appears that the purpose of the summons is 'a rambling exploration' of a third party's files, it will not be enforced.") (citations omitted).

[120] *Oklahoma Press Publ'g Co.,* 327 U.S. at 213.

[121] *Id.*

[122] *See* ECF 13 at 1 (The inquiry concerns "whether off-label promotion and/or unlawful dispensing of puberty blockers and cross-sex hormones for use by minors violated federal law, including the Food, Drug, and Cosmetic Act[]. Because public or private insurance plans were presented with claims related to off-label use of these medications, such a violation of the [Act] could constitute a federal health care offense."); *see also* Patients Case, ECF 16-1 at 2 ("[T]he United States is conducting a nationwide investigation involving potential violations of the [Act] relating to puberty blockers and cross-sex hormones when used to treat gender dysphoria and related disorders in minors.").

[123] Patients' Case, ECF 16 at 18.

[124] ECF 38 at 2.

[125] *Id.* at 5.

[126] Patients' Case, ECF 16-1 at 12 (Hsiao Decl. ¶ 34).

[127] *Id.* (Hsiao Decl. ¶¶ 35–36). We also take note of the inconsistency in Director Hsiao's Declaration. Director Hsiao's original Declaration represented under penalty of perjury "the Government is also aware of a lawsuit filed just this year" alleging misconduct by a former Hospital patient. ECF 33 at 29. The Department of Justice then replaced Director Hsiao's Declaration the following day and removed her sworn reference to a lawsuit. The revised sworn paragraph refers only to unspecified "allegations." Patients' Case, ECF 16-1 at 12 (Hsiao Decl. ¶ 36). The Hospital swears they are "unaware of any such lawsuit and ha[d] not been served" as of October 20, 2025. ECF 33 at 4. We cannot determine on this record whether the Department of Justice grounded its submission in substantiated evidence or in something far less reliable. We do not rest our reasoning on the shifting sworn statements but remind counsel sworn declarations filed in federal court must reflect verified facts, not speculation recast as fact. The integrity of the

process tolerates nothing less than full candor from officers of the Court regardless of their zeal to end a perceived warped ideology in medical care for children.

[128] ECF 38 at 4.

[129] Patients' Case, ECF 16 at 18. We earlier expressed concern with the veracity of Director Hsiao's sworn statements and appreciate her lawyers recognize false statements may be subject to a perjury investigation.

[130] *Id.* at 17.

[131] ECF 13 at 12; *see also id.* at 7 ("[T]he investigation relates to potential misconduct committed against vulnerable children, leaving lifelong mental and physical side effects and consequences.").

[132] Patients' Case, ECF 16 at 13 (citing Patients' Case, ECF 16-1 at 7–10 (Hsiao Decl. ¶¶ 22–29)).

[133] *See United States v. Skrmetti*, 605 U.S. 495, 523 (2025); ECF 36 at 9.

[134] Food and Drug Admin., *Understanding Unapproved Use of Approved Drugs "Off Label"* (Feb. 5, 2018), https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label (acknowledging "health[]care providers generally may prescribe [approved] drugs for an unapproved use when they judge that it is medically appropriate for their patient"); Food and Drug Admin., *Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products; Questions and Answers; Guidance for Industry* 8-9 (Jan. 2025), https://www.fda.gov/media/184871/download (acknowledging various circumstances in which health care providers may validly prescribe drugs for off-label use); *see also, e.g.*, *Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001) (Off-label use "is an accepted and necessary corollary of the [Food and Drug Administration]'s mission to regulate in this area without directly interfering with the practice of medicine."); *In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 240 (3d Cir. 2012) ("Because the [Act] does not regulate the practice of medicine, physicians may lawfully prescribe drugs for off-label uses."); *In re Zofran (Ondansetron) Prods. Liab. Litig.*, 541 F. Supp. 3d 164, 173 (D. Mass. 2021), *aff'd*, 57 F.4th 327 (1st Cir. 2023) ("It is generally lawful for physicians to prescribe medications for purposes for which they have not been [Food and Drug Administration]-approved."); *Wash. Legal Found. v. Henney*, 202 F.3d 331, 333 (D.C. Cir. 2000) ("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 [Food and Drug Administration].").

[135] *Ass'n of Am. Physicians & Surgeons v. U.S. Food & Drug Admin.*, 13 F.4th 531, 534 (6th Cir. 2021) (citing *Buckman*, 531 U.S. at 350-51).

[136] 21 U.S.C. § 396; *see also Shuker v. Smith & Nephew, PLC*, 885 F.3d 760, 766-67 (3d Cir. 2018) (The Act "expressly contemplates the possibility that physicians may use [approved products] for unapproved purposes.") (applying Pennsylvania law).

[137] *Seavey v. Globus Med., Inc.*, No. 11-2240, 2014 WL 1876957, at *15 (D.N.J. Mar. 11, 2014) (internal citations omitted).

[138] 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 (May 2019).

[139] John J. Smith, *Physician Modification of Legally Marketed Medical Devices: Regulatory Implications Under the Federal Food, Drug, & Cosmetic Act*, 55 Food & Drug L.J. 245, 251 (2000).

[140] *See* Patients' Case, ECF 16-1 at 4, 7 (Hsiao Decl. ¶¶ 13, 22). Director Hsiao advances the same premise under different statutory labels. She first invokes the misbranding provisions and asserts "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." *Id.* at 4 (Hsiao Decl. ¶ 13) (citing 21 U.S.C. §§ 331(a)-(c), (k) and 352(f)(1)). She then repeats the same reasoning under the "new drug" provision and claims "if a drug manufacturer or other person distributes (or causes the distribution of) an approved drug for an unapproved use, the manufacturer or other person could be charged with distributing an unapproved new drug." *Id.* at 6 (Hsiao Decl. ¶ 18) (citing 21 U.S.C. § 331(d)).

[141] *See supra* note 132; *Sommers v. UPMC*, 185 A.3d 1065, 1072 n.6 (Pa. Super. Ct. 2018).

[142] Patients' Case, ECF 16-1 at 5 (Hsiao Decl. ¶¶ 14–16). Labeling under the Act "is broadly defined as any 'written, printed, or graphic matter … *accompanying*' the drug. . . . 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." *Id.* (Hsiao Decl. ¶ 15) (citing 21 U.S.C. § 321(m) (emphasis in original)). It "can include promotional materials, advertisements, brochures, flyers, instruction sheets, posters, and similar materials." *Id.* (Hsiao Decl. ¶ 15).

[143] *See supra* notes 36–51.

[144] Patients' Case, ECF 16-1 at 8 (Hsiao Decl. ¶ 23).

[145] ECF 37 at 5–6.

[146] *See supra* notes 36–51.

[147] *Id.*

[148] ECF 37 at 6; *United States v. Regenerative Scis. LLC*, 741 F.3d 1314 (D.C. Cir. 2014).

[149] *Regenerative Scis. LLC*, 741 F.3d at 1318–19, 1324–25 (emphasis added).

[150] *Id.* at 1319.

[151] *Id.* at 1319–20.

[152] *See United States v. Jackson*, 126 F.4th 847, 860 (4th Cir. 2025) (rejecting the argument equating "the sort of off-label usage that [Section] 396 is designed to protect with the holding for sale of an adulterated device, an action *not* protected by the statute. Section 396 protects only physicians who 'prescribe or administer any *legally marketed* device.'" The Act "bars adulterated devices from the stream of commerce entirely, so they cannot be lawfully sold. . . . They therefore are not legally marketed devices within the meaning of [Section] 396. . . . And while off-label use is 'an accepted and necessary corollary of the [Food and Drug Administration]'s mission to regulate in this area without directly interfering with the practice of medicine,' . . . holding adulterated devices for sale is not.") (internal citations omitted); *United States v. Cal. Stem Cell Treatment Ctr., Inc.*, 117 F.4th 1213, 1217, 1220 (9th Cir. 2024) (adopting *Regenerative Sciences LLC's* reasoning to hold physicians who manufactured and administered unapproved stem-cell mixtures were subject to the Act).

[153] ECF 1 at 9; *Westinghouse*, 638 F.2d at 576, 578.

[154] *Westinghouse*, 638 F.2d at 576, 578.

[155] ECF 13 at 3. It is worth addressing the Department of Justice's first contention. It opens by calling the Hospital's reliance on *Westinghouse* a "novel" argument, insists our Court of Appeals "fashioned a non-statutory seven-factor test not found in any Supreme Court precedent or prior decision," and notes the Hospital "does not cite a single case applying the *Westinghouse* factors." *Id.* at 2. But it is of course within our Court of Appeals's prerogative to articulate a test for subpoenas implicating medical privacy so long as it fits within established limits. The Hospital's argument is novel only because our Circuit has not yet had occasion to consider a privacy challenge to a subpoena issued under Section 3486. The absence of such a case proves nothing beyond the fact the Hospital is the first to need to raise the issue to protect child-patient identities and medical records after *Westinghouse*. Its advocacy is not a defect in the Hospital's position. It is how law properly develops.

The Department's reference to a case in our Circuit "discussing a [Section 3486] subpoena [but] mak[ing] no mention at all of *Westinghouse*" does not alter this conclusion. *See* ECF 13 at 3 n.1 (citing *United States v. Hertel & Brown Physical & Aquatic Therapy*, No. 21-cr-39, 2025 WL 83789 (W.D. Pa. Jan. 13, 2025). Judge Baxter did not address patients' privacy interests in their own medical records in *Hertel*. *See infra* notes 195–99. Its silence on *Westinghouse* is of no moment.

[156] ECF 13 at 3.

[157] *Id*. at 4.

[158] *Id*.

[159] *Id*. at 3; *In re KB Toys Inc.* 736 F.3d 247, 251 (3d Cir. 2013).

[160] *Id*. at 4 (citing *In re Subpoena*, 228 F.3d at 350–51; *Doe v. United States*, 253 F.3d 256, 264–65 (6th Cir. 2001); *United States v. Whispering Oaks Residential Care Facility, LLC*, 673 F.3d 813, 817 (8th Cir. 2012)).

[161] ECF 20 at 2–3.

[162] *Id.* at 3–4; *see* 18 U.S.C. § 3486(a)(7) ("A summons issued under this section shall not require the production of anything that would be protected from production under the standards applicable to a subpoena duces tecum issued by a court of the United States.").

[163] *Id.* at 4.

[164] *Id.* at 5.

[165] *See* ECF 13 at 4 ("[A Section 3486] subpoena that meets the statutory requirements for enforcement satisfy the *Westinghouse* test (and the Constitution's privacy guarantees) as a matter of law; no further balancing is required."); *id.* ("[T]he Government's 'compelling interest in identifying illegal activity and in deterring future misconduct' using a § 3486 subpoena outweighs Constitutional privacy concerns as a matter of law…").

[166] *See Zadvydas v. Davis*, 533 U.S. 678, 695 (2001) ("The Government also looks for support to cases holding that Congress has 'plenary power' to create immigration law, and that the Judicial Branch must defer to Executive and Legislative Branch decisionmaking in that area. . . . But that power is subject to important constitutional limitations. *See INS v. Chadha,* 462 U.S. 919, 941–942 (1983) (Congress must choose 'a constitutionally permissible means of implementing' that power); *The Chinese Exclusion Case,* 130 U.S. 581, 604 (1889) (congressional authority limited 'by the Constitution itself and considerations of public policy and justice which control, more or less, the conduct of all civilized nations')."); *see also Patel v. Zemski*, 275 F.3d 299, 308 (3d Cir. 2001), *abrogated on other grounds by, Demore v. Kim,* 538 U.S. 510 (2003) (Congress'[s] power is subject to constitutional limitations, including due process constraints.); *Landau v. Corp. of Haverford College*, No. CV 24-2044, 2025 WL 1796473, at *2 (E.D. Pa. June 30, 2025) ("A court enforcing a federal statute must do so in a way that comports with the Constitution."). If Congress's plenary power over immigration cannot insulate executive detention from constitutional scrutiny, then certainly a statutory subpoena power under Section 3486 cannot displace the constitutional privacy protections recognized in *Westinghouse*.

[167] *Wentz*, 55 F.3d at 908 (citing *Whalen v. Roe,* 429 U.S. 589, 599 (1977) (in the context of a Federal Deposit Insurance Corporation administrative subpoena).

[168] *Id.* at 909 (quoting *Westinghouse* 638 F.2d at 577, 579).

[169] *Id*.

[170] *United States v. Oncology Servs. Corp.*, 60 F.3d 1015, 1020 (3d Cir. 1995) (citing *Westinghouse,* 638 F.2d at 578) (in the context of a Nuclear Regulatory Commission administrative subpoena).

[171] *Matter of Delaware River Stevedores*, 178 F.R.D. 51, 52 (E.D. Pa. 1997) (citing *Wentz,* 55 F.3d at 908–09; *Whalen,* 429 U.S. at 599; *Westinghouse,* 638 F.2d at 578) (in the context of a Federal Maritime Commission administrative subpoena); *see also In Matter of Petition for Enf't of Subpoenas of Fed. Mar. Comm'n Issued to Jose Diaz/Tioga Fruit Terminal, Inc., Chilean Line, Inc.*, No. 97-21, 1997 WL 414944, at *2 (E.D. Pa. July 22, 1997) (Our Court of Appeals "acknowledged that other factors may be considered; those factors include privacy, breadth, potential for harm from subsequent nonconsensual disclosure, adequacy of safeguards, and burden of production.") (also in the context of a Federal Maritime Commission administrative subpoena).

[172] *CMA CGM S.A. v. CIS Dev. Found., Inc.*, No. 24-364, 2024 WL 3964322, at *2 (D.N.J. Aug. 28, 2024) (citing *Wentz*, 55 F.3d at 908; *Whalen*, 429 U.S. at 599) (also in the context of a Federal Maritime Commission administrative subpoena).

[173] Courts in our Circuit invoke and apply *Westinghouse* in other contexts, further underscoring its continued force as controlling precedent on constitutional privacy interests. *See, e.g., Scheetz v. Morning Call, Inc.*, No. 89-6755, 1990 WL 82082, at *1–2 (E.D. Pa. June 11, 1990) (applying *Westinghouse* privacy balancing framework to a motion to quash a Rule 45 subpoena in a civil discovery dispute involving medical records); *Malleus v. George*, 10-1357, 2010 WL 3069669, at *3 (E.D. Pa. Aug. 5, 2010), *aff'd*, 641 F.3d 560 (3d Cir. 2011), *as amended* (June 6, 2011) (applying *Westinghouse* privacy balancing in a § 1983 action challenging the disclosure of confidential statements made during a school investigation); *Doe v. Luzerne Cnty.*, 660 F.3d 169, 178 (3d Cir. 2011) (applying *Westinghouse* privacy balancing in a § 1983 action challenging the disclosure of intimate photographs).

[174] ECF 13 at 3 (quoting *In re KB Toys Inc.*, 736 F.3d at 251).

[175] *In re KB Toys Inc.*, 736 F.3d at 251 (citing *Roth v. Norfalco L.L.C.,* 651 F.3d 367, 379 (3d Cir.2011) ("When the meaning of statutory text is plain, our inquiry is at an end.")). "[C]ourts 'must not be guided by a single sentence or member of a sentence, but look to the provisions of the whole law, and to its object and policy.'" *Id.* (quoting *Official Comm. of Unsecured Creditors of Cybergenics Corp. ex rel. Cybergenics Corp. v. Chinery,* 330 F.3d 548, 559 (3d Cir.2003) (en banc)). "If the statutory text is ambiguous, a court may look to the legislative history." *Id.* (citing *Blum v. Stenson,* 465 U.S. 886, 896 (1984)).

[176] *See* ECF 1 at 1–2; ECF 20 at 2–3.

[177] Neither party offered, and we are unable to find, a case analyzing this subsection in depth but its text supports the Hospital's reading.

[178] 673 F.3d 813, 818–19 (8th Cir. 2012). The subpoena sought "documents relating to goods and services provided at [the residential care facility], expenditures for those goods and services, personnel records and job descriptions, bank statements and tax returns for the care facility and management company as well as documents that describe the relationship between the two, and

any communications either company had with state agencies about governing health care regulations." *Id.*

[179] The facility challenged enforcement of the subpoena as violating its Fourth Amendment right "to be free from unreasonable searches" and argued certain requests were "overly broad" but its reasoning focused on "conclusory statements about the relevance of the requests to a lawful investigation." *Id.* at 816, 819.

[180] *Id.* at 817–19.

[181] 253 F.3d 256, 260 (6th Cir. 2001).

[182] *Id.* at 260–61 (emphasis added).

[183] *Id.* at 265.

[184] The physician challenged the other requests as "unreasonably burdensome" and "questioned [their] relevance." *Id.* at 261.

[185] *Id.* at 266.

[186] ECF 13 at 4.

[187] *Id.*

[188] 228 F.3d 341, 344 (4th Cir. 2000).

[189] *Id.* at 351.

[190] *Id.* at 739; *see also id.* at 729 (The government "offered to allow the movants to first produce all documents with the exception of patient treatment files and records pertaining to claim filing procedures. After reviewing these documents, the [Government] would then notify the movants what, if any, patient files and records pertaining to claim filing procedures [it] wished them to produce.").

[191] *In re Subpoenas Duces Tecum*, 51 F. Supp. 2d 726, 738–39 (W.D. Va. 1999), *aff'd, In re Subpoena Duces Tecum*, 228 F.3d 341 (4th Cir. 2000).

[192] *Id.* at 738–39.

[193] 228 F.3d 341, 351 (4th Cir. 2000).

[194] ECF 13 at 3 n.1 (citing *United States v. Hertel & Brown Physical & Aquatic Therapy*, No. 21-cr-39, 2025 WL 83789, at *7 (W.D. Pa. Jan. 13, 2025)).

[195] *Hertel,* 2025 WL 83789, at *1.

[196] *Id.*

[197] *Id.* at *2–5.

[198] *Id.* at *5.

[199] *Id.* at *7.

[200] ECF 13 at 5.

[201] *Id.*

[202] ECF 1 at 9 (citing *Westinghouse*, 638 F.2d at 578).

[203] The Department also seeks to group the third factor with the first two factors, but the third factor involves distinct considerations regarding potential harm from disclosure requiring we address it separately. *See* ECF 13 at 9–11.

[204] ECF 1 at 10–13.

[205] *Id.* at 10; *see supra* notes 12–15.

[206] *Id.* at 11.

[207] *Id.* (citing Dep't of Health and Hum. Servs., Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82462, 82464 (Dec. 28, 2000) ("If, in Justice Brandeis' words, the 'right to be let alone' means anything, then it likely applies to having outsiders have access to one's intimate thoughts, words, and emotions."); *Murray v. Pittsburgh Bd. of Educ.*, 759 F. Supp. 1178, 1181 (W.D. Pa. 1991) ("There can be no doubt that [this] information [is] of the types most associated with expectations of privacy."); *Haw. Psychiatric Soc., Dist. Branch of Am. Psychiatric Ass'n v. Ariyoshi*, 481 F. Supp. 1029, 1038 (D. Haw. 1979) ("Many courts and commentators have concluded that, because of the uniquely personal nature of mental and emotional therapy, accurate diagnosis and effective treatment require a patient's total willingness to reveal the most intimate personal matters, a willingness that can exist only under conditions of the strictest confidentiality.")).

[208] *Id.* at 12 (quoting *Westinghouse,* 638 F.2d at 579).

[209] *Id.* at 12–13.

[210] ECF 13 at 10.

[211] *Id.*

[212] *Id.*

[213] *Id.*

[214] *Id.* at 10–11. The "potential consumer-protection violations" include "false statements made to induce patient and parental consent to off-label drug use and other life-altering procedures; powerful pharmaceuticals casually being given off-label to very young minors, causing lifelong side effects; purported treatment guidelines based on false or insufficient evidence; and other alarming trends that the Executive Branch could reasonably believe deserve exploration." *Id.* at 11 (citing *Skrmetti*, 605 U.S. at 539–46).

[215] *Id.* at 11. The Department of Justice argues the Hospital's showing on the first three factors is outweighed by the need for records and Department's interest but again we are only considering the first two factors at this point and address the third factor separately. *See supra* note 203.

[216] *Westinghouse*, 638 F.2d at 577; *see also, e.g., In re Motions Seeking Access to 2019 Statements*, 585 B.R. 733, 752 (D. Del. 2018), *aff'd sub nom*., *In re A C & S Inc.*, 775 F. App'x 78 (3d Cir. 2019) (emphasizing "[w]here materials contain personal identifiers, paired with confidential medical information, the potential risk to privacy interests in disclosure is self-evident" and citing *Westinghouse*); *In re Search Warrant (Sealed)*, 810 F.2d 67, 71 (3d Cir. 1987) (recognizing an individual's constitutional right to privacy "extends to the individual interest in avoiding disclosure of personal matters" and "medical records are clearly within this constitutionally protected sphere"); *Papasavvas v. Davis*, No. 23-22165, 2024 WL 3585650, at *1 (D.N.J. July 30, 2024) (acknowledging "an individual's right to privacy in her medical records is well established" and finding mental health record medical records "are well within the ambit of materials entitled to privacy protection"); *United States v. Bowers*, 676 F. Supp. 3d 403, 423 (W.D. Pa. 2022) (noting medical records "are well within the ambit of materials entitled to privacy protection"); *Weisman v. Buckingham Twp.*, No. 04-4719, 2005 WL 1406026, at *7 (E.D. Pa. June 14, 2005) (same); *Wilson v. Pa. State Police Dep't*, No. 94-6547, 1999 WL 179692, at *2–3 (E.D. Pa. Mar. 11, 1999) (recognizing "the limited right to privacy in medical records" but finding the *Westinghouse* factors favored disclosure of the narrow "vision-related material[s]" at issue—while withholding names, addresses, and other identifying information—because the requested vision information was "not as intimate as many other kinds of medical information" and "it is difficult to see how the [individuals] would be harmed if their vision scores became public").

[217] *Doe v. Se. Pa. Trans. Auth.,* 72 F.3d 1133, 1138 (3d Cir. 1995), *cert. denied,* 519 U.S. 808 (1996).

[218] *Id.*

[219] *Sterling v. Borough of Minersville*, 232 F.3d 190, 196 (3d Cir. 2000) (internal quotations omitted); *Doe v. Delie*, 257 F.3d 309, 315 (3d Cir. 2001); *Gruenke v. Seip,* 225 F.3d 290, 301 (3d Cir. 2000).

[220] *See Doe v. Se. Pa. Transp. Auth.*, No. 93-5988, 1995 WL 334290, at *6 (E.D. Pa. June 2, 1995), *rev'd on other grounds*, 72 F.3d 1133 (3d Cir. 1995), *cert. denied,* 519 U.S. 808 (1996).

[221] *Doe v. Luzerne Cnty.*, 660 F.3d 169, 175 (3d Cir. 2011).

[222] ECF 13 at 10–11.

[223] *See supra* notes 58–59.

[224] *Id.*

[225] ECF 1 at 13–15.

[226] *Id.* at 13.

[227] *Id.*

[228] *Id.*

[229] *Id.* at 13–14.

[230] *Id.* at 14.

[231] *Id.* at 14–15.

[232] ECF 13 at 11.

[233] 729 F. Supp. 376, 378–79, 384 (D.N.J. 1990); *see also id*. at 385 ("Revealing that one's family or household member has AIDS causes the entire family to be ostracized.").

[234] *Id.* at 384; *see also Se. Pa. Transp. Auth.*, 72 F.3d at 1140 ("Although AIDS hysteria may have subsided somewhat, there still exists a risk of much harm from non-consensual dissemination of the information that an individual is inflicted with AIDS.").

[235] *Borough of Barrington*, 729 F. Supp. at 385 (relying on *Westinghouse* and distinguishing the factual circumstances).

[236] Patients' Case, ECF 16-1 at 14 (Hsiao Decl. ¶ 41).

[237] *Id.*

[238] The Hospital erroneously refers to this factor as Factor Five. *See* ECF 1 at 15.

[239] ECF 1 at 15.

[240] *Id.* at 15–16.

[241] *Id.*

[242] *Id.*

[243] *Id.* at 16.

[244] ECF 13 at 12.

[245] ECF 13 at 11–12.

[246] *Id.* at 12.

[247] *Id.*

[248] ECF 1 at 17.

[249] *Id.* at 17–18 (citing 18 U.S.C. § 3486(e)(1)); ECF 20 at 8–9. The full text of Section 3486(e)(1) reads: "Health 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 unless the action or investigation arises out of and is directly related to receipt of health care or payment for health care or action involving a fraudulent claim related to health; or if authorized by an appropriate order of a court of competent jurisdiction, granted after application showing good cause therefor." 18 U.S.C. § 3486(e)(1).

[250] *Id.* at 18–19 (citing 5 U.S.C. § 552a(b)(7), (9)); ECF 20 at 8.

[251] ECF 1 at 18–19.

[252] ECF 13 at 8 (citing *In re Subpoena*, 228 F.3d at 350; *Doe v. United States*, 253 F.3d at 264–65; *Whispering Oaks Residential Care Facility*, 673 F.3d at 817).

[253] *Id.* at 8–9 (citing 18 U.S.C. § 3486(a)(8), (e)(1)).

[254] *Id.* at 9.

[255] *Id.* at 9.

[256] See *supra* note 249.

[257] *See* 18 U.S.C. § 3486(a)(8).

[258] ECF 1 at 20.

[259] *Id.* at 20.

[260] ECF 13 at 6–7.

[261] *Id.* at 7–8.

[262] *Id.* at 8.

[263] ECF 20 at 9 (emphasis in original).

[264] *Id*.

[265] *Id.*

[266] ECF 33 at 6.

[267] *See supra* notes 122–25.

[268] ECF 1 at 39–40 (Subpoena Request Nos. 2–6).

[269] *Id.* at 40–41 (Subpoena Request Nos. 7–10 and 14).

[270] *Id.* at 40 (Subpoena Request Nos. 7–10).

[271] 458 U.S. 747, 756–57.

[272] *Id.*

[273] ECF 1 at 20.