EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Case No. 25-mc-00063-SKC-CYC

IN RE: DEPARTMENT OF JUSTICE ADMINISTRATIVE SUBPOENA No. 25-1431-030

DECLARATION OF LISA HSIAO

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

GENERAL BACKGROUND

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

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

3. Through Presidentially-appointed, Senate-confirmed officers of the Department of Justice, Enforcement is authorized to undertake appropriate investigations of any violations of the Food, Drug, and Cosmetic Act (FDCA) relating to the on- or off-label use by manufacturers and distributors of drugs, including puberty blockers, sex

hormones, or any other drug used to facilitate a child's so-called "gender transition." See AG Bondi Memo dated April 22, 2025.

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

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

6. The subpoena to Children's Hospital Colorado, No. 25-1431-030 was lawfully issued and authorized by Brett A. Shumate, Assistant Attorney General for the Civil Division, in connection with a valid investigation being conducted in my office.

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

LEGAL BACKGROUND

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

9. A "federal healthcare offense" for purposes of a subpoena issued under 18 U.S.C. § 3486 is defined by 18 U.S.C. § 24(a) as "a violation of, or a criminal conspiracy to violate … section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 331) … if the violation or conspiracy relates to a health benefit program." 18 U.S.C. § 24(a). The statute defines "health care benefit program" to mean "any public or private plan or contract, affecting commerce, under which any medical benefit, item, or service is provided to any individual, and includes any individual or entity who is providing a medical benefit, item, or service for which payment may be made under the plan or contract." 18 U.S.C. § 24(b). A subpoena issued under section 3486 (commonly referred to as a "HIPAA subpoena") may be used to investigate both substantive violations of the FDCA, as well as conspiracies to violate the FDCA if the violation or conspiracy relates to products or services that might ultimately be paid for by a private or public health insurance program.

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

FDA'S APPROVAL OF DRUGS

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

12. A drug manufacturer obtains FDA approval for a new drug through a new drug application ("NDA") that demonstrates that its drug is safe and effective for each of its intended uses. 21 U.S.C. § 355(a). As part of the approval process, FDA reviews the proposed labeling for the drug in the NDA, which must include adequate directions for how to use the drug for each of its intended uses. 21 U.S.C. § 352(f); 21 C.F.R. § 201.5. When FDA approves a drug, FDA approves it as safe and effective for the particular use or uses in the NDA. Similarly, as part of its approval, FDA approves the labeling in the NDA as having adequate directions for the particular use or uses in the NDA. FDA's

approval of a drug does not mean that the drug is safe and effective for unapproved uses or that the drug has adequate directions for unapproved uses. While it is possible for doctors to prescribe an approved drug for an unapproved use, prescriptions for unapproved uses may involve violations of the FDCA.

MISBRANDING OF DRUGS PRESCRIBED FOR UNAPPROVED USES THROUGH ILLEGAL LABELING

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

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

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

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

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

ILLEGAL DISTRIBUTION OF AN UNAPPROVED NEW DRUG

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

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

INTENT FOR FDCA CRIMES

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

20. A felony FDCA violation is the same as a misdemeanor FDCA violation with the addition of an intent to defraud or mislead. 21 U.S.C. § 333(a). Evidence of an intent to defraud or mislead a government agency or some other third-party, such as a patient or

an insurance company, in connection with an FDCA violation can be enough to prove a felony FDCA violation. Evidence of an intent to defraud or mislead can include taking steps to avoid detection of the illegal conduct.

THE DRUGS AT ISSUE IN THIS INVESTIGATION

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

22. FDA has not determined these drugs to be either safe or effective for the treatment of gender dysphoria. FDA has not approved any of these prescription drugs for the treatment of gender dysphoria or any other psychiatric disorder. While these drugs are FDA-approved for other indications (e.g., precocious puberty, prostate cancer, hypogonadism, etc.), FDA has not approved any NDA that establishes the safety and efficacy of these drugs for use in minors with gender dysphoria. As explained above,

introducing a such "new drug" into interstate commerce without an approved indication is unlawful. Thus, to the extent these drugs are marketed or promoted for treating gender dysphoria in minors, they constitute unapproved new drugs under federal law, and their distribution for that unapproved indication violates the FDCA and is a federal crime.

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

24. The United States government is aware of credible, publicly available evidence relating to the widespread practice of prescribing cross-sex hormones and puberty blockers to treat gender dysphoria in minors and casts doubt on the safety and efficacy of those practices. The United States Department of Health and Human Services ("HHS"), of which FDA is a component agency, has determined that the evidence for the safety and efficacy of these drugs for the treatment of gender dysphoria in minors is weak. *See generally*, U.S. DEP'T OF HEALTH & HUMAN SVCS., TREATMENT FOR PEDIATRIC GENDER DYSPHORIA, REVIEW OF EVIDENCE AND BEST PRACTICES (May 2025) (available at https://opa.hhs.gov/gender-dysphoria-report) ("The HHS Report"). Specifically, this report found that some of the pharmacologic interventions under investigation here "carry risk of significant harms including infertility/sterility, sexual dysfunction, impaired bone

density accrual, adverse cognitive impacts, cardiovascular disease and metabolic disorders, [and] psychiatric disorders." *Id.* at 10. HHS further determined that "the overall quality of [scientific] evidence concerning the effects of any intervention on psychological outcomes, quality of life, regret, or long-term health is **very low**." *Id.* at 13 (emphasis added).

25. The government is also aware of other high-level, publicly available information that looks skeptically upon the efficacy of puberty blockers and other medical interventions to treat youth for gender dysphoria. In the United Kingdom, for example, the British National Health Service ("NHS") commissioned an independent review led by Dr. Hilary Cass, a pediatrician and the former President of the Royal College of Paediatrics and Child Health, to evaluate how NHS was providing care for children experiencing gender-related distress. *See generally* NHS England, *Independent Review of Gender Identity Services for Children and Young People: Final Report* (Apr. 10, 2024), *available at* https://cass.independent-review.uk/home/publications/final-report/ ("*Cass Review*"). Dr. Cass's review concluded: "This is an area of remarkably weak evidence, and yet results of studies are exaggerated or misrepresented by people on all sides of the debate to support their viewpoint. The reality is that we have no good evidence on the long-term outcomes of interventions to manage gender-related distress." *Cass Review* at 13.

26. With regard to puberty blockers, Dr, Cass reported that a systematic review conducted by the University of York "found no evidence that puberty blockers improve body image or dysphoria" while "a known side effect of puberty blockers on mood is that

it may reduce psychological functioning." *Id.* at 179. Similarly, with regard to cross-sex hormones, the *Cass Review* agreed with another systematic review that concluded that: "There is a lack of high-quality research assessing the outcomes of hormone interventions in adolescents with gender dysphoria/incongruence, and few studies that undertake long-term follow up. No conclusions can be drawn about the effect on gender dysphoria, body satisfaction, psychosocial health, cognitive development, or fertility. Uncertainty remains about the outcomes for height/growth, cardiometabolic and bone health." *Id.* at 184.

27. As a result of the *Cass Review's* findings, in December 2024, the United Kingdom banned puberty blocker treatment for gender dysphoria. *See* Press Release, U.K. Department of Health & Social Care, *Ban on Puberty Blockers to be Made Indefinite on Experts' Advice* (Dec. 11, 2024), https://www.gov.uk/government/news/ban-on-puberty-blockers-to-be-made-indefinite-on-experts-advice (stating that "there is currently an unacceptable safety risk in the continued prescription of puberty blockers to children"). Press reports indicate that the U.K. is similarly considering banning cross-sex hormones for minors. *See* Alison Holt, *Cross-Sex Hormones for Under 18s Could be Restricted or Banned*, BBC News (May 22, 2025), https://www.bbc.com/news/articles/cg711xevd89o.

28. Other European countries have likewise enacted restrictions on the use of these pharmacologic interventions for treating gender-related disorders in minors, or are considering them. *See, e.g., Sweden Puts Brakes on Treatments for Trans Minors*, FRANCE 24 (Aug. 2, 2023), https://www.france24.com/en/live-news/20230208-sweden-puts-brakes-on-treatments-for-trans-minors; Siobhan Harris, *Europe & the Puberty*

Blocker Debate, MEDSCAPE MED. NEWS (Apr. 25, 2024), https://www.medscape.com/viewarticle/europe-and-puberty-blocker-debate-2024a1000831 (reporting on European countries' practices and findings including France's National Academy of Medicine recommendation that the "greatest reserve" be used in puberty blockers and/or hormones in children and adolescents; Sweden's conclusion that the risks of puberty blockers and hormones currently outweigh the potential benefits).

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

RELEVANT FACTS ABOUT CHILDREN'S HOSPITAL COLORADO

30. From testimonies of public whistleblowers and leading medical experts nationally on the subject matter, the Government is aware of potential violations of federal law in connection with the provision of gender-related treatments for minors occurring at healthcare providers across the country.

31. This includes allegations and evidence of fraudulent billing practices to secure insurance coverage/payment. Such practices include, but are not limited to, providers (i)

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

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

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

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

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

34. The Government did not issue its subpoena to Children's Hospital Colorado at random. Children's Hospital Colorado houses the "TRUE Center for Gender Diversity" a clinic that explicitly holds itself out in marketing and promotional materials (including through an internet website) as specializing in the treatment of children and adolescents who suffer from gender dysphoria, including by providing puberty blockers and cross-sex hormones to minors for non-FDA approved uses. Children's Hospital Colorado prominently advertises these services under "TRUE Center for Gender Diversity," "*See, e.g.,* https://www.childrenscolorado.org/doctors-and-departments/departments/gender-diversity-center/ ("Providing comprehensive care to gender-diverse children, adolescents, and their families." Referring to "Puberty-delaying Treatments" and "Hormone therapy.")

35. Statements on Children's Hospital Colorado's website may qualify as drug labeling under the FDCA, including its TRUE Center webpage describing specialty services. "Puberty-delaying treatments" gives written explanations of how the drugs work, describes them as safe, and how they are used—that is, information that supplements and explains the drug. The TRUE Center website also contains information related to "Hormone therapy" and explains how the medications may be used and their

intended effects. These statements have not been evaluated by the FDA related to the off-label use of the drugs presumably being used, and may contain arguably false and misleading information, making the distribution of these materials an act that renders the drugs misbranded. For example, the TRUE Center webpage states that "These medicines can postpone puberty changes that do not align with one's gender identity." This assertion omits information that is potentially material to the decision of whether to undergo treatment with medication, the effects of which are serious and may be irreversible. Other statements about the safety of treatment on Children's Hospital Colorado's website are likewise potentially false or misleading, including statements that these treatments are safely prescribed and monitored, which downplays and minimizes the known risks and uncertainties (due to the limited data and the "very low" quality of that data).

36. Although Children's Hospital Colorado purportedly adheres to certain standards of care and provides individualized treatment plans, many of its patients are given hormone replacement drugs, which can permanently alter person's physiology, upon mere referral and consent of a minor patient's guardians—often on an initial visit. According to a lawsuit filed by the ACLU under a pseudonym, a former Children's Hospital Colorado TRUE Clinic patient was prescribed testosterone, a schedule III controlled substance, in March 2022, after being referred to the TRUE Center in "early 2022." *Caden Kent v. Children's Hospital Colorado*, 2024-CV-30455 Dkt. 1 ¶¶ 24-25. In addition to this practice of prescribing cross-sex hormones soon after a patient's initial visit, the number of Children's Hospital Colorado patients given puberty blockers or hormone therapies increased dramatically during this same timeframe. Between 2019

and 2022, Children's Hospital Colorado furnished these drugs to between four and fourteen patients annually; in 2022, the facility treated more than 60 children with puberty blockers or hormone therapies. https://stoptheharmdatabase.com/hospital/childrens-hospital-colorado ("Deeper Dive" chart below "Total Hormone and Puberty Blocker Patients").

37. Moreover, there is evidence that Children's Hospital Colorado, and its associates may have knowingly violated the FDCA—either directly or through a conspiracy with others (e.g., with pharmacies, drug manufacturers, and/or distributors)—with the intent to defraud and mislead. As specified earlier, although violations of the FDCA are strict liability misdemeanors, if done with the intent to defraud or mislead, they are felonies. Children's Hospital Colorado's website explicitly states that "gender-affirming medical care is a growing science." It further acknowledges that it is "contributing to the academic research that informs evidence-based medicine." https://www.childrenscolorado.org/doctors-and-departments/departments/gender-diversity-center/. These statements conflict with the website's assertions that the "treatments are safely prescribed," because, in fact, the treatments are not being administered with drugs approved by the FDA for the purpose of treating gender dysphoria. Rather, Children's Hospital Colorado concedes that gender-affirming medicine is experimental, calling it an "emerging science." The statement that the facility is "contributing to academic research that informs evidence-based medicine" may be misleading: in prescribing and administering to minors drugs for non-FDA approved uses, Children's Hospital Colorado is suggesting, falsely, that the use of these

medications is supported by evidence-based studies and has been evaluated and approved in the United States for treatment of gender dysphoria. This falsity may provide the requisite *mens rea* for an FDCA felony, and this practice may also violate other federal criminal statutes such as 18 U.S.C. § 1035 (false statements relating to health care matters) and 18 U.S.C. § 1347 (health care fraud). It is not uncommon to charge additional federal crimes, *i.e.,* Title 18 offenses, along with FDCA criminal offenses.

38. Further, the Government is aware of insurance claims data showing that potentially fraudulent billing occurring at Children's Colorado Hospital. For example, insurance industry claims data related to Children's Hospital Colorado shows that since 2015, Children's Hospital Colorado first diagnosed minors with central precocious puberty at age 10 or older, including at least one minor receiving the diagnosis at age 13. According to Children's Hospital Colorado itself, these are well beyond the ages at which children are typically diagnosed with precocious puberty, shedding doubt on the legitimacy of these diagnoses. https://www.childrenscolorado.org/conditions-and-advice/conditions-and-symptoms/conditions/pediatric-puberty-disorders

39. Additionally, Children's Hospital Colorado is affiliated with the University of Colorado Anschutz, and Children's Hospital Colorado is described as being located on the University of Colorado's campus. https://www.cuanschutz.edu/patient-care Multiple University of Colorado providers were attendees and presenters at the national conferences discussed in paragraph 33 above. https://medschool.cuanschutz.edu/docs/librariesprovider323/default-document-library/meet-our-team.pdf?sfvrsn=74e3f6ba_2

40. One of Children's Hospital Colorado's own providers has published articles describing decreased bone density among children who are given puberty blockers. https://pubmed.ncbi.nlm.nih.gov/38562129/ The same author in another published article acknowledged the risks of high red blood cell counts, high cholesterol, and heart attack among transgender patients. https://pmc.ncbi.nlm.nih.gov/articles/PMC10424140/ These risks are not described in the TRUE Center's advertising.

41. All of the foregoing information supports the Government's decision to investigate the conduct of Children's Hospital Colorado as it relates to the provision of these drugs to minors, including its relationships with other persons and entities involved in the distribution and promotion of these drugs, is a valid subject of this investigation.

THE SUBPOENA SPECIFICATIONS SEEK INFORMATION RELEVANT TO THE INVESTIGATION

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

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

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

45. The third group of requests (relating to relationships with drug manufacturers, distributors, and pharmacies) are probative of an intent to market or promote drugs for unapproved uses. If Children's Hospital Colorado, or one of its affiliated healthcare providers, received promotional materials, "scientific exchange information," or payments to encourage prescribing of puberty blockers or cross-sex hormones, such information would support a FDCA theory (including conspiracy) involving unlawful off-label promotion. Similarly, information regarding financial arrangements (consulting agreements, sponsorships, speaking honoraria) may suggest improper influence to reinforce a showing an intent to misbrand, including with intent to defraud or mislead.

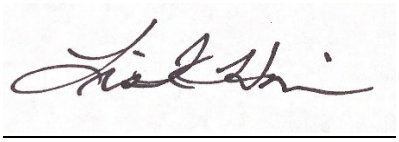
46. The final group of requests (relating to patient-level clinical practices and drug safety) will permit the United States to evaluate the scope of prescribing the drugs described herein (including the number and age range of patients treated), and consistency of diagnoses. It also establishes the scope of interstate distribution and the scale of potential FDCA violations. Linking each patient's clinical record to corresponding billing and insurance claims can demonstrate whether diagnoses were miscoded, which can prove fraudulent intent. Documentation of clinical justification, informed consent, and disclosure of off-label use is key to assessing whether the clinic (and/or potential co-conspirators) concealed or downplayed risks associated with using these drugs in a manner not approved by FDA. Absence or minimization of such warnings could establish the intent to mislead. Patient charts also typically capture adverse outcomes, side effects, and complications of drug use. By reviewing multiple patient records, the investigative team may reveal systemic use of the same masking codes, fraudulent informed consent documents, etc. This enables investigators to distinguish between mere errors and an institutionalized practice. Finally, providing patient records, including patient identities, can provide essential investigative leads. Parents may be witnesses about what disclosures were made. Patients (depending on age and circumstances) may provide information about the informed consent process, side effects, or other false or misleading information about the drugs conveyed during treatment. Health benefit programs tied to identified patients could provide additional information, including claim records, creating a triangulated evidentiary record. In sum, without this information, the government cannot fully determine the scope of the

violations, identify patterns of misbranding or fraudulent billing, or assess whether the conduct was undertaken with intent to defraud or mislead, as required for felony liability under 21 U.S.C. § 333(a)(2).

GOVERNMENT INVESTIGATIVE RESOURCES

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

I declare under penalty of perjury that the foregoing is true and correct. Executed on this 10th day of October, 2025.



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