Exhibit A

DECLARATION OF LISA K. HSIAO

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

GENERAL BACKGROUND

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

2. EALB's Enforcement Section ("ES") is the successor to the Consumer Protection Branch ("CPB") and is vested with CPB's legal authorities, including handling investigations and litigation arising under federal statutes that protect consumers' health, safety, economic security, and identity integrity. ES, 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., and related matters. *See* 28 C.F.R. § 0.45(i) and Justice Manual 4-8.000, 4-1.313.

3. EALB-ES is currently conducting an investigation of potential 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."

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. Under the authority of 18 U.S.C. § 3486 and the Attorney General's delegation of authority, on July 3, 2025, the Assistant Attorney General for the Civil Division, Brett A. Shumate, lawfully issued an administrative subpoena to Rhode Island Hospital ("RIH") in connection with an investigation being conducted in my office. The subpoena was served on RIH on July 11, 2025.

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. Among other statutory and regulatory authorities, EALB-ES investigates and brings actions to enforce the FDCA. 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. *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, *inter alia,* "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 its drug is safe and effective for each of its intended uses. 21 U.S.C. § 355(a). As part of the approval process, FDA reviews the proposed labeling for the drug in the NDA, which must include adequate directions for how to use the drug for each of its intended uses. 21 U.S.C. § 352(f); 21 C.F.R. § 201.5. When FDA approves an NDA, it determines that the drug is safe and effective **for the specific use or uses identified in the application.** As part of that approval, FDA also approves the product's proposed labeling, including prescribing information, as providing adequate directions for use for those approved indications. FDA's approval of a drug for one or more particular uses does **not** mean that the drug is safe and effective for unapproved uses, nor does approval mean that the labeling provides adequate directions for unapproved uses. While physicians are permitted to prescribe an FDA-approved drug for an unapproved use, such prescribing may warrant investigation because it may provide evidence of FDCA violations by others. *See, e.g.*, *infra* ¶¶ 13–18. Also, depending on the circumstances, prescribing for unapproved uses can itself involve FDCA violations—for example, where the physician is engaged in the distribution or labeling of an unapproved drug.

MISBRANDING OF DRUGS PRESCRIBED FOR UNAPPROVED USES THROUGH ILLEGAL LABELING

13. A drug is misbranded if its labeling does not have adequate directions for the use of the drug. 21 U.S.C. § 352(f). FDA-approved labeling contains directions only for the drug's approved uses. If a drug manufacturer or other person distributes an approved drug for an unapproved use, the manufacturer or other person could be charged with misbranding the drug or distributing a misbranded drug with labeling that lacks adequate directions for its intended uses.[1] 21 U.S.C. §§ 331(a), 331(b), 331(c), 331(k), and 352(f)(1). Enforcement's predecessor, CPB, 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 is also misbranded if its labeling is false or misleading in any particular. 21 U.S.C. § 352(a).

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

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

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). Enforcement's predecessor, CPB, participated in successful prosecutions of manufacturers for false and misleading labeling. *See, e.g., United States v. Avanos Medical, Inc.*, Case No. 21-CR-0307-E (N.D. Tex. 2021) (deferred prosecution agreement for false and misleading labeling for medical device).

ILLEGAL DISTRIBUTION OF AN UNAPPROVED NEW DRUG

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

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

INTENT IN FDCA CRIMES

19. A violation of 21 U.S.C. § 331 is a federal criminal offense that is punished as a strict liability misdemeanor without any proof of criminal intent. *See Park*, 421 U.S. at 672–73; *United States v. Wiesenfeld Warehouse Co.*, 376 U.S. 86, 91 (1964). Through its strict liability misdemeanor provision, the FDCA imposes rigorous criminal

accountability on companies and individuals involved with drugs that affect the health of consumers in circumstances where consumers realistically cannot protect themselves. *See Wiesenfeld*, 376 U.S. at 91; *Dotterweich*, 320 U.S. at 280–81. This heightened accountability is even more acute when the consumers at risk are children. Consequently, any violation of Section 331, including the causing of any prohibited act listed in Section 331, is a federal crime, even in the absence of any criminal intent.

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

THE DRUGS AT ISSUE IN THIS INVESTIGATION

21. This investigation focuses on prescription drugs typically used in gender-related care for children and adolescents suffering from a recognized mental disorder known amongst clinicians 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. Nor has FDA approved any of these drugs for the treatment of gender dysphoria or any other psychiatric disorder. While these prescription drugs are FDA-approved for other indications (*e.g.*, precocious puberty, prostate cancer, hypogonadism, etc.), FDA has not approved any NDA that establishes the safety and efficacy of these drugs for use in minors with gender dysphoria. As explained above, introducing a such "new drug" into interstate commerce without an FDA-approved indication is unlawful. Thus, to the extent these drugs are intended to treat gender dysphoria in minors, they constitute unapproved new drugs under federal law, and their distribution for that unapproved indication violates the FDCA and is a federal crime.

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

24. The United States Government is aware of credible, publicly available evidence relating to the widespread practice of prescribing cross-sex hormones and puberty blockers to treat gender dysphoria in minors that casts doubt on the safety and efficacy of

this practice. The United States Department of Health and Human Services ("HHS"), of which FDA is a component agency, has determined that the evidence for the safety and efficacy of these drugs for the treatment of gender dysphoria in minors is weak. *See generally*, U.S. DEP'T OF HEALTH & HUMAN SERVS., TREATMENT FOR PEDIATRIC GENDER DYSPHORIA, REVIEW OF EVIDENCE AND BEST PRACTICES (Nov. 19, 2025) t https://opa.hhs.gov/gender-dysphoria-report("HHS REVIEW"). 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. In December, 2025, the Assistant HHS Secretary for Health, Admiral Brian Christine, M.D., issued a public health message to healthcare providers stating that: "Current evidence does not support claims that puberty blockers, cross-sex hormones, and surgeries are safe and effective treatments for pediatric gender dysphoria … Healthcare providers caring for children and adolescents with gender dysphoria should refuse to provide puberty blockers, cross-sex hormones, or surgical interventions to children and adolescents, as these treatments pose unnecessary and disproportionate risks of harm with insufficient evidence of benefit." U.S. Dep't of Health & Human Servs., *Evidence-Based Care for Children and Adolescents with Gender Dysphoria* (Dec. 18,

2025), https://health.gov/sites/oash/files/Message_Pediatric_Gender_Dysphoria_Treatment.pdf.

26. The Government is also aware of other major scientific publications and national health authorities that have questioned the strength and quality of the evidence base for the efficacy of puberty blockers and other medical interventions to treat youth for gender dysphoria. In the United Kingdom, for example, the British National Health Service ("NHS") commissioned an independent review led by Dr. Hilary Cass, a pediatrician and the former President of the Royal College of 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), 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.

27. 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. 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.

28. 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/cg711xevd890.

29. Several other 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); *New Zealand Halts New Puberty Blockers for Young Transgender People*, NBC NEWS, (Nov. 20, 2025), https://www.nbcnews.com/world/asia/new-zealand-halts-new-puberty-blockers-young-transgender-people-rcna244925.

30. Most recently, just last month researchers analyzed a large Finnish nationwide cohort (2,083 gender disordered individuals matched with 16,643 controls) and found that adolescents who were referred for gender-identity services (such as hormonal or surgical treatment) had substantially higher rates of severe psychiatric morbidity than matched peers—both before and after treatment. The study determined that these patients' psychiatric needs not only persisted after undergoing sex-rejecting medical interventions, but even intensified. Those who underwent such procedures had elevated risks of psychiatric morbidity, "with hazard ratios approximately three times higher than female controls and five times higher than male controls." Sami-Matti Ruuska et al., *Psychiatric Morbidity Among Adolescents Who Contacted Specialised Gender Identity Services in Finland in 1996–2019: A Register Study*, ACTA PAEDIATRICA (2026), https://doi.org/10.1111/apa.70533.

31. Both the HHS review and the UK's independent *Cass Review*—along with numerous other systematic reviews of the evidence that the government is aware of—justify questioning the scientific foundation for prescribing puberty blockers and cross-sex hormones for minors. Not only has FDA not approved them for these purposes, but it

is far from certain, therefore, that prescribing these drugs would ever be considered by the agency as safe and effective for that indication. To the contrary, the available public record suggests there is serious potential for harm.

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

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

33. 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

[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."

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.

34. The Government also knows of evidence and allegations of many cases where providers failed to supply adequate labeling and to give 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.

35. The Government has also reviewed evidence (including transcripts and video recordings) from national conferences on treating patients with gender dysphoria, including minors, 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.

36. The subpoena at issue here is one of several investigative tools the United States has been employing in its ongoing and legitimate investigation concerning the provision of medical sex trait modification services, including issues related to violations of the FDCA. The investigation has proceeded through multiple channels, including the analysis of insurance claims data, billing records, and other lawfully obtained material. Information developed through those efforts has raised questions concerning whether

puberty blockers and cross-sex hormones have been fraudulently distributed for unapproved uses involving RIH patients. For example, based on diagnosis codes, it appears that between 2020 and 2025, there were at least 4 minors first diagnosed at RIH with central precocious puberty at age 12 or older. This is well beyond the age at which children are typically diagnosed with precocious puberty. *See, e.g.*, Pediatric Endocrine Society, *Precocious Puberty: A Guide for Families,* https://pedsendo.org/patient-recourse/precocious-puberty (Apr. 29, 2026) ("Precocious puberty is usually defined as onset of puberty before age 8 in girls and before age 9 in boys.").

37. Moreover, claims analysis shows that between 2020 and 2025, the number of RIH patients with claims bearing a diagnosis code for gender dysphoria more than doubled; the number of claims for "endocrine disorder" experienced similar growth.

38. In addition, the director of RIH's pediatric "Gender and Sexuality Program" (and the principal author of the American Academy of Pediatrics' gender policy statement) was responsible for at least 14 insurance claims for RIH patients bearing an "endocrine disorder" diagnosis code over the last decade—indeed more than his claims bearing a "gender dysphoria" diagnosis code over the same period.

39. As part of this investigation, the United States has also reviewed medical records obtained from other pediatric hospitals that have treated gender dysphoria with sex trait modification services, including through the use of pharmaceuticals. Those medical records reflect multiple instances in which diagnostic or billing codes for medical conditions such as "endocrine disorder, unspecified" notwithstanding clinical notes that reflect that the true disorder being treated with the drugs is gender

dysphoria/transsexualism. Some records further reflect that certain speech or vocal interventions are coded as treatment for vocal disorders even where the purpose is voice femininization or masculinization. These observations form part of the ongoing and developing factual basis for the Government's continuing investigation of similarly situated treatment centers, such as RIH.

THE SUBPOENA SPECIFICATIONS SEEK INFORMATION RELEVANT TO THE INVESTIGATION

40. The fifteen requests in the investigative HIPAA subpoena issued to RIH 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).

41. 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.

42. 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.

43. 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 RIH, 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.

44. 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 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

45. This is a bona fide, high-priority, and substantial 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 ("FBI") 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. In addition to FBI, FDA has also assigned agents from its Office of Criminal Investigations. The scope and coordination of these efforts reflect the seriousness with which the Government is pursuing potential violations of federal law.

RIH'S FAILURE TO COMPLY WITH THE SUBPOENA

46. The return date on the subpoena was Thursday, August 7, 2025. In early conversations with counsel for RIH, the Government communicated that it would be willing to receive documents responsive to the subpoena past the return date but that it did not expect to extend that grace period beyond reason. Counsel for RIH has communicated several times that it intends to and would be producing responsive documents. However, the last such communication was on February 4, 2026, and to date, RIH has produced only one document totaling six pages. In other words, RIH has failed to comply in any meaningful way with the subpoena.

I declare under penalty of perjury that the foregoing is true and correct. Executed on this 30th day of April, 2026.

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