U.S. Department of
JUSTICE

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

IN THE MATTER OF ADMINISTRATIVE SUBPOENA 25-1431-032

NO. 4-26MC-006-O

GOVERNMENT'S PETITION FOR ENFORCEMENT OF ADMINISTRATIVE SUBPOENA PURSUANT TO 18 U.S.C. § 3486(c)

On July 3, 2025, the Department of Justice (Department) served a Health Insurance Portability and Accountability Act (HIPAA) administrative subpoena on Rhode Island Hospital (RI Hospital), with a return date of Thursday, August 7, 2025. The subpoena is within the Department's statutory authority to investigate violations of the Federal Food, Drug, and Cosmetic Act (FDCA), the information requested is relevant to the Department's inquiry, and the subpoena is neither overbroad nor unduly burdensome. Yet, over ten months after service, RI Hospital has not complied with the subpoena. In fact, it has produced only one six-page document in response to the Department's fifteen document requests. The Department therefore moves for an order compelling RI Hospital to fully comply.

BACKGROUND

This case concerns an investigation into the distribution of certain prescription drugs to minors with gender dysphoria and related disorders—intended uses for which the Food

and Drug Administration (FDA) has determined neither their safety nor effectiveness. These include drugs that suppress the production of sex hormones to delay puberty (commonly referred to as "puberty blockers") and 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. *See United States v. Skrmetti*, 605 U.S. 495 503-04 (2025) (describing use of these drugs). Although these drugs are approved by FDA for some uses, the agency has not determined that any of these drugs are safe or effective for the treatment of gender dysphoria, nor has FDA approved them for the treatment of gender dysphoria or any other psychiatric disorder.

A primary focus of the Department's investigation—which is being carried out in the Northern District of Texas, *see* 18 U.S.C. § 3486(c)—is potential violations of the FDCA. The FDCA generally prohibits "misbranding" a drug. *See* 21 U.S.C. § 352; *id.* § 331(a)-(c), (k). A drug may be misbranded if, among other things, its labeling is false or misleading, *id.* § 352(a), or if its labeling does not bear adequate directions for its intended use, *id.* § 352(f)(1). "Intended use" means the "objective intent of the persons legally responsible for the labeling of an article (or their representatives)." 21 C.F.R. § 201.128. Such intent "may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives." *Id.* And the "intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer." *Id.* If, for example, a seller "intends an article for different uses than those intended by the person from whom he or she received the article," then the "seller is required to supply adequate labeling in accordance with the new intended uses." *Id.*

Under the FDCA, drug labeling is broadly defined to include any "written, printed, or graphic matter . . . accompanying" the drug. 21 U.S.C. § 321(m). The term "accompanying" includes materials that are separate from but related to the drug and any material that supplements, explains, or is designed for use with the drug. *See id.* § 321(m); 21 C.F.R. § 1.3(a); *Kordel v. United States*, 335 U.S. 345, 349-50 (1948); *United States v. Urbuteit*, 335 U.S. 355, 357 (1948); *United States v. 47 Bottles, More or Less, Etc.*, 320 F.2d 564, 569 (3d Cir. 1963). Labeling can include promotional materials, advertisements, brochures, flyers, instruction sheets, posters, and similar materials.

Misdemeanor violations of the FDCA are punishable on a strict liability basis, without any proof of criminal intent. *See* 21 U.S.C. § 331, § 333(a)(1); *United States v. Wiesenfeld Warehouse Co.*, 376 U.S. 86, 91 (1964). For example, if a drug manufacturer or other person causes the distribution of an approved drug for an unapproved use, the manufacturer or other person could be charged with misbranding the drug by distributing it with labeling that lacks adequate directions for its intended uses. 21 U.S.C. §§ 331(a)-(c), (k), 352(f)(1). Where a violator has an intent to defraud or mislead, an FDCA violation may be punishable as a felony. *Id.* § 333(a)(2).

In the investigation of a "Federal health care offense," HIPAA permits the Attorney General to issue a subpoena. 18 U.S.C. § 3486(a)(1)(A)(i)(I). A federal health care offense includes a "violation of, or a criminal conspiracy to violate" 21 U.S.C. § 331, "if the violation or conspiracy relates to a health care benefit program," 18 U.S.C. § 24(a)(2). And a "health care benefit program" is "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." *Id.* § 24(b).

Because public or private insurance plans were presented with claims related to off-label use of puberty blockers and cross-sex hormones, such a violation of the FDCA could constitute a "federal health care offense" as defined by 18 U.S.C. § 24. *See* Ex. A (Hsiao Decl.). Accordingly, the Assistant Attorney General signed a HIPAA subpoena, which was served on RI Hospital on July 11, 2025. *See* Ex. B (Subpoena); Ex. C (Proof of Service). After the review of claims data and billing records, the Department is investigating whether RI Hospital patients have received misbranded drugs. Hsiao Decl. ¶ 36. Also, the Department has reason to suspect that RI Hospital employees might have engaged in false billing concerning patients suffering from gender dysphoria. *Id.* ¶¶ 37–38. Medical records from other pediatric hospitals suggest that RI Hospital is not unique in this regard. *Id.* ¶ 39. The return date specified in the subpoena was reasonable and was set as August 7, 2025. Hsiao Decl. ¶ 46; Ex. B. But, to date, RI Hospital remains non-complaint. Indeed, over the past ten months, RI Hospital has provided only *one* document totaling *six* pages. Hsiao Decl. ¶ 46.[1]

[1] Partial compliance does not foreclose a petition to enforce. *See, e.g., Equal Emp. Opportunity Comm'n v. MTV Food, Inc.*, No. 23-MC-278, 2024 WL 4164507, at *1 (S.D.N.Y. Sept. 12, 2024) (granting petition to enforce in the absence of full compliance); *United States v. Sysco Corp.*, 25 F. Supp. 2d 684, 685 (D. Md. 1998) (granting a motion to enforce after the recipient "only partially complied with the subpoenas"); *see also United States v. Transocean Deepwater Drilling, Inc.*, 767 F.3d 485, 488 (5th Cir. 2014) (affirming judgment granting petition to enforce after the recipient "failed to comply fully" with the subpoenas").

ARGUMENT

The Fifth Circuit "has consistently recognized the summary nature of administrative subpoena enforcement proceedings," *Burlington N. R. Co. v. Off. of Inspector Gen., R.R. Ret. Bd.*, 983 F.2d 631, 637 (5th Cir. 1993), and said that "when reviewing an administrative subpoena, the court plays a strictly limited role," *Sandsend Fin. Consultants, Ltd. v. Fed. Home Loan Bank Bd.*, 878 F.2d 875, 879 (5th Cir. 1989). The requirements for enforcement are "minimal"—"courts will enforce an administrative subpoena if: (1) the subpoena is within the statutory authority of the agency; (2) the information sought is reasonably relevant to the inquiry; and (3) the demand is not unreasonably broad or burdensome." *Burlington N. R. Co.*, 983 F.2d at 637-38; *see United States v. Zadeh*, 820 F.3d 746, 756 (5th Cir. 2016) (applying this standard "in the context of an administrative subpoena seeking an individual's medical records"). Here, all three prerequisites are met. *See United States v. Transocean Deepwater Drilling, Inc.*, 767 F.3d 485, 489 (5th Cir. 2014) (explaining that the Government has the "minimal" burden of making a "prima facie case").[2]

I. The Subpoena Is Within the Department's Statutory Authority.

An agency's subpoena must be enforced unless it is "plainly incompetent or irrelevant to any lawful purpose." *Fed. Election Comm'n v. Lance*, 617 F.2d 365, 368 (5th Cir. 1980) (quoting *Endicott Johnson Corp. v. Perkins*, 317 U.S. 501, 509 (1943)); *accord,*

[2] To the extent the Fifth Circuit also requires a showing that "the required administrative steps have been followed," *Burlington N. R. Co.*, 983 F.2d at 637 n.2, the Department meets that requirement too. The subpoena was signed by the Assistant Attorney General, properly served on RI Hospital, and calls for the production of nonprivileged documents relevant to the investigation within 500 miles of RI Hospital. *See* Subpoena; 18 U.S.C. § 3486(a)(3).

e.g., *United States v. Sturm, Ruger & Co.*, 84 F.3d 1, 5–6 (1st Cir. 1996) ("As long as the agency's assertion of authority is not obviously apocryphal, a procedurally sound subpoena must be enforced.").

The subpoena at issue is plainly relevant to a lawful purpose. Congress has expressly authorized the Attorney General to issue subpoenas to investigate potential "Federal health care offense[s]," including qualifying offenses in the FDCA. 18 U.S.C. § 3486(a)(1)(A)(i)(I). The subpoena in this case was issued for that very purpose, as described above. The subpoena to RI Hospital will assist the Department's efforts to "investigate Federal health care offenses," Subpoena at 1. Accordingly, the subpoena issued to RI Hospital plainly comes within the Department's statutory authority. *See Burlington N. R. Co.*, 983 F.2d at 637-38.

II. The Subpoena Seeks Documents Reasonably Relevant to the Investigation.

The subpoena seeks information "reasonably relevant" to the Department's investigation in two different ways. *Burlington N. R. Co.*, 983 F.2d at 638; *see FTC v. Texaco, Inc.*, 555 F.2d 862, 874 (D.C. Cir. 1977) (en banc) ("[I]n the pre-complaint stage, . . . the relevance of the agency's subpoena requests may be measured only against the general purposes of its investigation."). First, the Department seeks records to determine whether RI Hospital itself may have engaged in conduct that implicates the FDCA. Second, the Department seeks records from RI Hospital to determine whether manufacturers and distributors of the drugs at issue may have violated the FDCA.

In the subpoena are 15 Requests, all of which extend from January 1, 2020, to the present. *See* Subpoena at 4, 7-9. The fifteen 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). As the Hsiao Declaration explains, all 15 requests—and all four categories—are reasonably related to identifying evidence that could be used to shed light on the Government's lawful investigation. *See* Hsiao Decl. ¶¶ 40–44.

Request 1 seeks information to identify who had authority to direct prescribing, billing, or marketing practices to determine liability. Subpoena at 7. 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. Hsiao Decl. ¶ 41. Personnel files also show financial incentives, disciplinary history, and/or training which can establish knowledge and intent. *Id.*

Requests 2 through 6 (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 disguise or hide potential FDCA violations and potentially secure health care benefit program reimbursements through fraud. Subpoena at 7-8; Hsiao Decl. ¶ 42. 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. Hsiao Decl. ¶ 42. Moreover, training materials and internal discussions can reveal whether improper coding was a deliberate strategy. *Id.*

Requests 7 through 10 (relating to relationships with drug manufacturers, distributors, and pharmacies) seek evidence of an intent to market or promote drugs for unapproved uses in violation of the FDCA. Subpoena at 8; Hsiao Decl. ¶ 43. Communications between pharmaceutical sales representatives and prescribing physicians can provide evidence of off-label promotion, which would be relevant to an FDCA prosecution for misbranding drugs. *See, e.g.*, Information at 4-5, ¶¶ 12-18, *United States v. Cephalon, Inc.*, No. 2:08-cr-598 (E.D. Pa. Sep. 29, 2008), Dkt. No. 1; Press Release, U.S. Dep't of Just., *Eli Lilly and Company to Pay U.S. $36 Million Relating to Off-Label Promotion* (Dec. 21, 2005), https://perma.cc/2Y64-FUK5 (announcing guilty plea of drug manufacturer involving illegal off-label promotion and highlighting evidence that the defendant "[e]ncourag[ed] sales representatives . . . to send unsolicited medical letters to promote the drug for an unapproved use to doctors").[3] If RI Hospital, or one of its affiliated health care 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 the illegal misbranding of drugs and distribution of misbranded drugs or unapproved new drugs.

[3] There are many similar examples. *See, e.g.*, Press Release, U.S. Dep't of Just., *Genzyme Corporation to Pay $32.5 Million to Resolve Criminal Liability Relating to Seprafilm* (Sep. 3, 2015), https://perma.cc/P7AT-MUVT (highlighting evidence that manufacturer encouraged off-label uses by distributing promotional materials citing a misleading scientific study); *United States v. Endo Pharms., Inc.*, No. 1:14-CR-66 (N.D.N.Y. Feb. 21, 2014), Dkt. 2 (deferred prosecution agreement regarding drug manufacturer's off-label promotion of drug, highlighting evidence that manufacturer distributed a misleading scientific study and promoted off-label uses at educational presentations for physicians); Press Release, U.S. Dep't of Just., *Wyeth Pharmaceutical Agrees to Pay $490.9 Million for Marketing the Prescription Drug Rapamune for Unapproved Uses* (July 30, 2013), https://archives.fbi.gov/archives/oklahomacity/press-releases/2013/wyeth-pharmaceutical-agrees-to-pay-490.9-million-for-marketing-the-prescription-drug-rapamune-for-unapproved-uses (highlighting evidence that manufacturer paid bonuses to incentivize off-label sales).

Hsiao Decl. ¶ 43. Similarly, information regarding financial arrangements (consulting agreements, sponsorships, speaking honoraria) may suggest improper influence to reinforce a showing of an intent to misbrand the drugs, including with an intent to defraud or mislead. *Id.*

Requests 11 through 15 (relating to patient-level clinical practices and drug safety) will permit the United States to evaluate the scope of prescribing (including the number and age range of patients treated), and consistency of diagnoses. Subpoena at 8-9; *see* Hsiao Decl. ¶ 44. Such information also establishes the scope of interstate distribution and the scale of potential FDCA violations. Hsiao Decl. ¶ 44. Linking each patient's clinical record to corresponding billing and insurance claims can demonstrate whether diagnoses were miscoded, which can prove fraudulent intent. *Id.* Documentation of clinical justification, informed consent, and disclosure of unapproved use is key to assessing whether the clinic (and/or potential co-conspirators) concealed or downplayed risks associated with the unapproved use of these drugs. *Id.* Absence or minimization of such warnings could establish the intent to mislead. *Id.* Patient charts also typically capture adverse outcomes, side effects, and complications of drug use. *Id.* By reviewing multiple patient records, the investigative team may reveal systemic use of the same masking codes and fraudulent informed consent documents. *Id.* This enables investigators to distinguish between mere errors and an institutionalized practice.

Providing patient records including patient identities can also provide essential investigative leads. *Id.* 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. *Id.* Health benefit programs tied to identified patients could provide additional information including claim records, creating a reinforced evidentiary record. *Id.* 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).

For these reasons, the information sought is "reasonably relevant," *Morton Salt,* 338 U.S. at 652, to the "general purposes of the agency's investigation," *Dow Chem. Co. v. Allen*, 672 F.2d 1262, 1268 (7th Cir. 1982) (alteration adopted and quotation omitted)). Accordingly, the Court should enforce the subpoena. *See United States v. Zadeh*, No. 4:14-CV-105-O, 2015 WL 418090, at *7 (N.D. Tex. Jan. 31, 2015) (O'Connor, J.) ("For the purposes of administrative subpoenas, the notion of relevancy is a broad one, and so long as the material requested touches a matter under investigation, the subpoena will survive a challenge that it is not relevant.").

III. The Subpoena's Demands Are Reasonable.

Finally, the subpoena's demands are "not unreasonably broad or burdensome." *Burlington N. R. Co.*, 983 F.2d at 638.

Because the Department's "inquiry" is "a relatively broad one," "the permissible scope of materials that [can] reasonably be sought [is] necessarily equally broad." *McPhaul v. United States*, 364 U.S. 372, 382 (1960); *see Securities & Exch. Comm'n v. McGoff*, 647 F.2d 185, 192-93 (D.C. Cir. 1981) ("We agree that the demands are broad.

But the nature of the inquiry precludes a trim list of requests." (footnote omitted)). And the Department's requests are not atypical in this area. *See, e.g.*, *In re Subpoena Duces Tecum*, 228 F.3d 341, 350 (4th Cir. 2000) ("[I]f Bailey had treated 15,000 patients over a period of seven years and all of them were reimbursed on claims he submitted, a suspicion of fraud on these claims would justify a review of Bailey's documentation of services to these patients, of the claims submitted on their behalf, and of the reimbursements collected."); *cf. Zadeh*, 820 F.3d at 758 (agreeing that "the subpoena was not unduly broad or burdensome albeit implicating privacy interests of patients whose records are produced but are not parties to this litigation"). The Department's requests are also limited in "time and scope," asking only for records since January 1, 2020. *Zadeh*, 2015 WL 418090 at *5.

The subpoena is also not unduly burdensome. The information sought is relevant and not otherwise available, meaning that the subpoena is "unreasonably burdensome" only if "compliance threatens to unduly disrupt or seriously hinder normal operations of a business." *F.T.C. v. Jim Walter Corp.*, 651 F.2d 251, 258 (5th Cir. 1981) (quotation omitted), *abrogated on other grounds as recognized by Republic of Panama v. BCCI Holdings (Luxembourg) S.A.*, 119 F.3d 935, 943 (11th Cir. 1997). RI Hospital has not presented to the Department any evidence demonstrating that compliance with the subpoena would cause such a disruption or hindrance. *Id.* ("The subpoenaed party may not merely utter the claim; it must persuade us."). Notably, other hospitals to whom the

Department issued similar subpoenas have complied with the subpoena without any disruption or hindrance. The Court therefore should enforce the subpoena in its entirety.[4]

CONCLUSION

The Government respectfully requests an order from the Court compelling Rhode Island Hospital to comply with the subpoena.

Dated: April 30, 2026

Respectfully submitted,

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[4] The Fifth Circuit has provided that "[c]ourts will not enforce an administrative subpoena . . . if the subpoena was issued for an improper purpose, such as harassment." *Burlington N. R. Co.*, 983 F.2d at 638. The Department acknowledges that a handful of mistaken district judges have found "improper purpose" given the administration's policy positions and priorities. *See, e.g.*, *QueerDoc, PLLC v. U.S. Dep't of Just.*, 807 F. Supp. 3d 1295, 1303-04 (W.D. Wash. 2025); *In re Admin. Subpoena No. 25-1431-019*, 800 F. Supp. 3d 229, 239 (D. Mass. 2025). These decisions are wrong and currently on appeal. There is no basis in law or logic to conclude that an administration's policy positions prevent it from enforcing existing federal law. And, given that existing federal law, even if an administration's policy views might be treated as an improper purpose, this is no reason to deny the Department's motion. Denial is only warranted when the sole purpose behind a subpoena's issuance is an improper one. *See Donaldson v. United States*, 400 U.S. 517, 533 (1971) (inquiring whether "the sole objective of the investigation is to" impermissibly use a civil subpoena to "obtain evidence for use in a criminal prosecution"); *Lynn v. Biderman*, 536 F.2d 820, 826 (9th Cir. 1976) ("It is not . . . a ground to deny enforcement of a subpoena that it is being employed for a wrongful purpose if there is also a legitimate purpose for the subpoena.").

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