

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

IN THE MATTER OF
ADMINISTRATIVE SUBPOENA 25-
1431-032

Civil Action No. 4:26-MC-0006-O

EMERGENCY MOTION FOR STAY PENDING APPEAL

Rhode Island Hospital moves the Court for a stay pending appeal of its April 30, 2026, Order enforcing the above-captioned administrative subpoena. RIH requests that this Court rule on its motion for a stay pending appeal by **Friday, May 8, 2026, at 12:00 p.m.** Counsel for RIH conferred with counsel for the Government, who stated that the Government opposes the requested relief.

TABLE OF CONTENTS

	Page
TABLE OF AUTHORITIES.....	ii
INTRODUCTION	1
BACKGROUND	1
LEGAL STANDARD.....	3
ARGUMENT.....	4
I. Rhode Island Hospital is likely to succeed on the merits	4
A. The Court erroneously denied Rhode Island Hospital an opportunity to respond to the petition.....	4
B. Venue is improper in this District	6
C. The subpoena is unlawful	8
II. Rhode Island Hospital will suffer irreparable harm without a stay	12
III. The public interest and balance of equities favor a stay	14
CONCLUSION.....	15
CERTIFICATE OF CONFERENCE	16
CERTIFICATE OF SERVICE	17

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>In re 2025 UPMC Subpoena,</i> No. 25-mc-1069, 2025 WL 3724705 (W.D. Pa. Dec. 24, 2025)	11
<i>In re Administrative Subpoena No. 25-1431-019,</i> 800 F. Supp. 3d 229 (D. Mass. 2025)	11
<i>In re Anthony Marano Co.,</i> 51 F.4th 722 (7th Cir. 2022)	5
<i>Ass’n of Am. Physicians & Surgeons v. FDA,</i> 13 F.4th 531 (6th Cir. 2021)	10
<i>Bellaire Gen. Hosp. v. Blue Cross Blue Shield of Mich.,</i> 97 F.3d 822 (5th Cir. 1996)	7
<i>Book People, Inc. v. Wong,</i> 91 F.4th 318 (5th Cir. 2024)	12
<i>Castille v. Port Arthur ISD,</i> 168 F.4th 240 (5th Cir. 2026)	4
<i>In re Celexa & Lexapro Mktg. & Sales Pracs. Litig.,</i> 915 F.3d 1 (1st Cir. 2019).....	9
<i>In re Child.’s Nat’l Hosp.,</i> No. 25-cv-3780, 2026 WL 160792 (D. Md. Jan. 21, 2026).....	11, 12
<i>Cleveland Bd. of Educ. v. Loudermill,</i> 470 U.S. 532 (1985).....	4
<i>Cobbledick v. United States,</i> 309 U.S. 323 (1940).....	3
<i>Conger v. Danek Med., Inc.,</i> 27 F. Supp. 2d 717 (N.D. Tex. 1998)	9
<i>FEC v. Comm. to Elect Lyndon La Rouche,</i> 613 F.2d 849 (D.C. Cir. 1979).....	8
<i>First Choice Women’s Res. Ctrs., Inc. v. Davenport,</i> No. 24-781, slip. op. (U.S. Apr. 29, 2026).....	5, 13, 14

FTC v. Jim Walter Corp.,
651 F.2d 251 (5th Cir. 1981)7, 8

Garcia v. Posada,
No. 24-cv-360, 2024 WL 4415280 (N.D. Tex. Apr. 9, 2024)15

Harbor Healthcare Sys., L.P. v. United States,
5 F.4th 593 (5th Cir. 2021)13

Nken v. Holder,
559 U.S. 418 (2009).....3, 14

NLRB v. Cooper Tire & Robber Co.,
438 F.3d 1198 (D.C. Cir. 2006)7

NLRB v. Line,
50 F.3d 311 (5th Cir. 1995)7

Okla. Press Pub. Co. v. Walling,
327 U.S. 186 (1946).....5

QueerDoc, PLLC v. U.S. Dep’t of Just.,
807 F. Supp. 3d 1295 (W.D. Wash. 2025).....11

Republic of Pan. v. BCCI Holdings (Luxembourg) S.A.,
119 F.3d 935 (11th Cir. 1997)7

Sandsend Fin. Consultants, Ltd. v. Fed. Home Loan Bank Bd.,
878 F.2d 875, 881 (5th Cir. 1989)4, 6

In re Schering Plough Corp. Intron/Temodar Consumer Class Action,
678 F.3d 235 (3d Cir. 2012).....9

Shotkin v. Nelson,
146 F.2d 402 (10th Cir. 1944)5

In re Subpoena Duces Tecum No. 25-1431-016,
No. 25-mc-41, 2025 WL 3562151 (W.D. Wash. Sept. 3, 2025)11

In re Subpoena No. 25-1431-014,
810 F. Supp. 3d 555 (E.D. Pa. 2025) 9-12

Tex. Keystone, Inc. v. Prime Nat. Res., Inc.,
694 F.3d 548, 549, 552, 556 n.5 (5th Cir. 2012) 4-6

United States v. Sturm, Ruger & Co., Inc.,
84 F.3d 1 (1st Cir. 1996).....5

United States v. Transocean Deepwater Drilling, Inc.,
767 F.3d 485 (5th Cir. 2014)5, 6, 8

Veasy v. Perry,
769 F.3d 890 (5th Cir. 2014)3

Wash. Legal Found. v. Henney,
202 F.3d 331 (D.C. Cir. 2000)9

Statutes

18 U.S.C. § 3486.....1

18 U.S.C. § 3486(a)(1)(A)(i)(I)8

18 U.S.C. § 3486(a)(1)(B)(i).....8

18 U.S.C. § 3486(c)6

21 U.S.C. § 331.....10

21 U.S.C. § 333(a)(1).....10

21 U.S.C. § 352(f).....9

21 U.S.C. § 396.....9

28 U.S.C. § 1291.....3

Other Authorities

21 C.F.R. § 201.128.....8

21 C.F.R. § 202.1(l)(2).....10

Understanding Unapproved Use of Approved Drugs “Off Label,” U.S. Food &
Drug Admin. (Feb. 5, 2018), [https://www.fda.gov/patients/learn-about-expanded-
access-and-other-treatment-options/understanding-unapproved-use-approved-
drugs-label](https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label).....9

INTRODUCTION

Last Thursday evening, without any notice to Rhode Island Hospital, the Government petitioned this Court to enforce a ten-month-old administrative subpoena. That same day, without giving RIH any opportunity to respond, this Court entered an Order enforcing the subpoena and giving RIH only 14 days to comply. That Order is legally and procedurally unsound. RIH has promptly appealed it. Given that RIH is likely to succeed on appeal and will suffer irreparable harm if the Order is enforced in the meantime, this Court should stay its Order for the duration of the appeal.

BACKGROUND

On July 9, 2025, the Department of Justice served an administrative subpoena on RIH at its principal place of business in Providence, Rhode Island. *See* Pet. Ex. B, ECF No. 1-2, at 2, 4;¹ Pet. Ex. C, ECF No. 1-3, at 2 (proof of service).² The Government set a return date of August 7 and requested production at the office of the DOJ's Consumer Protection Branch (now the Enforcement and Affirmative Litigation Branch), which is located in Washington, D.C. ECF No. 1-2 at 2. The Government purported to issue the subpoena under the Health Insurance Portability and Accountability Act (HIPAA), 18 U.S.C. § 3486, to "investigate Federal health care offenses." ECF No. 1-2 at 2.

The subpoena contains fifteen requests for documents, including three that explicitly call for sensitive patient information:

¹ Citations to public record pages are to the page numbers that appear in the header generated by the Court's ECF system.

² The Court's Order mistakenly states that service occurred on July 3, 2025. *See* Order, ECF No. 2, at 1. The Government's petition mistakenly (and contradictorily) states that service occurred on July 3, 2025, and on July 11, 2025. *See* Pet., ECF No. 1, at 1, 4. The Government's own exhibit reflects that service occurred on July 9, 2025. *See* ECF No. 1-3 at 2.

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

Id. at 9.

Following service of the subpoena, counsel for RIH and the Government began to discuss RIH's compliance efforts. Ex. 1 at App. 6, ¶ 8 ; *see* Declaration of Lisa K. Hsiao ("Hsiao Decl."), ECF No. 1-1, at 20, ¶ 46. Counsel for the Government informed Glenn Friedemann, Associate General Counsel for Brown Health (the parent organization of RIH), that the Government did not believe that RIH had engaged in any criminal wrongdoing. Ex. 1 at App. 6, ¶ 8. The Government also "communicated that it would be willing to receive documents responsive to the subpoena past the return date." Hsiao Decl. at 20, ¶ 46.

On January 29, 2026, RIH, through undersigned counsel Eric Olshan, notified the Government that it was prepared to produce additional responsive documents in the weeks to come, and that it would first send the Government proposed search terms for review. *See* Ex. 2 at App. 10. RIH sent the Government the proposed search terms on February 4, 2026. *See id.* RIH anticipated making a production upon the Government's confirmation of the search terms, but the Government did not respond, even to confirm receipt. *See id.*

RIH did not hear from the Government again until April 28, requesting that counsel "conference this week regarding status." *Id.* Although counsel for RIH responded the next day,

the next communication RIH received from the Government was not about scheduling; rather, it was an email sent after the close of business at 6:10 p.m. Eastern Time on Thursday, April 30, informing RIH that the Government had filed a petition to enforce the subpoena in this Court. *Id.* at 9. The Government did not confer with RIH in advance of the filing of the petition.

The Court granted the petition the same day it was filed and executed the Government's proposed order, requiring that RIH "provide all records responsive to each request in the subpoena within 14 days of the entry of this order"—by May 14, 2026—and stating that "failure to fully comply with the subpoena or show just cause for continued noncompliance may result in sanctions up to and including this Court holding [RIH] in contempt." *See* Order, ECF No. 2, at 1-2. RIH received no opportunity to respond to the petition.

The Court's Order enforcing the administrative subpoena is an appealable final judgment. *See Cobbletick v. United States*, 309 U.S. 323, 330 (1940); 28 U.S.C. § 1291. RIH seeks a stay of the Court's Order pending resolution of its appeal to the Fifth Circuit.

LEGAL STANDARD

In deciding whether to enter a stay pending appeal, courts consider "(1) whether the stay applicant has made a strong showing that he or she is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies." *Veasy v. Perry*, 769 F.3d 890, 892 (5th Cir. 2014) (quoting *Nken v. Holder*, 559 U.S. 418, 426 (2009)). "The first two factors of the traditional standard are the most critical." *Id.* (quoting *Nken*, 559 U.S. at 434).

ARGUMENT

This Court denied RIH due process and erroneously ordered enforcement of a legally improper subpoena. RIH is appealing this decision. While the appeal is pending, this Court should stay its Order. The Court's refusal to give RIH an opportunity to respond in opposition to the Government's petition is reversible error, and the subpoena is otherwise legally unsound. The remaining stay factors also support a stay.

I. Rhode Island Hospital is likely to succeed on the merits.

RIH has multiple grounds for its appeal on which it is highly likely to succeed. Because the Court refused to allow adversarial testing of the Government's petition, the Fifth Circuit is likely to reverse. That error also meant that RIH had no chance to raise its other arguments against the subpoena's enforcement, which buttress its likely success on appeal.

A. The Court erroneously denied Rhode Island Hospital an opportunity to respond to the petition.

This Court impermissibly denied RIH due process by issuing its Order without allowing RIH to be heard. Procedural due process requires that a recipient of an administrative subpoena have both "notice and an opportunity to respond" before enforcement. *Castille v. Port Arthur ISD*, 168 F.4th 240, 252 (5th Cir. 2026) (quoting *Cleveland Bd. of Educ. v. Loudermill*, 470 U.S. 532, 546 (1985)). RIH received neither. It will thus prevail in its appeal.

The Fifth Circuit has repeatedly confirmed this due process requirement in administrative subpoena enforcement proceedings. In *Sandsend Financial Consultants, Ltd. v. Federal Home Loan Bank Board*, the Fifth Circuit held that, by ruling on a motion to quash an administrative subpoena before receiving a response, the district court "robb[ed]" the subpoena's issuer of "its right to be heard." 878 F.2d 875, 881 (5th Cir. 1989). And again, in *Texas Keystone, Inc. v. Prime Natural Resources, Inc.*, the Fifth Circuit held that the district court violated procedural due process

by granting a motion to quash the day after it was filed, without giving the issuer “an opportunity to respond in opposition.” 694 F.3d 548, 549, 552, 556 n.5 (5th Cir. 2012).

This right to respond applies in proceedings to quash administrative subpoenas and to enforce them alike. “An administrative subpoena is not self-executing”; enforcing one thus requires “judicial review and enforcement.” *United States v. Sturm, Ruger & Co., Inc.*, 84 F.3d 1, 3 (1st Cir. 1996). Indeed, the “enforcement process for administrative subpoenas” is designed to give the “subpoenaed party . . . an opportunity to be heard during the enforcement proceeding itself.” *In re Anthony Marano Co.*, 51 F.4th 722, 734 (7th Cir. 2022). More precisely, due process requires the opportunity to be heard *before* enforcement. See *Okla. Press Pub. Co. v. Walling*, 327 U.S. 186, 195 (1946) (describing administrative subpoenas enforced “pursuant to orders of court authorized by law and made after adequate opportunity to present objections”); *Sturm*, 84 F.3d at 3 (“[T]he subject of an administrative subpoena has an opportunity to challenge the subpoena before yielding the information.”); *Shotkin v. Nelson*, 146 F.2d 402, 405 (10th Cir. 1944) (“[T]he trial court should have given . . . notice and an opportunity to be heard before the enforcement order was issued.”).

This right to respond is critical, not just to a participant’s due process rights, but also to ensure adversarial “testing [of] the subpoena in federal court.” *First Choice Women’s Res. Ctrs., Inc. v. Davenport*, No. 24-781, slip. op. at 18 (U.S. Apr. 29, 2026) (internal quotation marks omitted). The standards for judicial enforcement of administrative subpoenas confirm the need for a fulsome adversarial process. Again, these subpoenas are not self-enforcing—a court must decide whether to enforce one by evaluating whether “(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.” *United States v. Transocean Deepwater*

Drilling, Inc., 767 F.3d 485, 488 (5th Cir. 2014). “The Government bears the initial burden to show that these criteria have been met,” and “[o]nce the Government has made a prima facie case, the burden of going forward shifts to the party opposing the subpoenas.” *Id.* at 489 (emphasis added). That burden-shifting cannot happen if the opposing party has no chance to respond. Nor can a court adequately assess the controlling factors without hearing from both sides.

The Court’s refusal to give RIH an opportunity to respond in opposition to the Government’s petition is a procedural error that will result in reversal on appeal. *See Tex. Keystone*, 694 F.3d at 555; *Sandsend*, 878 F.2d at 881 (explaining that this “procedural error[] . . . would be dispositive”).

B. Venue is improper in this District.

The Court’s Order is also erroneous because the Government improperly filed its petition in this District. This Court is not the proper venue to adjudicate the Government’s petition. Title 18 U.S.C. § 3486(c) permits enforcement of an administrative subpoena in “any court of the United States within the jurisdiction of which the investigation is carried on or of which the subpoenaed person is an inhabitant, or in which he carries on business or may be found.” The Government’s petition conclusorily asserts that the investigation “is being carried out in the Northern District of Texas.”³ Pet., ECF No. 1, at 2. The lack of evidentiary support for that assertion is fatal to the Government’s enforcement effort in this District.

Neither the Government’s petition nor its accompanying exhibits identify any nexus between its investigation and this District. The administrative subpoena demanded production at the Consumer Protection Branch office in Washington, D.C. ECF No. 1-2 at 1. The DOJ officials

³ The Government does not assert any other basis for venue, and RIH’s principal place of business is in Rhode Island. *See* ECF No. 1-2 at 4.

who have communicated with RIH about the subpoena have done so from that office in Washington, D.C. *See* ECF No. 1-3 at 3; *see also* Pet. 13; Ex. 2 at App. 9-10. The Government has not identified any target of the investigation based in the Northern District of Texas. RIH itself has no ties there. And the declaration of Lisa Hsiao, Acting Director of EALB, makes no mention of any investigative activities in the Northern District of Texas, as opposed to Washington D.C., where the EALB's office is located. *See generally* Hsiao Decl.; *see also* Pet. 13; Ex. 3 at App. 12.

The record contains no support for the Government's claim that its investigation is being carried on in the Northern District of Texas, let alone that it is being carried out here "to any substantial degree." *FTC v. Jim Walter Corp.*, 651 F.2d 251, 254 (5th Cir. 1981), *abrogated on other grounds as recognized by Republic of Pan. v. BCCI Holdings (Luxembourg) S.A.*, 119 F.3d 935, 943 (11th Cir. 1997).⁴ Nothing supports enforcement in a district with such a tenuous and unproven connection to the underlying investigation.⁵ Indeed, even when an investigation is "nationwide in scope," venue cannot be simply based on the Government's "choice of any forum it like[s]." *NLRB v. Cooper Tire & Robber Co.*, 438 F.3d 1198, 1200, 1202 (D.C. Cir. 2006). Venue then lies in the "command center" or "hub" of the investigation—here, the entirety of the investigative contact between RIH and the Government prior to the petition's filing makes clear that that would be the District of Columbia, not the Northern District of Texas. *Id.* at 1202; *see*

⁴ The Fifth Circuit has expressed "grave misgivings" regarding the assertion of personal jurisdiction over a party that lacks minimum contacts with the forum. *Bellaire Gen. Hosp. v. Blue Cross Blue Shield of Mich.*, 97 F.3d 822, 826 (5th Cir. 1996). RIH's lack of contacts with the Northern District of Texas further shows that the Government's "choice of forum" is "unreasonable" for purposes of the venue analysis. *Jim Walter*, 651 F.2d at 254; *NLRB v. Cooper Tire & Robber Co.*, 438 F.3d 1198, 1202 (D.C. Cir. 2006) (also assessing reasonableness).

⁵ *See NLRB v. Line*, 50 F.3d 311, 313-14 (5th Cir. 1995) (district where the underlying labor practices under investigation occurred); *Jim Walter*, 651 F.2d at 254 (district where "[m]any of the building and marketing practices under investigation" occurred and where the agency managed the investigation).

FEC v. Comm. to Elect Lyndon La Rouche, 613 F.2d 849, 857 (D.C. Cir. 1979); *see also Jim Walter*, 651 F.2d at 254 (considering where the agency “managed [its] investigation”).

C. The subpoena is unlawful.

Even if venue were proper in this District, this Court should have denied the Government’s petition.

To start, the subpoena lacks a congressionally authorized and legitimate investigatory purpose. *See Transocean*, 767 F.3d at 488-89. Through HIPAA, Congress delegated the authority to issue subpoenas in connection with an investigation of a “Federal health care offense.” 18 U.S.C. § 3486(a)(1)(A)(i)(I). The Government’s authority is limited to seeking items that are “relevant to the investigation” of such an offense. *Id.* § 3486(a)(1)(B)(i).

The Government bases the subpoena on its authority to investigate violations of the Food, Drug, and Cosmetic Act (FDCA). *See* Pet. 2. The Government’s proffered theory of criminal FDCA liability is that “off-label use of puberty blockers and cross-sex hormones” is “a violation of the FDCA.” *Id.* at 4. That theory is wrong.

The Government arrives at that liability theory through a series of convoluted steps that lack support in the FDCA’s text. The Government asserts that a drug is “misbranded” if “its labeling does not bear adequate directions for its intended use.” *Id.* at 2. The term “intended use” comes from a regulation of the Food and Drug Administration, which states that the “intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer.” 21 C.F.R. § 201.128. The Government’s apparent theory is that if a drug’s “intended use” changes as it makes its way from manufacturer to patient—including even when a physician prescribes the drug for an “off-label use”—then the drug becomes “misbranded” in violation of the FDCA,

because its labeling will no longer match the “intended use” of the physician. *See* Pet. 2, 4. In this respect, the Government asserts, “off-label use” by physicians violates the FDCA. *Id.* at 4.

The Government’s theory is contrary to the statute and cannot stand. The federal government lacks authority to regulate the practice of medicine, including a physician’s off-label prescription of drugs, under the FDCA. The FDCA’s text explicitly confirms that. *See* 21 U.S.C. § 396 (“Nothing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship.”). As is well recognized, the FDCA “regulates how manufacturers label medical devices and drugs”—not “the practice of medicine.” *Conger v. Danek Med., Inc.*, 27 F. Supp. 2d 717, 720 (N.D. Tex. 1998). “Physicians routinely use products for ‘off-label’ purposes,” and “[s]uch off-label use is appropriate, rational, and accepted medical practice and can be of great value.” *Id.*; *see In re Celexa & Lexapro Mktg. & Sales Pracs. Litig.*, 915 F.3d 1, 5 (1st Cir. 2019); *In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 240 (3d Cir. 2012); *Wash. Legal Found. v. Henney*, 202 F.3d 331, 332-33 (D.C. Cir. 2000).⁶

Because physicians can lawfully prescribe drugs off-label, the concept of “intended use” (and misbranding predicated on intended use) is not applicable to physicians’ treatment decisions. Misbranding liability predicated on the lack of “adequate directions for use” attaches only to those who manufacture and distribute a drug. 21 U.S.C. § 352(f); *see In re Subpoena No. 25-1431-014*, 810 F. Supp. 3d 555, 568 (E.D. Pa. 2025). The FDCA thus ensures that manufacturers and distributors are accountable for drug labeling and the representations they make about drug

⁶ *See also Understanding Unapproved Use of Approved Drugs “Off Label,”* U.S. Food & Drug Admin. (Feb. 5, 2018), <https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label>.

products placed into the stream of commerce. But misbranding liability does not attach to physicians based on off-label prescribing. *See Ass’n of Am. Physicians & Surgeons v. FDA*, 13 F.4th 531, 544 (6th Cir. 2021) (“The Act regulates drug distribution; it does not bar doctors from prescribing an approved drug (like hydroxychloroquine) for an off-label use (like COVID-19).”).

The Government’s theory would turn the FDCA on its head by imposing criminal liability based on off-label prescribing—a lawful practice. The Government seeks to impose criminal liability on everyone up the supply chain from a doctor who engages in off-label prescribing (*e.g.*, drug manufacturers and distributors) based on the doctor’s own lawful decision to prescribe a drug off-label. And because the FDCA is a strict-liability statute that imposes criminal liability for misbranding “without any proof of criminal intent” or “direct participation,” Pet. 3 (citing 21 U.S.C. §§ 331, 333(a)(1)); *id.* at 7, under the Government’s reading of the statute, anyone in the supply chain or peripherally involved could be held criminally liable for a doctor’s subsequent and lawful off-label prescription. That theory badly misreads the FDCA and cannot support the Government’s investigation into RIH or any other entity.

In short, the Government asserts sweeping authority to criminally punish anyone in the stream of distribution for “misbranding” solely based on whether a physician has intended to engage in the lawful practice of off-label prescribing.⁷ No such authority exists, and the Government therefore lacks statutory authority to investigate that lawful practice.

⁷ In addition to targeting “manufacturers and distributors,” the Government states without elaboration that it “seeks records to determine whether RI Hospital itself may have engaged in conduct that implicates the FDCA.” Pet. 6. Under the FDA’s own understanding of the Act, however, “misbranding” through false or misleading “labeling” occurs in materials “supplied by the manufacturer, packer, or distributor of the drug”—not the downstream provider. *See* 21 C.F.R. § 202.1(l)(2); *In re Subpoena No. 25-1431-014*, 810 F. Supp. 3d at 567, 586. This position is also inconsistent with representations made by Government counsel to RIH. Ex. 1 at App. 6, ¶ 8.

Given the faulty statutory basis on which the Government rests its investigation, district courts around the country have correctly held that the Government lacks authority to enforce identical subpoenas, and in turn has issued those subpoenas for an improper purpose. *See In re Child. 's Nat'l Hosp.*, No. 25-cv-3780, 2026 WL 160792, at *8 (D. Md. Jan. 21, 2026); *QueerDoc, PLLC v. U.S. Dep't of Just.*, 807 F. Supp. 3d 1295, 1302-03 (W.D. Wash. 2025), *appeal pending*, No. 25-7384 (9th Cir.); *In re Administrative Subpoena No. 25-1431-019*, 800 F. Supp. 3d 229, 237-38 (D. Mass. 2025), *appeal pending*, No. 26-1093 (1st Cir.); *In re Subpoena Duces Tecum No. 25-1431-016*, No. 25-mc-41, 2025 WL 3562151, at *8-12 (W.D. Wash. Sept. 3, 2025). RIH is likely to succeed in demonstrating the same.

RIH is also likely to succeed in showing that, as multiple courts have concluded, the subpoena is overly broad and burdensome. *See In re Child. 's Nat'l Hosp.*, 2026 WL 160792, at *8; *QueerDoc*, 807 F. Supp. 3d at 1304; *In re Administrative Subpoena No. 25-1431-019*, 800 F. Supp. 3d at 238. Even if the Government were properly investigating potential FDCA violations (it is not), the subpoena overreaches with its intrusive request for patient records that include sensitive personally identifiable information (names, dates of birth, Social Security numbers, and home addresses), medical diagnoses, and other sensitive medical documents. *See* ECF No. 1-2 at 9-10 (requests 11-13).

These requests for patient records are not relevant to any inquiry into potential FDCA violations, even under the Government's untenable reading of the law. *See In re 2025 UPMC Subpoena*, No. 25-mc-1069, 2025 WL 3724705, at *3 (W.D. Pa. Dec. 24, 2025) (limiting subpoena to strike requests that pertain to patient records); *In re Subpoena No. 25-1431-014*, 810 F. Supp. 3d at 578-81 (same). Concluding otherwise would again stretch the FDCA's text beyond recognition. The FDCA regulates "the introduction, labeling, and distribution of drugs in interstate

commerce; it does not govern how physicians diagnose patients, obtain consent, document treatment, or communicate” with patients. *In re Subpoena No. 25-1431-014*, 810 F. Supp. 3d at 579; see *In re Child. ’s Nat’l Hosp.*, 2026 WL 160792, at *8.

In addition, contrary to the Government’s assertion, producing these records “threatens to unduly disrupt or seriously hinder” RIH’s operations. *Contra* Pet. 11 (citation omitted). The Government faults RIH for not “present[ing] to the Department any evidence demonstrating that compliance with the subpoena would cause such a disruption or hindrance.” *Id.* But RIH does not have to present that evidence “to the Department”—the time and place to present such evidence would have been to *this Court*, in opposition to the petition for enforcement. The attached declarations detail the burden on RIH and its employees, including the threats that the ordered full production would pose to RIH patient relationships at the core of the hospital’s operations. Ex. 1 at App. 6-7, ¶¶ 10-13; Ex. 4 at App. 15-16, ¶¶ 4-11; Ex. 5 at App. 20, ¶¶ 12-14.

In sum, RIH’s appeal will raise multiple challenges to the subpoena’s enforcement and is likely to succeed on the merits of those challenges. This factor weighs strongly in favor of a stay.

II. Rhode Island Hospital will suffer irreparable harm without a stay.

The irreparable constitutional and monetary injuries RIH will suffer without a stay also support the requested relief.

For one, if RIH must comply with the subpoena with no opportunity to respond, this litigation will become moot without RIH ever receiving an opportunity to be heard. Its resulting deprivation of its due process right would constitute irreparable harm. See *Book People, Inc. v. Wong*, 91 F.4th 318, 340-41 (5th Cir. 2024).

Moreover, compliance with a subpoena later held unlawful produces irreparable monetary harm. See *id.* at 341. Any production will involve collecting information from disparate platforms

and then processing, de-duplicating, anonymizing, and reviewing these documents for privilege and confidentiality. This process takes time and costs money—upwards of millions of dollars. Ex. 1 at App. 6-7, ¶¶ 10-13. Any such compliance will thus cause expenses that RIH can never recoup. *Id.* at 7, ¶ 13.

RIH will also suffer irreparable harm to its patient relationships without a stay. Among other things, RIH will have to turn over highly sensitive medical records that contain comprehensive psychosocial evaluations and deeply personal disclosures by children about their bodies, sexuality, trauma, family dynamics, self-harm, mental-health history, and cognitive and emotional functioning. Ex. 5 at 19, ¶¶ 6-8.

Patients rely on RIH to maintain the confidentiality of exactly this information. *Id.* at 20, ¶ 11; Ex. 4 at 14-15, ¶¶ 5-6. But as the Supreme Court recently confirmed, disclosure pursuant to a subpoena produces real risks of that “information becoming public,” even when the Government promises confidentiality (and even if a court enters a protective order). *First Choice*, slip op. at 21. The information “might wind up in the public domain due to a hack or leak,” creating a “risk of harassment and reprisals” of RIH employees and patients. *Id.* Forced compliance thus threatens irreparable harm to those patients and, in turn, their relationships with their providers at RIH and RIH’s overall operations.

Indeed, just as a subpoena “is enough to discourage reasonable individuals from associating,” it can also discourage patients from consulting their medical providers and seeking the medical care they need. *Id.*; see Ex. 4 at App. 15, ¶¶ 8-9; Ex. 5 at 20, ¶ 12. Enforcement of this subpoena therefore risks irreparable harm to RIH’s ability to provide sound medical treatment by intruding upon its private records. See *Harbor Healthcare Sys., L.P. v. United States*, 5 F.4th

593, 600 (5th Cir. 2021) (“The government’s ongoing intrusion on . . . privacy constitutes an irreparable injury.”). This factor also warrants a stay.

III. The public interest and balance of equities favor a stay.

Finally, the last two factors—the harm to the opposing party and the public interest—weigh heavily in favor of a stay. These two factors “merge when the Government is the opposing party.” *Nken*, 556 U.S. at 435. Any potential harm to the Government from a stay would be minimal. The Government allowed ten months to pass before seeking to enforce its subpoena without warning. Up to the filing of the enforcement petition, the Government communicated no objection to delayed production. The Government did not seek immediate or emergency relief in its petition and has identified no basis for urgency. Meanwhile, RIH will retain and protect responsive documents. Ex. 1 at App. 7, ¶ 14. As a result, the additional time needed to remedy the Court’s due process violation and address the unlawful subpoena will not substantially prejudice the Government’s investigation.

The privacy interests at stake further tip the balance of the equities away from the Government. *See First Choice*, slip op. at 21. The Government seeks vast swaths of private patient information untethered to its investigative authority. The Government’s purported investigatory interest therefore cannot outweigh the harm to RIH and its patients.

In sum, all four stay factors strongly justify a stay.

CONCLUSION

For these reasons, the Court should stay the Court's April 30, 2026, order pending resolution of RIH's appeal to the Fifth Circuit.⁸

Dated: May 6, 2026

Respectfully submitted,

/s/ Mindy M. Sauter

Mindy M. Sauter
Texas Bar No. 24033114
MCGUIREWOODS LLP
2601 Olive Street
Suite 2100
Dallas, Texas 75201
T: (469) 372-3916
F: (214) 273-7470
msauter@mcguirewoods.com

Eric G. Olshan (*Pro Hac Vice* pending)
MCGUIREWOODS LLP
Tower Two-Sixty, 260 Forbes Avenue
Suite 1800
Pittsburgh, PA 15222
T: (412) 667-6000
F: (412) 667-6050
eolshan@mcguirewoods.com

Kathryn M. Barber (*Pro Hac Vice* pending)
MCGUIREWOODS LLP
800 East Canal Street
Richmond, VA 23219
T: (804) 775-1227
F: (804) 698-2227
kbarber@mcguirewoods.com

Attorneys for Rhode Island Hospital

⁸ Should the Court decline to enter a full stay pending appeal, RIH requests that the Court enter a temporary administrative stay pending the Fifth Circuit's decision on RIH's motion for a stay pending appeal, which RIH will file in the Fifth Circuit if this Court denies the requested stay. *See Garcia v. Posada*, No. 24-cv-360, 2024 WL 4415280, at *1 (N.D. Tex. Apr. 9, 2024) (entering an administrative stay of one week to permit sufficient time for review on appeal).

CERTIFICATE OF CONFERENCE

On May 3 and May 4, 2026, counsel for Rhode Island Hospital, Eric Olshan, corresponded by email with counsel of record for the Government (Ross Goldstein, Patrick Runkle, Scott Dahlquist, and Ethan Womble) regarding this Motion for Stay Pending Appeal. The Government does not consent to the requested relief, and the parties therefore could not reach agreement. Accordingly, pursuant to Local Rule 7.1(b), the undersigned states that this motion is opposed.

Dated: May 6, 2026

Respectfully submitted,

/s/ Mindy M. Sauter
Mindy M. Sauter
Texas Bar No. 24033114
MCGUIREWOODS LLP
2601 Olive Street
Suite 2100
Dallas, Texas 75201
T: (469) 372-3916
F: (214) 273-7470
msauter@mcguirewoods.com

Eric G. Olshan (*Pro Hac Vice* pending)
MCGUIREWOODS LLP
Tower Two-Sixty, 260 Forbes Avenue
Suite 1800
Pittsburgh, PA 15222
T: (412) 667-6000
F: (412) 667-6050
eolshan@mcguirewoods.com

Kathryn M. Barber (*Pro Hac Vice* pending)
MCGUIREWOODS LLP
800 East Canal Street
Richmond, VA 23219
T: (804) 775-1227
F: (804) 698-2227
kbarber@mcguirewoods.com

Attorneys for Rhode Island Hospital

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing Emergency Motion for Stay Pending Appeal was filed electronically with the clerk of court via ECF, which will provide electronic service on all counsel of record.

Dated: May 6, 2026

Respectfully submitted,

/s/ Mindy M. Sauter

Mindy M. Sauter
Texas Bar No. 24033114
MCGUIREWOODS LLP
2601 Olive Street
Suite 2100
Dallas, Texas 75201
T: (469) 372-3916
F: (214) 273-7470
msauter@mcguirewoods.com

Eric G. Olshan (*Pro Hac Vice* pending)
MCGUIREWOODS LLP
Tower Two-Sixty, 260 Forbes Avenue
Suite 1800
Pittsburgh, PA 15222
T: (412) 667-6000
F: (412) 667-6050
eolshan@mcguirewoods.com

Kathryn M. Barber (*Pro Hac Vice* pending)
MCGUIREWOODS LLP
800 East Canal Street
Richmond, VA 23219
T: (804) 775-1227
F: (804) 698-2227
kbarber@mcguirewoods.com

Attorneys for Rhode Island Hospital