

No. 26-1568

**In the United States Court of Appeals
for the First Circuit**

IN RE: MOTION TO QUASH ADMINISTRATIVE SUBPOENA TO RHODE ISLAND
HOSPITAL

CHILD ADVOCATE FOR RHODE ISLAND, et al.,
Petitioner-Appellees,
v.
UNITED STATES OF AMERICA,
Respondent-Appellant.

On Appeal from the United States District Court
for the District of Rhode Island

**BRIEF OF LAMBDA LEGAL DEFENSE AND EDUCATION FUND, INC.
AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER-APPELLEES
AND AFFIRMANCE**

Omar Gonzalez-Pagan
Jessica Polansky
LAMBDA LEGAL DEFENSE AND
EDUCATION FUND, INC.
120 Wall Street, 19th Floor
New York, NY 10005
Phone: (212) 809-8585

Morgan J. Walker
LAMBDA LEGAL DEFENSE AND
EDUCATION FUND, INC.
3500 Oak Lawn Avenue, Suite 500
Dallas, TX 75219
Phone: (214) 219-8585

A.D. Sean Lewis
LAMBDA LEGAL DEFENSE AND
EDUCATION FUND, INC.
800 South Figueroa Street, Suite 1260
Los Angeles, CA 90017
Phone: (213) 382-7600

Karen L. Loewy
LAMBDA LEGAL DEFENSE AND
EDUCATION FUND, INC.
815 16th Street NW, Suite 4140
Washington, DC 20006
Phone: (202) 804-6245

Counsel for Amicus Curiae

CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, *amicus curiae* Lambda Legal Defense and Education Fund, Inc. certifies that it is a nonprofit organization, that it has no parent corporation, and that no corporation owns 10% or more of its stock.

TABLE OF CONTENTS

DISCLOSURE STATEMENT ii

TABLE OF CONTENTS..... iii

TABLE OF AUTHORITIES iv

INTEREST OF *AMICUS CURIAE*..... 1

INTRODUCTION AND SUMMARY OF THE ARGUMENT3

ARGUMENT6

 I. THE SUBPOENA TO RIH IS PART OF THE ADMINISTRATION’S
 TARGETED ATTACKS ON TRANSGENDER PEOPLE.7

 A. The Administration Has Targeted Transgender People for Discrimination
 and Barred Government Acknowledgement of Their Existence.8

 B. The Administration’s Endgame is to Eliminate GAMC, Particularly for
 Adolescents.....11

 C. The Subpoenas to Healthcare Providers Like RIH Are Part of the
 Administration’s Mission to Discriminate Against Transgender People and
 End GAMC.....16

 II. DOJ’S UNFOUNDED ALLEGATIONS OF HEALTHCARE OFFENSES
 AGAINST GAMC PROVIDERS LIKE RIH ILLUSTRATE THE
 SUBPOENA’S IMPROPER PURPOSE.18

 A. Off-label Prescription of Medications Does Not Violate the FDCA or
 Otherwise Constitute a Healthcare Offense.19

 B. Informing Patients About Off-Label Use of Puberty Blockers and Hormone
 Therapy Does Not Violate the FDCA.22

 III. DOJ’S GAMESMANSHIP BOLSTERS THE ILLEGITIMACY OF ITS
 ISSUANCE OF THE SUBPOENA.....24

CONCLUSION29

CERTIFICATE OF COMPLIANCE.....31

CERTIFICATE OF SERVICE32

TABLE OF AUTHORITIES

Cases	Page(s)
<i>Am. Ass’n of Physicians for Hum. Rts., Inc. v. Nat’l Insts. of Health</i> , 795 F.Supp.3d 678 (D. Md. 2025)	1, 11
<i>Ass’n of Am. Physicians & Surgeons v. U.S. Food & Drug Admin.</i> , 13 F.4th 531 (6th Cir. 2021).....	20
<i>Buckman Co. v. Plaintiffs’ Legal Comm.</i> , 531 U.S. 341 (2001)	20, 24
<i>Coe v. Blanche</i> , No. 1:26-CV-04641, 2026 WL 1951390 (S.D.N.Y. July 6, 2026), <i>appeal docketed</i> , No. 26-1886 (2d Cir. July 10, 2026).....	1, 26
<i>Dekker v. Weida</i> , 679 F.Supp.3d 1271 (N.D. Fla. 2023).....	24
<i>Doe v. McHenry</i> , 763 F.Supp.3d 81 (D.D.C. 2025), <i>vacated and remanded sub nom.</i> <i>Doe v. Blanche</i> , 172 F.4th 901 (D.C. Cir. 2026)	10
<i>Endocrine Soc’y v. Fed. Trade Comm’n</i> , No. 26-cv-00512-JEB, 2026 WL 1257289 (D.D.C. May 7, 2026).....	10, 16
<i>Hodgens v. Gen. Dynamics Corp.</i> , 144 F.3d 151 (1st Cir. 1998)	29
<i>In re 2025 Subpoena to Children’s Nat’l Hosp.</i> , No. 1:25-CV-03780-JRR, 2026 WL 160792 (D. Md. Jan. 21, 2026), <i>appeal docketed</i> , No. 26-1104 (4th Cir. Feb. 2, 2026)	4
<i>In re 2025 UPMC Subpoena</i> , No. 2:25-MC-01069-CB, 2025 WL 3724705 (W.D. Pa. Dec. 24, 2025), <i>judgment entered</i> , 2026 WL 570419 (W.D. Pa. Mar. 2, 2026), <i>appeal docketed</i> , No. 26-1401 (3d Cir. Mar. 4, 2026).....	4, 12
<i>In re Admin. Subpoena No. 25-1431-019</i> , 800 F.Supp.3d 229, 237 (D. Mass. 2025), <i>appeal docketed</i> , No. 26-1093 (1st Cir. Jan. 30, 2026).....	4, 27

<i>In re Administrative Subpoena 25-1431-032,</i> No. 4-26MC-006-0, 2026 WL 1204327 (N.D. Tex. Apr. 30, 2026), <i>stay denied</i> <i>pending appeal</i> , 2026 WL 1406051 (N.D. Tex. May 10, 2026).....	7
<i>In re Department of Justice Administrative Subpoena 25-1431-030,</i> No. 25-MC-00063-SKC-CYC, 2026 WL 33398 (D. Colo. Jan. 5, 2026)	4
<i>In re Subpoena Duces Tecum No. 25-1431-016,</i> No. 2:25-MC-00041-JHC, 2025 WL 3562151 (W.D. Wash. Sept. 3, 2025), <i>appeal docketed, sub nom. Seattle Children’s Hosp. v. U.S. Dep’t of Justice,</i> No. 26-4009 (9th Cir. June 23, 2026)	4, 17
<i>In re Subpoena No. 25-1431-014,</i> 810 F.Supp.3d 555 (E.D. Pa. 2025)	4, 27
<i>Kadel v. Folwell,</i> 100 F.4th 122 (4th Cir. 2024), <i>cert. granted, judgment vacated</i> , 145 S.Ct. 2838 (2025).....	1
<i>Kingdom v. Trump,</i> No. 1:25-CV-691-RCL, 2025 WL 1568238 (D.D.C. June 3, 2025)	10
<i>Melone v. Coit,</i> 100 F.4th 21 (1st Cir. 2024).....	29
<i>Oregon v. Kennedy,</i> No. 6:25-CV-02409-MTK, 2026 WL 1048354 (D. Or. Apr. 18, 2026).....	16, 26
<i>Patriot Cinemas, Inc. v. Gen. Cinemas Corp.,</i> 834 F.2d 208 (1st Cir. 1987).	29
<i>PFLAG, Inc. v. Trump,</i> 769 F.Supp.3d 405 (D. Md. 2025), <i>appeal docketed</i> , No. 25-1279 (4th Cir. Mar. 24, 2025).....	1, 9
<i>QueerDoc, PLLC v. U.S. Dep’t of Justice,</i> 807 F.Supp.3d 1295 (W.D. Wash. 2025), <i>appeal docketed</i> , No. 25-7384 (9th Cir. Nov. 24, 2025)	4, 25, 29
<i>San Francisco AIDS Found. v. Trump,</i> 786 F.Supp.3d 1184 (N.D. Cal. 2025), <i>appeal docketed</i> , No. 25-4988 (9th Cir. Aug. 7, 2025).....	1, 10

<i>Schlacter v. United States</i> , 804 F.Supp.3d 592 (D. Md. 2025)	10
<i>Talbott v. United States</i> , 176 F.4th 720 (D.C. Cir. 2026)	10
<i>United States ex rel. Wilson v. Bristol-Myers Squibb, Inc.</i> , 750 F.3d 111 (1st Cir. 2014)	23
<i>United States v. Evers</i> , 643 F.2d 1043 (5th Cir. 1981).....	23
<i>United States v. Facteau</i> , 89 F.4th 1 (1st Cir. 2023)	20, 23
<i>United States v. Morton Salt Co.</i> , 338 U.S. 632 (1950)	6
<i>United States v. Powell</i> , 379 U.S. 48 (1964)	6
<i>United States v. R.I. Hosp.</i> , No. 26-10431 (5th Cir. May 12, 2026)	6
<i>United States v. Skrmetti</i> , 605 U.S. 495 (2025)	1
<i>VRCompliance LLC v. Homeaway, Inc.</i> , 715 F.3d 570 (4th Cir. 2013).....	25
<i>Washington Legal Found. v. Henney</i> , 202 F.3d 331 (D.C. Cir. 2000)	20
<i>World Pro. Ass’n for Transgender Health v. FTC</i> , No. 26-cv-00532-JEB, 2026 WL 1257321 (D.D.C. May 7, 2026).....	16
<i>Z.A. v. Blanche</i> , No. 26-CV-04998-PCP, 2026 WL 1907181 (N.D. Cal. July 2, 2026), <i>appeal docketed</i> , No. 26-4388 (9th Cir. July 10, 2026).....	26

Statutes

21 U.S.C. § 301 *et seq.*.....5

21 U.S.C. § 396.....20

Regulations

Medicaid Program; Prohibition on Federal Medicaid and Children’s Health Insurance Program Funding for Sex-Rejecting Procedures Furnished to Children,
90 Fed. Reg. 59441-01 (proposed Dec. 19, 2025)14

Medicare and Medicaid Programs; Hospital Condition of Participation: Prohibiting Sex-Rejecting Procedures for Children,
90 Fed. Reg. 59463-01 (proposed Dec. 19, 2025)14

Nondiscrimination on the Basis of Disability in Programs or Activities Receiving Federal Financial Assistance,
90 Fed. Reg. 59478-01 (proposed Dec. 19, 2025)14

Rules

Fed. R. App. P. 29(a)(2).....2

Executive Orders

Exec. Order 14151, *Ending Radical and Wasteful DEI Programs and Preferencing*, 90 Fed. Reg. 8339 (Jan. 20, 2025)9

Exec. Order 14168, *Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government*, 90 Fed. Reg. 8615 (Jan. 20, 2025)..... 3, 8, 9, 10

Exec. Order 14183, *Prioritizing Military Excellence and Readiness*, 90 Fed. Reg. 8757 (Jan. 27, 2025).....9

Exec. Order 14187, *Protecting Children From Chemical and Surgical Mutilation*,

90 Fed. Reg. 8771 (Jan. 28, 2025)	3, 12, 16, 18, 24
Exec. Order 14190, <i>Ending Radical Indoctrination in K-12 Schooling</i> , 90 Fed. Reg. 8853 (Jan. 29, 2025)	9
Exec. Order 14201, <i>Keeping Men Out of Women’s Sports</i> , 90 Fed. Reg. 9279 (Feb. 11, 2025).....	9

Other Authorities

Alex R. Dopp et al., <i>Interventions for Gender Dysphoria and Related Health Problems in Transgender and Gender-Expansive Youth: A Systematic Review of Benefits and Risks to Inform Practice, Policy, and Research</i> (RAND Corp., 2024), https://tinyurl.com/4fmhjs5u	13
Am. Acad. of Pediatrics, <i>Policy Statement – Off-Label Use of Drugs in Children</i> , 133 Pediatrics 563 (2014)	22
Appellants’ Brief, <i>U.S. Dep’t of Justice v. QueerDoc</i> , No. 25-7384 (9th Cir. Dec. 19, 2025) (ECF 25.1)	28
Christopher M. Wittich et al., <i>Ten common questions (and their answers) about off-label drug use</i> , 87 Mayo Clinic Proc. 982 (2012), https://doi.org/10.1016/j.mayocp.2012.04.017	21
<i>Declaration of HHS Secretary Re: Safety, Effectiveness, and Professional Standards of Care for Sex-Rejecting Procedures on Children and Adolescents</i> (Dec. 18, 2025), https://tinyurl.com/8fumfxwu	14
Electronic Order, <i>In re Admin. Subpoena No. 25-1431-019</i> , No. 1:25-mc-91324 (D. Mass. Nov. 24, 2025) (ECF 52).....	26
FBI (@FBI), X.com (June 2, 2025, at 7:15pm CT), https://tinyurl.com/2uvarm55 [https://perma.cc/6WRE-RZRG]	16
FDA, <i>Understanding Unapproved Use of Approved Drugs “Off Label”</i> (Feb. 5, 2018), https://tinyurl.com/pd6ff88v [https://perma.cc/XT3K-4R57]	21
G. Nic Rider et al., <i>Scientific integrity and pediatric gender healthcare: Disputing the HHS Review</i> , Sexuality Research and Social Policy 1-6 (2025), https://tinyurl.com/mpf2tcnb	13
Gov’t Opp’n to Mot. to Seal Docket, <i>QueerDoc, PLLC v. U.S. Dep’t of Justice</i> , No. 2:25-mc-00042 (W.D. Wash. filed July 17, 2025) (ECF 8).....	28
Gov’t’s Praeipice to file Additional Document, <i>QueerDoc, PLLC v. U.S. Dep’t of</i>	

<i>Justice</i> , No. 2:25-mc-00042 (filed Sept. 26, 2025) (ECF 24-1)	28
H. Christine Allen et al., <i>Off-Label Medication use in Children, More Common than We Think: A Systematic Review of the Literature</i> , 111 J Okla State Med Assoc. 776 (2018), https://pmc.ncbi.nlm.nih.gov/articles/PMC6677268/	21
Health Council of the Netherlands, <i>Transgender Care for Adolescents: Executive Summary</i> (June 30, 2026), https://tinyurl.com/2vhp9mcf [https://perma.cc/MQP4-EN9A]	13
HHS General Counsel Mike Stuart (@HHSGCMikeStuart), X.com (Feb. 3, 2026, at 5:25pm CT), https://tinyurl.com/45yu5sra [https://perma.cc/DF65-GQJ6]	15
Ilan H. Meyer & Lauren J. Bouton, The Williams Inst., <i>Impact of Executive Orders on Access to Federal Data</i> (Feb. 2025), https://tinyurl.com/2c9a4d4y	11
James M. Beck & Elizabeth D. Azari, <i>FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions</i> , 53 Food & Drug L.J. 71 (1998).....	20, 21
Jo Yurcaba, <i>DOJ subpoenas more than 20 doctors and clinics that provide trans care to minors</i> , NBC News (July 10, 2025), https://tinyurl.com/5fa2d853	17
Joanne LaFleur et al., Univ. of Utah Coll. of Pharmacy, <i>Gender-Affirming Medical Treatments for Pediatric Patients with Gender Dysphoria</i> (Nov. 2024), https://le.utah.gov/AgencyRP/downloadFile.jsp?submissionId=287 [https://perma.cc/7EWJ-7BDE]	13
Juliana Kim, <i>Park Service erases ‘transgender’ on Stonewall website, uses the term ‘LGB’ movement</i> , NPR (Feb. 14, 2025), https://tinyurl.com/3pj27pap	11
Letter from James O’Neill, Deputy Secretary of Health and Human Servs., to Kate Fryer, Chief Executive Officer, Endocrine Society, Re: HHS Actions to End Sex Rejecting Procedures on Minors and Request for Information (Dec. 30, 2025), https://tinyurl.com/2czk42	15
Mem. in support of Mot. to Alter J., <i>In re: Administrative Subpoena No. 25-1431-019</i> , No. 25-mc-91324-MJJ (D. Mass. filed Oct. 7, 2025) (ECF 36)	27
Nadia Dowshen et al., <i>A Critical Scientific Appraisal of the Health and Human Services Report on Pediatric Gender Dysphoria</i> , 77 J. Adolesc. Health 342-45 (2025), https://tinyurl.com/2579tmf6	13
Off. of Assistant Att’y Gen., <i>Memorandum: Civil Division Enforcement Priorities</i> (June 11, 2025), https://www.justice.gov/civil/media/1404046/dl [https://perma.cc/P273-8QQE].....	17

Off. of Att’y Gen., <i>Memorandum: Preventing the Mutilation of American Children</i> (Apr. 22, 2025), https://www.justice.gov/ag/media/1402396/dl [https://perma.cc/MJD7-AX9L]	17
Orion Rummeler, <i>Three hospitals are under investigation for providing gender-affirming care to trans youth</i> , The 19th (Jan. 7, 2026), https://tinyurl.com/3muuawv7	14
<i>Paediatric off-label prescribing in the USA</i> , 1773 <i>Reactions Weekly</i> 10 (2019) https://doi.org/10.1007/s40278-019-68767-y	21
Phie Jacobs, <i>Researchers slam HHS report on gender-affirming care for youth</i> , Science (May 2, 2025), https://tinyurl.com/326md8yf	13
Susan J. Kressly, <i>AAP Statement on HHS Report Treatment for Pediatric Gender Dysphoria</i> , Am. Acad. Pediatrics (May 1, 2025), https://tinyurl.com/478yckca	13
The White House, <i>National Child Abuse Prevention Month, 2025</i> (Apr. 3, 2025), https://tinyurl.com/42swzwe5 [https://perma.cc/3ZCX-X7ZL]	12
The White House, <i>Supreme Court Bolsters President Trump’s Push to Eliminate Transgender Insanity</i> (June 30, 2026), https://tinyurl.com/5cbukkw7 [https://perma.cc/484A-4MDN]	11
Tr. of Oral Decision, <i>Coe v. Blanche</i> , No. 1:26-cv-04641-KPF (S.D.N.Y. June 24, 2026) (ECF 77), https://tinyurl.com/p374nf72	8, 25, 26
U.S. Dep’t of Health & Hum. Servs., <i>Treatment for Pediatric Gender Dysphoria: Review of Evidence and Best Practices</i> (May 2025, rev. Nov. 2025), https://tinyurl.com/yw8svcfr [https://perma.cc/E2FN-E3TT]	12
U.S. Dep’t of Health & Hum. Servs., <i>Urgent Review of Quality Standards and Gender Transition Procedures</i> (May 28, 2025), https://tinyurl.com/4j2bt2zd [https://perma.cc/9F7N-8V8D]	13
William M. Janssen, <i>A Historical Perspective on Off-Label Medicine: From Regulation, Promotion, and the First Amendment to the Next Frontiers</i> , SSRN Elec. J. (2014), https://doi.org/10.2139/ssrn.2519223	21

INTEREST OF *AMICUS CURIAE*¹

Amicus curiae **Lambda Legal Defense and Education Fund, Inc.** is the nation’s oldest and largest legal organization dedicated to achieving full recognition of the civil rights of LGBTQ+ people and everyone living with HIV through impact litigation, education, and policy advocacy. Since its founding, Lambda Legal has sought to eliminate discriminatory barriers to healthcare for LGBTQ+ people, particularly transgender people. *See, e.g., United States v. Skrametti*, 605 U.S. 495 (2025); *Kadel v. Folwell*, 100 F.4th 122, 133 (4th Cir. 2024), *cert. granted, judgment vacated*, 145 S.Ct. 2838 (2025). This includes fighting the Administration’s targeting and defunding of researchers and healthcare entities serving transgender people. *See, e.g., Coe v. Blanche*, No. 1:26-cv-04641-KPF, 2026 WL 1951390 (S.D.N.Y. July 6, 2026), *appeal docketed*, No. 26-1886 (2d Cir. July 10, 2026); *Am. Ass’n of Physicians for Hum. Rts., Inc. v. Nat’l Insts. of Health*, 795 F.Supp.3d 678 (D. Md. 2025) (“GLMA”); *San Francisco AIDS Found. v. Trump*, 786 F.Supp.3d 1184 (N.D. Cal. 2025) (“SFAF”), *appeal docketed*, No. 25-4988 (9th Cir. Aug. 7, 2025); *PFLAG, Inc. v. Trump*, 769 F.Supp.3d 405 (D. Md. 2025) (“PFLAG”), *appeal docketed*, No. 25-1279 (4th Cir. Mar. 24, 2025).

¹ No party’s counsel authored this brief in whole or in part, and no party or party’s counsel contributed money to fund preparing or submitting this brief. No person other than *amicus*, its members, or its counsel made a monetary contribution to its preparation or submission.

Having long litigated cases involving gender-affirming medical care (“GAMC”), *Amicus* offers perspectives on the Administration’s targeting of transgender people and their healthcare providers, on the provider conduct alleged to be unlawful, and on the Department of Justice’s (“DOJ”) gamesmanship in its alleged investigations as the Court considers the improper purpose underlying the administrative subpoenas sent to providers like Rhode Island Hospital (“RIH”).

Amicus respectfully submits this brief pursuant to Federal Rule of Appellate Procedure 29(a)(2). All parties have consented to its filing.

INTRODUCTION AND SUMMARY OF THE ARGUMENT

In June 2025, DOJ issued substantively identical administrative subpoenas to more than twenty healthcare institutions that provided GAMC to transgender adolescents. The latest salvo in the Administration’s discriminatory campaign against transgender people, the subpoenas were issued to intimidate providers of evidence-based healthcare for transgender adolescents and to end GAMC entirely.

The Administration’s attacks on transgender people began on day one of this term with a mandate to eradicate “gender ideology,” its derogatory term for acknowledging that transgender people exist. Exec. Order 14168, *Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government*, 90 Fed. Reg. 8615 (Jan. 20, 2025) (“Gender EO”). The following week, the President established as “the policy of the United States that it will not fund, sponsor, promote, assist, or support” GAMC for minors, and “will rigorously enforce all laws that prohibit or limit” such care, declaring it to be a “stain on our Nation’s history” that “must end.” Exec. Order 14187, *Protecting Children From Chemical and Surgical Mutilation*, 90 Fed. Reg. 8771, § 1 (Jan. 28, 2025) (“Denial-of-Care EO”). A series of sweeping implementation efforts followed, including by the Department of Health and Human Services (“HHS”) and the Federal Trade Commission (“FTC”), and also DOJ, culminating in investigative demands and subpoenas, including the one issued to RIH.

But the Administration’s animus towards transgender people and its rancor towards those who support GAMC are not lawful bases for administrative subpoenas. As every court that has considered motions to quash or limit these subpoenas has concluded, they lack a legitimate investigatory basis and their improper purpose is clearly reflected “in the DOJ’s own public record”—“publicly characteriz[ing] gender-affirming care for minors as abuse, direct[ing] the DOJ to bring its practice to an end, and celebrat[ing] when hospitals curtailed such programs as a result of this subpoena campaign.” Addendum to Gov’t Br. (“Add.”) 21.²

In quashing the subpoena to RIH, the district court properly rejected DOJ’s efforts to legitimize its investigation. DOJ attempts to tie the subpoena to purported

² See also *In re Dep’t of Just. Admin. Subpoena No. 25-1431-030*, No. 25-MC-00063-SKC-CYC, 2026 WL 33398, at *7 (D. Colo. Jan. 5, 2026) (“government’s aim is not actually to investigate FDCA violations, but to use the FDCA as a smokescreen for its true objective of pressuring pediatric hospitals into ending gender-affirming care through commencing vague, suspicionless ‘investigations.’”); *In re 2025 Subpoena to Children’s Nat’l Hosp.*, No. 1:25-CV-03780-JRR, 2026 WL 160792 (D. Md. Jan. 21, 2026), *appeal docketed*, No. 26-1104 (4th Cir. Feb. 2, 2026); *In re 2025 UPMC Subpoena*, No. 2:25-MC-01069-CB, 2025 WL 3724705, at *2 (W.D. Pa. Dec. 24, 2025), *judgment entered*, 2026 WL 570419 (W.D. Pa. Mar. 2, 2026), *appeal docketed*, No. 26-1401 (3d Cir. Mar. 4, 2026); *In re Admin. Subpoena No. 25-1431-019*, 800 F.Supp.3d 229, 237, 239 (D. Mass. 2025), *appeal docketed*, No. 26-1093 (1st Cir. Jan. 30, 2026); *In re Subpoena No. 25-1431-014*, 810 F.Supp.3d 555, 583 (E.D. Pa. 2025); *QueerDoc, PLLC v. U.S. Dep’t of Justice*, 807 F.Supp.3d 1295, 1303 (W.D. Wash. 2025), *appeal docketed*, No. 25-7384 (9th Cir. Nov. 24, 2025); *In re Subpoena Duces Tecum No. 25-1431-016*, No. 2:25-MC-00041-JHC, 2025 WL 3562151, at *10-11 (W.D. Wash. Sept. 3, 2025), *appeal docketed, sub nom. Seattle Children’s Hosp. v. U.S. Dep’t of Justice*, No. 26-4009 (9th Cir. June 23, 2026).

investigations of healthcare offenses pursuant to the Food, Drug, & Cosmetic Act, 21 U.S.C. § 301 *et seq.* (“FDCA”), *see* Gov’t Br. 10-12, 30-38, but its allegations regarding off-label use of medications to treat gender dysphoria, misbranding by physicians, and patient outcomes bear no resemblance to any offense prohibited by that statute. These theories are rooted in the Administration’s disdainful, inflammatory narrative regarding transgender people and GAMC, relying on commissioned sources designed to fit that narrative. The district court correctly rejected the government’s manufactured violations, concluding that the “sweeping subpoena” amounted to an “unprecedented intrusion into the private medical information of children” and “cannot be justified by any legitimate law enforcement.” JA13-14.

Finally, DOJ’s tactical and procedural gamesmanship underscore that its demands are inextricably tied to the Administration’s attacks on transgender people and GAMC. On the heels of numerous orders quashing similar subpoenas, DOJ took the highly unusual step of moving to enforce the instant subpoena in Texas—despite Texas having *no* connection to the hospital, patients, or providers—as well as pursuing identical grand jury subpoenas. Along with DOJ’s pattern of misrepresentations to the court and improper procedural maneuvers, this conduct is clearly part of DOJ’s “crusade to obtain transgender children’s medical records.”

Add.9. DOJ’s evolving post-hoc explanations for identical subpoenas simply seek to conceal DOJ’s improper motive rather than providing a lawful predicate.

Because the subpoena to RIH is rooted in an improper purpose, this Court should affirm its quashal.

ARGUMENT

While an administrative subpoena is generally permissible so long as it “is within the authority of the agency, the demand is not too indefinite and the information sought is reasonably relevant,” *United States v. Morton Salt Co.*, 338 U.S. 632, 652-53 (1950), a court may not enforce an administrative subpoena issued for an improper purpose or in bad faith such that enforcing it “would be an abusive use of the court’s process.” *United States v. Powell*, 379 U.S. 48, 51 (1964). Such an abuse of process includes when a subpoena is issued “to harass the [recipient] or to put pressure on [it] to settle a collateral dispute, or for any other purpose reflecting on the good faith of the particular investigation.” *Id.* at 58.

DOJ cannot establish reasonable relevance of the subpoena to RIH to any legitimate investigation. As nearly every court to consider objections to DOJ’s effectively identical subpoenas to GAMC providers has found, DOJ’s efforts to legitimize its purpose fail.³ It is impossible to view the subpoenas in isolation; they

³ Admittedly, the Northern District of Texas granted DOJ’s motion to enforce the RIH subpoena within hours, before any notice or opportunity to oppose. *See In*

are pivotal aspects of the Administration’s relentless campaign to erase transgender people from public life, to end GAMC, and to disparage its providers and supporters.

The district court properly rejected DOJ’s proffered arguments about the legitimacy of its investigation into healthcare offenses under the FDCA as DOJ’s legal theories do not address any form of illegal conduct. Far from ensuring that providers of GAMC are acting lawfully, DOJ’s filings frame the ordinary practice of medicine in this context as inherently unlawful. This provides no proper purpose for the subpoena.

On the contrary, DOJ’s litigation gamesmanship and ever-evolving justifications bolster that the subpoena was issued in bad faith and for an improper purpose—to harass RIH and pressure it into ending the provision of GAMC to transgender adolescents.

I. THE SUBPOENA TO RIH IS PART OF THE ADMINISTRATION’S TARGETED ATTACKS ON TRANSGENDER PEOPLE.

DOJ’s subpoenas to providers like RIH are a direct result of the Administration’s relentless targeting of transgender people for unequal treatment, including its multifaceted campaign to eliminate the provision of GAMC to

Re: Administrative Subpoena 25-1431-032, No. 4-26MC-006-0, 2026 WL 1204327 (N.D. Tex. Apr. 30, 2026). While that court and the Fifth Circuit denied a stay pending appeal, *see* 2026 WL 1406051 (N.D. Tex. May 10, 2026); *United States v. R.I. Hosp.*, No. 26-10431 (5th Cir. May 12, 2026), neither considered a motion to quash. Only the district court below did, properly quashing the subpoena. *See* Add.4-27.

adolescents. Given the impossibility of extricating the subpoena from these efforts to exclude transgender people from public life and deny them needed healthcare, the inexorable conclusion is that the subpoena is imbued with an improper purpose, and this Court should affirm the quashal order.

A. The Administration Has Targeted Transgender People for Discrimination and Barred Government Acknowledgement of Their Existence.

“[I]n the first few days of the current administration, multiple executive orders were issued that sought to identify, to demonize, and ultimately to eradicate an entire population of transgender people.” Tr. of Oral Decision, *Coe v. Blanche*, No. 1:26-cv-04641-KPF (S.D.N.Y. June 24, 2026) (ECF 77) (“*Coe Tr.*”), at 5, <https://tinyurl.com/p374nf72>. Indeed, on day one, the President issued the Gender EO, a cross-cutting effort to reverse existing protections and deny recognition of transgender people’s existence. *See* Gender EO § 2 (declaring “the policy of the United States to recognize two sexes, male and female;” rejecting that a person might have a gender identity different from their birth-assigned sex as a “false claim”). The Gender EO mandated that all agencies interpret sex-based terms as birth-assigned sex, including on identification documents and personnel records, § 3(c), (d); rescinded prior executive order provisions combating discrimination against LGBTQ people, § 7(b); barred federal funding from being “used to promote gender ideology,” § 3(g); mandated housing in accordance with birth-assigned sex in

prisons and shelters, § 4; and directed agencies to rescind guidance, forms, and policies acknowledging transgender people’s existence, §§ 3(e), 7(c).

Additional executive orders (EOs) followed, with the Administration using the power of the purse to enforce its erasure of transgender people; targeting GAMC for transgender adolescents; excluding transgender people from military service; threatening funding for schools that affirm transgender students’ identities; and barring transgender athletes from school sports. *See, e.g.*, EO 14151, *Ending Radical and Wasteful DEI Programs and Preferencing*, 90 Fed. Reg. 8339 (Jan. 20, 2025); EO 14183, *Prioritizing Military Excellence and Readiness*, 90 Fed. Reg. 8757 (Jan. 27, 2025) (“Military Ban EO”); EO 14190, *Ending Radical Indoctrination in K-12 Schooling*, 90 Fed. Reg. 8853 (Jan. 29, 2025); EO 14201, *Keeping Men Out of Women’s Sports*, 90 Fed. Reg. 9279 (Feb. 11, 2025) (“Sports Ban EO”).

These EOs employ dehumanizing, inaccurate rhetoric to cast transgender people, GAMC, and transgender-inclusive policies as an existential threat to “the validity of the entire American system,” Gender EO § 1, as antonymic with “an honorable, truthful, and disciplined lifestyle,” lacking “humility and selflessness,” Military Ban EO § 1, and as a source of “endangerment, humiliation, and silencing of women and girls,” Sports Ban EO § 1. No mere policy preferences, these EOs seek to erase transgender people and punish organizations that provide them necessary services and care. *See, e.g., PFLAG*, 769 F.Supp.3d at 443-44 (“The Court

cannot fathom discrimination more direct than the plain pronouncement of a policy resting on the premise that the group to which the policy is directed does not exist.”); *SFAF*, 786 F.Supp.3d at 1215-16 (“[T]he Gender Order necessarily singles out transgender people and excludes them from being able to benefit from federal funds.”); *Endocrine Soc’y v. Fed. Trade Comm’n*, No. 26-cv-00512-JEB, 2026 WL 1257289, at *2 (D.D.C. May 7, 2026) (The EOs “exhorted federal agencies to put a stop to any acknowledgment of gender dysphoria or that some individuals are transgender.”); *cf. Talbott v. United States*, 176 F.4th 720, 746 (D.C. Cir. 2026) (military ban premised “on a non-legitimate state interest to harm the politically unpopular group of transgender persons”).

Federal agencies took immediate action to implement the EOs’ campaign against transgender people. State Department staff were ordered “to suspend any [passport] application where the applicant is seeking to change their sex marker from the definition provided in [the Gender EO]” or “requesting an ‘X’ sex marker.” *Schlacter v. United States*, 804 F.Supp.3d 592, 598 (D. Md. 2025) (quotations omitted). The Bureau of Prisons began transferring transgender women to men’s prisons, paused access to GAMC, and discontinued gender-affirming clothing and toiletries. *See Doe v. McHenry*, 763 F.Supp.3d 81, 84 (D.D.C. 2025), *vacated and remanded sub nom. Doe v. Blanche*, 172 F.4th 901 (D.C. Cir. 2026); *Kingdom v. Trump*, No. 1:25-CV-691-RCL, 2025 WL 1568238, at *1 (D.D.C. June 3, 2025).

Agencies from the National Park Service to the Centers for Disease Control removed references to transgender people from government websites. *See, e.g.,* Juliana Kim, *Park Service erases ‘transgender’ on Stonewall website, uses the term ‘LGB’ movement*, NPR (Feb. 14, 2025), <https://tinyurl.com/3pj27pap>; Ilan H. Meyer & Lauren J. Bouton, The Williams Inst., *Impact of Executive Orders on Access to Federal Data* (Feb. 2025), <https://tinyurl.com/2c9a4d4y>. And the National Institutes of Health terminated hundreds of grants relating to LGBTQ+ people because the research addressed “transgender issues” and, according to the Administration, “research based on gender identity ... ignore[s] biological realities.” *GLMA*, 795 F.Supp.3d at 688, 696-97.

The breadth of these actions, which the Administration trumpets as “eliminat[ing] transgender insanity,”⁴ has had a dramatic impact on transgender people’s ability to navigate our government and broader society.

B. The Administration’s Endgame is to Eliminate GAMC, Particularly for Adolescents.

The sharpest tip of the Administration’s attacks is aimed at transgender adolescents, their families and supporters, their medical providers, and associations that express affirming viewpoints about GAMC. The Executive’s statements about

⁴ The White House, *Supreme Court Bolsters President Trump’s Push to Eliminate Transgender Insanity* (Jun. 30, 2026), <https://tinyurl.com/5cbukkw7> [<https://perma.cc/484A-4MDN>].

transgender people and GAMC providers are “provocative and unabashedly so.” *In re 2025 UPMC Subpoena*, 2025 WL 3724705, at *2. DOJ has characterized GAMC as “a radical ideological agenda”; an “infect[ion visited upon] an entire generation”; “barbaric practice[s]” that “maim and steriliz[e] children”; and as “genital mutilation.” *Id.* at *2 (quoting DOJ statements). The President has characterized GAMC for adolescents as child abuse, referring to “the sinister threat of gender ideology” as “one of the most prevalent forms of child abuse facing our country today.” The White House, *National Child Abuse Prevention Month, 2025* (Apr. 3, 2025), <https://tinyurl.com/42swzwe5> [<https://perma.cc/3ZCX-X7ZL>]. Such “rhetoric regarding gender-affirming care reflects callous indifference, if not abject cruelty.” *In re 2025 UPMC Subpoena*, 2026 WL 570419, at *2.

As directed by the Denial-of-Care EO, multiple agencies have acted to enforce the Administration’s singular viewpoint opposing GAMC and punishing entities that take a contradictory view. HHS published a report allegedly reviewing literature about GAMC for adolescents. U.S. Dep’t of Health & Hum. Servs., *Treatment for Pediatric Gender Dysphoria: Review of Evidence and Best Practices* (May 2025, rev. Nov. 2025), <https://tinyurl.com/yw8svcfr> [<https://perma.cc/E2FN-E3TT>] (“HHS Report”). The HHS Report was lambasted by the medical establishment for its “extensive violations of scientific norms, misrepresentations of science, and wanton disregard of the expert standard of care for TGD youth,”—“a dangerous

incursion of politics into science and medicine.” Nadia Dowshen et al., *A Critical Scientific Appraisal of the Health and Human Services Report on Pediatric Gender Dysphoria*, 77 J. Adolesc. Health 342-45 (2025), <https://tinyurl.com/2579tmf6>.⁵

Indeed, multiple studies and systematic reviews have found GAMC for adolescents to be evidence-based care for which there is low regret, low dissatisfaction, low side effects, and documented improvements in gender dysphoria and body satisfaction, as well as other mental health improvements.⁶ Despite widespread critiques of the Report, HHS notified healthcare providers of the Report’s findings and requested detailed information about GAMC for minors. See U.S. Dep’t of Health & Hum.

⁵ See also, e.g., G. Nic Rider et al., *Scientific integrity and pediatric gender healthcare: Disputing the HHS Review*, Sexuality Research and Social Policy 1-6 (2025), <https://tinyurl.com/mpf2tcnb> (condemning its “political motivations,” failure to “consult[] pediatric gender care experts and organizations” and “misrepresentation of the evidence” supporting GAMC); Susan J. Kressly, *AAP Statement on HHS Report Treatment for Pediatric Gender Dysphoria*, Am. Acad. Pediatrics (May 1, 2025), <https://tinyurl.com/478yckca> (HHS report “misrepresent[s] the current medical consensus and fail[s] to reflect the realities of pediatric care.”); Phie Jacobs, *Researchers slam HHS report on gender-affirming care for youth*, Science (May 2, 2025), <https://tinyurl.com/326md8yf>.

⁶ See, e.g., Health Council of the Netherlands, *Transgender Care for Adolescents: Executive Summary* (June 30, 2026), <https://tinyurl.com/2vhp9mcf> [<https://perma.cc/MQP4-EN9A>]; Joanne LaFleur et al., Univ. of Utah Coll. of Pharmacy, *Gender-Affirming Medical Treatments for Pediatric Patients with Gender Dysphoria* (Nov. 2024), <https://le.utah.gov/AgencyRP/downloadFile.jsp?submissionId=287> [<https://perma.cc/7EWJ-7BDE>]; Alex R. Dopp et al., RAND Corp., *Interventions for Gender Dysphoria and Related Health Problems in Transgender and Gender-Expansive Youth: A Systematic Review of Benefits and Risks to Inform Practice, Policy, and Research* (2024), <https://tinyurl.com/4fmhjs5u>.

Servs., *Urgent Review of Quality Standards and Gender Transition Procedures* (May 28, 2025), <https://tinyurl.com/4j2bt2zd> [<https://perma.cc/9F7N-8V8D>].

In December 2025, HHS Secretary Kennedy went further, seeking by fiat to establish that *any* provision of GAMC for minors is *per se* below the standard of care. See *Declaration of HHS Secretary Re: Safety, Effectiveness, and Professional Standards of Care for Sex-Rejecting Procedures on Children and Adolescents* (Dec. 18, 2025) (“Kennedy Declaration”), <https://tinyurl.com/8fumfxwu>. That day, HHS proposed rules barring Medicaid and the Children’s Health Insurance Program from paying for GAMC,⁷ prohibiting hospitals from providing GAMC as a condition of participation in Medicare and Medicaid,⁸ and excluding gender dysphoria from disability-based antidiscrimination protections.⁹ HHS’s General Counsel also publicized his referrals of children’s hospitals providing GAMC to HHS’s Office of Inspector General (“OIG”) for purportedly “failing to meet ‘recognized standards of health care,’ citing Kennedy’s declaration.”¹⁰

⁷ *Medicaid Program; Prohibition on Federal Medicaid and Children’s Health Insurance Program Funding for Sex-Rejecting Procedures Furnished to Children*, 90 Fed. Reg. 59441-01 (proposed Dec. 19, 2025).

⁸ *Medicare and Medicaid Programs; Hospital Condition of Participation: Prohibiting Sex-Rejecting Procedures for Children*, 90 Fed. Reg. 59463-01 (proposed Dec. 19, 2025).

⁹ *Nondiscrimination on the Basis of Disability in Programs or Activities Receiving Federal Financial Assistance*, 90 Fed. Reg. 59478-01 (proposed Dec. 19, 2025).

¹⁰ Orion Rummler, *Three hospitals are under investigation for providing*

Within days, reaffirming “this administration’s priority to end all sex-rejecting procedures on minors,” HHS sent letters to medical organizations, requesting that they end their “promot[ion]” of GAMC and “revise [their] medical guidelines and guidance that advise medical professionals to provide these procedures to minors.” Letter from James O’Neill, Deputy Secretary of Health and Human Servs., to Kate Fryer, Chief Executive Officer, Endocrine Society, Re: HHS Actions to End Sex Rejecting Procedures on Minors and Request for Information (Dec. 30, 2025), at 2-3, <https://tinyurl.com/2czkkp42>. HHS further threatened that if they did not do so, HHS “will use all authority under the law ... to aggressively pursue any medical organization” providing GAMC for youth. *Id.* at 3. HHS officials celebrated that “more than 30 hospitals and hospital systems ... have announced they are no longer performing sex-mutilating and sex-rejecting procedures for minors,” and continued to refer non-compliant hospital groups for investigation by the HHS’s OIG. *See* HHS General Counsel Mike Stuart (@HHSGCMikeStuart), X.com (Feb. 3, 2026, at 5:25pm CT), <https://tinyurl.com/45yu5sra> [<https://perma.cc/DF65-GQJ6>].

The Kennedy Declaration has since been found unlawful, both procedurally and substantively, with a court noting that, in issuing it, Secretary Kennedy exhibited

gender-affirming care to trans youth, The 19th (Jan. 7, 2026), <https://tinyurl.com/3muuawv7>.

a “wanton disregard for the rule of law [that] causes very real harm to very real people,” and “act[ed] with cruelty.” *Oregon v. Kennedy*, No. 6:25-CV-02409-MTK, 2026 WL 1048354, at *1 (D. Or. Apr. 18, 2026).

Courts have similarly held unlawful other agencies’ targeting of medical associations that support providing GAMC to adolescents, finding that the FTC’s demands for information constituted unconstitutional retaliation against organizations’ “work on transgender-health issues,” which “reasonably appear[ed] to be one more step in a multiagency campaign to stamp out dissenters.” *Endocrine Soc’y*, 2026 WL 1257289, at *12; *see also World Pro. Ass’n for Transgender Health v. FTC*, No. 26-cv-00532-JEB, 2026 WL 1257321, at *1, *4 (D.D.C. May 7, 2026).

C. The Subpoenas to Healthcare Providers Like RIH Are Part of the Administration’s Mission to Discriminate Against Transgender People and End GAMC.

The Denial-of-Care EO required DOJ to explore legal avenues for limiting or ending the provision of GAMC. Attorney General Bondi diligently took on these mandates, with law enforcement entities publicly proclaiming their intent to target transgender people and medical care providers. *See, e.g.*, FBI (@FBI), X.com (June 2, 2025, at 7:15pm CT), <https://tinyurl.com/2uvarm55> [<https://perma.cc/6WRE-RZRG>] (“As the Attorney General has made clear, we will protect our children and hold accountable those who mutilate them under the guise of gender-affirming care.

Report tips of any hospitals, clinics, or practitioners performing these surgical procedures on children[.]”).

In April 2025, AG Bondi directed the Civil Division “to undertake appropriate investigations of any violations of the Food, Drug, and Cosmetic Act by manufacturers and distributors engaged in misbranding by making false claims about the on- or off-label use of puberty blockers, sex hormones, or any other drug used to facilitate a child’s so-called ‘gender transition.’”¹¹ The Civil Division issued a June 2025 memorandum prioritizing these investigations.¹²

As DOJ acknowledges, Gov’t Br. 12-13, immediately thereafter, DOJ issued subpoenas to more than twenty healthcare institutions that provide GAMC. *See* Jo Yurcaba, *DOJ subpoenas more than 20 doctors and clinics that provide trans care to minors*, NBC News (July 10, 2025), <https://tinyurl.com/5fa2d853>. And as below, every court to consider challenges to these subpoenas has determined that they were issued for an improper purpose, *see* Add.21; n.2, *supra*, unequivocally tying these subpoenas to the Administration’s broader aim: “to end gender-related treatment for minors.” *Seattle Children’s*, 2025 WL 3562151, at *11.

¹¹ Off. of Att’y Gen., *Memorandum: Preventing the Mutilation of American Children* (Apr. 22, 2025), <https://www.justice.gov/ag/media/1402396/dl> [<https://perma.cc/MJD7-AX9L>] (“Bondi Memo”).

¹² Off. of Assistant Att’y Gen., *Memorandum: Civil Division Enforcement Priorities* (June 11, 2025), <https://www.justice.gov/civil/media/1404046/dl> [<https://perma.cc/P273-8QQE>] (“Shumate Memo”).

The evidence offered through the Hsiao Declaration underscores this conclusion, illustrating the subpoenas' purpose of carrying out the Denial-of-Care EO. The declaration mirrors the language of the Bondi Memo; relies on the HHS Report's politically driven and false determination that GAMC lacks robust evidence of its safety and efficacy as the basis for alleging that providers are deceiving patients and parents; and attests that the government has committed vast resources to its investigation of "the provision of gender-related care for minors." JA 94-96, 99. There can be no clearer evidence that the subpoena to RIH was issued for the improper purpose of fulfilling the Administration's goal to end access to GAMC as part of its broad attacks on transgender people.¹³

II. DOJ'S UNFOUNDED ALLEGATIONS OF HEALTHCARE OFFENSES AGAINST GAMC PROVIDERS LIKE RIH ILLUSTRATE THE SUBPOENA'S IMPROPER PURPOSE.

Not only is the subpoena to RIH inextricable from the Administration's targeting of transgender people and GAMC, but DOJ's attempts to justify it betray the pretextual nature of its actions. Specifically, while conceding that merely prescribing medication for an off-label use would not result in FDCA liability, the Government's unfounded assertions that prescribing an approved medication for

¹³ The district court found the Hsiao Declaration's representations regarding RIH's efforts to comply with the subpoena "clearly misleading, if not utterly false," and its assertion that DOJ needed identifying information "at best, deceptive, if not intentionally and knowingly false." Add.8-9.

GAMC and clinical consultations regarding that off-label use constitute FDCA violations, JA4-6; Gov’t Br. 12-14, 29-37, show that the subpoenas are part of a legally meritless fishing expedition designed to end the provision of evidence-based, established care, rather than a routine mechanism to collect information reasonably relevant to a genuine investigation.

A. Off-label Prescription of Medications Does Not Violate the FDCA or Otherwise Constitute a Healthcare Offense.

From the outset, DOJ has asserted that the subpoenas are investigating “whether off-label promotion and/or unlawful dispensing of puberty blockers and cross-sex hormones for use by minors violated” the FDCA, JA240, mirroring the language of the DOJ memos. In so doing, the Government wrongfully implied that a doctor issuing an off-label prescription of an otherwise lawful medication as GAMC violates the FDCA. DOJ attempted to expand upon this theory through the Hsiao Declaration, which misleadingly suggested that prescribing GAMC for an “unapproved” use is either unlawful, or at least is evidence of some illegal activity. JA90-100; *see also* Gov’t Br. 9-12.¹⁴

But the FDCA does not prohibit doctors from off-label prescribing. “Although the [FDCA] regulates a manufacturer’s distribution of drugs, it does not go further

¹⁴ While DOJ disclaims that off-label prescribing itself violates the FDCA, Gov’t Br. 35-36, it still contends liability may attach for this particular off-label use by a physician, *id.* at 36-37.

by regulating a doctor’s practice of medicine. The Act thus does not prohibit doctors from prescribing an FDA-approved drug ... for an ‘off-label’ use. ... It instead leaves the regulation of doctors to the states.” *Ass’n of Am. Physicians & Surgeons v. U.S. Food & Drug Admin.*, 13 F.4th 531, 534 (6th Cir. 2021) (citations omitted).

DOJ’s argument ignores controlling precedent that the FDCA does not, and Congress did not intend it to, regulate the practice of medicine. “Off-label” usage “is an accepted and necessary corollary of the FDA’s mission to regulate in this area without directly interfering with the practice of medicine.” *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 350 (2001) (citing, *inter alia*, James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 Food & Drug L.J. 71 (1998)). In *Buckman*, the Court interpreted 21 U.S.C. § 396 as “expressly disclaim[ing] any intent to directly regulate the practice of medicine,” and acknowledged that “off-label use is generally accepted.” 531 U.S. at 351. In fact,

[i]t is an accepted principle that once FDA determines that a drug or device can be marketed, a physician’s discretionary use of that product (the practice of medicine) is not restricted to the uses indicated on FDA-regulated labels. Off-label use is widespread in the medical community and often is essential to giving patients optimal medical care, both of which medical ethics, FDA, and most courts recognize.

Beck & Azari, *supra*, at 72.¹⁵

¹⁵ See also *United States v. Facticeau*, 89 F.4th 1, 15 (1st Cir. 2023) (quoting 21 U.S.C. § 396); *Washington Legal Found. v. Henney*, 202 F.3d 331, 333 (D.C. Cir.

The FDA’s website expressly identifies the lawful reasons a doctor might prescribe off-label and makes clear that providers may exercise clinical judgment to prescribe medication for a reason other than that for which the FDA has granted approval.¹⁶ DOJ is simply wrong to suggest that off-label prescribing is illegal or evidence of an unlawful act.

Longstanding medical practice bears this out. Off-label use of medications in pediatric patients is “a common practice,”¹⁷ particularly given “paediatric drug testing barriers,”¹⁸ including ethical concerns.¹⁹ Off-label use is often necessary to deliver the best evidence-based care.²⁰ These principles apply equally to GAMC. Prescribing puberty blockers and hormone therapy to treat an adolescent’s gender dysphoria despite FDA approval of those medications having been for other conditions does not make them “unapproved new” drugs. Gov’t Br. 4, 6-8. To the

2000).

¹⁶ FDA, *Understanding Unapproved Use of Approved Drugs “Off Label”* (Feb. 5, 2018), <https://tinyurl.com/pd6ff88v> [<https://perma.cc/XT3K-4R57>].

¹⁷ H. Christine Allen et al., *Off-Label Medication use in Children, More Common than We Think: A Systematic Review of the Literature*, 111 J Okla State Med Assoc. 776-783 (2018), <https://pmc.ncbi.nlm.nih.gov/articles/PMC6677268/>.

¹⁸ *Paediatric off-label prescribing in the USA*, 1773 Reactions Weekly 10 (2019), <https://doi.org/10.1007/s40278-019-68767-y>.

¹⁹ See also Christopher M. Wittich et al., *Ten common questions (and their answers) about off-label drug use*, 87 Mayo Clinic Proc. 982, 983 (2012), <https://doi.org/10.1016/j.mayocp.2012.04.017>.

²⁰ See William M. Janssen, *A Historical Perspective on Off-Label Medicine: From Regulation, Promotion, and the First Amendment to the Next Frontiers*, SSRN Elec. J. (2014), <https://doi.org/10.2139/ssrn.2519223>.

contrary, “in no way does a lack of labeling signify that therapy is unsupported by clinical experience or data in children.” Am. Acad. of Pediatrics, *Policy Statement – Off-Label Use of Drugs in Children*, 133 Pediatrics 563, 564 (2014). A lack of labeling should not be confused with finding contraindication or unsafety. *Id.* To suggest otherwise is erroneous and contravenes common medical practice.

DOJ’s attempt to shoehorn a provider’s lawful exercise of clinical judgment to prescribe FDA-approved medications to treat gender dysphoria into an FDCA violation or other healthcare offense illustrates the subpoena’s lack of legitimate purpose. Because RIH’s off-label prescribing is plainly authorized, this justification is pretextual.

B. Informing Patients About Off-Label Use of Puberty Blockers and Hormone Therapy Does Not Violate the FDCA.

Recognizing that off-label use alone cannot establish a healthcare offense, DOJ now alleges that information RIH provides to patients regarding GAMC constitutes “misbranding” under the FDCA or that RIH may have violated the FDCA if RIH “causes the distribution of an approved drug for an unapproved use[.]” Gov’t Br. 6-7. Ultimately, DOJ is arguing that any representation of the safety and efficacy of GAMC is a form of misbranding. *Id.* at 10-14. These recast arguments fare no better.

First, this “misbranding” theory ignores the FDCA’s distinction between manufacturers and pharmacies on the one hand, and doctors on the other. *See, e.g.,*

U.S. ex rel. Wilson v. Bristol-Myers Squibb, Inc., 750 F.3d 111, 113 (1st Cir. 2014) (noting that physicians may lawfully prescribe off-label, but manufacturers cannot promote such uses to doctors); *Facteau*, 89 F.4th at 15 (while a manufacturer’s off-label marketing of a device would constitute “misbrand[ing],” “the FDCA expressly protects the ‘authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease.’”). The FDCA was never intended to interfere with medical practice, which includes a provider’s explanation of the risks and benefits of a particular medicine to patients.

The Fifth Circuit rejected the notion that a doctor’s providing (or failing to provide) adequate directions for an off-label use of an FDA-approved drug could constitute “misbranding” in *United States v. Evers*, 643 F.2d 1043, 1053 (5th Cir. 1981). Calling the Government’s interpretation of the statute “nonsensical,” the Court rejected “that this interpretation was intended by the drafters of the statute.” *Id.* DOJ’s overbroad interpretation of “misbranding” is similarly nonsensical. Even the Bondi Memo from which these subpoenas directly flow only authorizes investigations of FDCA violations by drug manufacturers and distributors and not providers. DOJ’s newly-created “violation” does not justify the subpoena.

Second, DOJ’s claims that RIH’s representations regarding the risks and benefits of GAMC are potentially “false and misleading” flow directly from the Administration’s campaign against this care, rather than from science or research.

Although these treatments have long been recognized as the standard of care in accordance with evidence-based clinical guidelines, *see Dekker v. Weida*, 679 F.Supp.3d 1271, 1285-86 (N.D. Fla. 2023), DOJ’s position reflects the Administration’s opposition to GAMC generally. Gov’t Br. 39-44.

The sources DOJ points to for its position that “these interventions are unproven, unsafe, unnecessary, and unethical,” Gov’t Br. 41, were created pursuant to the Denial-of-Care EO, §§ 1, 3, 5. DOJ relies on the HHS Report and Kennedy Declaration, claiming that they “determined that ‘[a]vailable evidence cannot support determinations regarding the effectiveness of these medical interventions’” for the treatment of gender dysphoria in minors. Gov’t Br. 12. But, as discussed *supra*, this Report, with a predetermined outcome, is highly flawed, and the Kennedy Declaration has been held unlawful.

The government’s disagreement with physicians’ off-label prescribing and evidence-based representations regarding safety and efficacy cannot transform those prescribing practices or clinical consultations into an FDCA violation. To do so would regulate the practice of medicine in a manner expressly rejected in *Buckman*, 531 U.S. at 350.

III. DOJ’S GAMESMANSHIP BOLSTERS THE ILLEGITIMACY OF ITS ISSUANCE OF THE SUBPOENA.

DOJ’s highly irregular and improper litigation tactics undercut any alleged legitimate purposes underlying the subpoenas and highlight that they are pretext for

the Administration’s discriminatory targeting of transgender people and their medical providers.

DOJ’s tactical and procedural gamesmanship speaks to its overzealous pursuit of the Administration’s aims. After “its disastrous showing in the courts,” *Coe Tr.* at 5, DOJ sought out a more hospitable forum, moving to enforce the RIH subpoena in Texas despite zero nexus between the subpoena, hospital, and jurisdiction. “It did so in an obvious effort to shield its recent investigative tactics—previously rejected by every other court to review them—from this Court’s review, in favor of a distant forum that DOJ deems friendly to its political positions.” Add.4. Courts routinely reject such forum shopping as “procedural gamesmanship.” *VRCompliance LLC v. Homeaway, Inc.*, 715 F.3d 570, 575-576 (4th Cir. 2013).

More starkly, the district court concluded that in doing so, DOJ “misrepresented and withheld information,” “under oath, misrepresented salient facts,” and “misled the parties with whom it was negotiating,” ultimately concluding that “[t]he presumption of regularity that has previously been extended to [DOJ] that it could be taken at its word—with little doubt about its intentions and stated purposes—no longer holds.” Add.4-5, 26 (quotation omitted).

Nor was this the first time DOJ failed to comply with court rules in its defense of these administrative subpoenas. *See, e.g., QueerDoc*, 807 F.Supp.3d at 1303 n.2 (discussing DOJ’s “fundamental misunderstanding—or deliberate misuse—of court

procedure”); Electronic Order, *In re Admin. Subpoena No. 25-1431-019*, No. 1:25-mc-91324 (D. Mass. Nov. 24, 2025) (ECF 52). Thus, as other courts have observed, this Administration’s “unserious approach to governance stumbles far below the necessary commitment to a constitutional democracy that requires the rule of law to be regarded, respected, and honored as sacred.” *Oregon*, 2026 WL 1048354, at *19.

Finally, seeking to bolster its demands’ chances, DOJ abandoned some administrative subpoenas and “issue[d] nearly identical document requests in the form of grand jury subpoenas emanating from the Northern District of Texas.” *Coe Tr.* at 5. Like the Rhode Island Child Advocate, patients at some of the hospitals believed to have received these grand jury subpoenas sought protection of their constitutional privacy rights, successfully obtaining preliminary injunctions barring DOJ from seeking their identities and sensitive health information through demands identical to those enjoined by the district court here. *See Coe*, 2026 WL 1951390; *Z.A. v. Blanche*, No. 26-CV-04998-PCP, 2026 WL 1907181 (N.D. Cal. July 2, 2026), *appeal docketed*, No. 26-4388 (9th Cir. July 10, 2026). Each court refused to “blind itself to [the] reality ... of DOJ’s efforts ... to recast discredited civil administrative subpoenas as grand jury subpoenas from a hand-picked faraway jurisdiction in order to minimize judicial review of constitutional infirmities.” *Coe Tr.* at 8; *Z.A.*, 2026 WL 1907181, at *5.

DOJ's efforts to bolster the legitimacy of its investigations backfire, with its evolving rationales for nearly identical subpoenas underscoring that they are post-hoc and pretextual. As one court noted, DOJ "has shifted its explanations for the investigation before us as our colleagues across the Nation have identified problems with the Department's numerous subpoenas," and these "evolving rationales expose a uniquely misplaced view of its ability to expand the limits Congress imposed" on the investigations DOJ is authorized to pursue. *In re Subpoena No. 25-1431-014*, 810 F.Supp.3d at 581, 583.

In an early attempt to defend the subpoenas, DOJ posited that they related to an investigation of providers' promotion and prescription of puberty blockers and hormone therapy for the off-label use of treating gender dysphoria. *In re Admin. Subpoena No. 25-1431-019*, 800 F.Supp.3d at 237-38. After the court quashed that subpoena, rejecting DOJ's assertion that Boston Children's Hospital ("BCH")'s mere provision of GAMC was sufficient, *id.* at 238-39, DOJ changed its tune. Seeking to alter that judgment, DOJ alleged the subpoena was investigating "whether BCH made false statements about pharmaceuticals and/or illegally distributed pharmaceuticals without valid prescriptions." Mem. in support of Mot. to Alter J., *In re: Administrative Subpoena No. 25-1431-019*, No. 25-mc-91324-MJJ (D. Mass. filed Oct. 7, 2025) (ECF 36).

DOJ did a similar about-face defending the subpoena to QueerDoc, initially framing it as effectuating the Bondi and Shumate Memos, Gov’t Opp’n to Mot. to Seal Docket, *QueerDoc, PLLC v. U.S. Dep’t of Justice*, No. 2:25-mc-00042 (W.D. Wash. filed July 17, 2025) (ECF 8); two months later as investigating the mere prescription of a drug for off-label use, *see* Gov’t’s Praecipe to file Additional Document, *QueerDoc*, (filed Sept. 26, 2025) (ECF 24-1); and on appeal, conceding that off-label use itself does not violate the FDCA and re-framing it as an investigation into “misbranding drugs for off-label uses and filing deceptive insurance claims.” Appellants’ Br., *U.S. Dep’t of Justice v. QueerDoc*, No. 25-7384 (9th Cir. Dec. 19, 2025) (ECF 25.1).

DOJ’s justifications continued to diverge across the cases seeking to quash these subpoenas, including as described *supra* in the instant matter. DOJ now offers that it is investigating RIH itself and manufacturers or distributors, and is also investigating billing codes, misbranding, off-label promotion, and monitoring patients’ health outcomes, Gov’t Br. 9-14, 30-44—a veritable buffet of the different investigations alleged to justify these subpoenas, none of which suffices.

Rather than bolstering the subpoena’s proper purpose, DOJ’s ever-changing justifications show that none of the proffered “legitimate” bases are real. They are “belated post hoc rationalization[s] of ... finding[s] in litigation.” *Melone v. Coit*, 100 F.4th 21, 31 (1st Cir. 2024). In short, “DOJ issued the subpoena[s] first, and

searched for a justification second.” *QueerDoc*, 807 F.Supp.3d at 1303. The “weaknesses, implausibilities, inconsistencies, incoherencies, and contradictions in [DOJ’s] proffered legitimate reasons” render them “unworthy of credence,” leaving the inference that DOJ acted for an improper purpose. *Hodgens v. Gen. Dynamics Corp.*, 144 F.3d 151, 168 (1st Cir. 1998).

At the end of the day, these bad faith actions reflect DOJ’s “playing fast and loose with the courts,” *Patriot Cinemas, Inc. v. Gen. Cinemas Corp.*, 834 F.2d 208, 212 (1st Cir. 1987), and underscore the impropriety of the subpoenas.

CONCLUSION

Given the inextricable throughline from the Administration’s discriminatory targeting of transgender people to the subpoena, that DOJ’s claims of healthcare offenses are baseless, and DOJ’s gamesmanship in its relentless pursuit of transgender youth’s identifying and sensitive health information, the Court should recognize the subpoena as a “fishing expedition” that “seeks to rifle through thousands of patient records hoping to find something—anything—to justify its predetermined goal of ending gender-affirming care.” *QueerDoc*, 807 F.Supp.3d at 1304. This Court should affirm the quashal of the subpoena.

Dated: July 24, 2026

Respectfully submitted,

/s/ A.D. Sean Lewis

Omar Gonzalez-Pagan (Bar No. 1167550)
Jessica Polansky (Bar No. 1136450)
LAMBDA LEGAL DEFENSE
AND EDUCATION FUND, INC.
120 Wall Street, 19th Floor
New York, NY 10005
(212) 809-8585
ogonzalez-pagan@lambdalegal.org
jpolansky@lambdalegal.org

Morgan J. Walker
LAMBDA LEGAL DEFENSE
AND EDUCATION FUND, INC.
3500 Oak Lawn Avenue, Suite 500
Dallas, TX 75219
(214) 219-8585
mwalker@lambdalegal.org

A.D. Sean Lewis (Bar No. 1222300)
LAMBDA LEGAL DEFENSE
AND EDUCATION FUND, INC.
800 South Figueroa Street, Suite 1260
Los Angeles, CA 90017
(213) 382-7600

Karen L. Loewy (Bar No. 98898)
LAMBDA LEGAL DEFENSE
AND EDUCATION FUND, INC.
815 16th Street NW, Suite 4140
Washington, DC 20006
(202) 804-6245
kloewy@lambdalegal.org

Counsel for Amicus Curiae

CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(g), the undersigned hereby certifies that the foregoing filing complies with the relevant type-volume and typeface requirements of the Federal Rules of Appellate Procedure and the Court's Local Rules.

Excluding the exempted portions of the brief, as provided in Fed. R. App. P. 32(f), the petition contains 6,498 words.

This brief has been prepared in proportionally spaced typeface using Microsoft Word in 14-point Times New Roman font. As permitted by Fed. R. App. P. 32(g), the undersigned has relied upon the word count feature of this word processing system in preparing this certificate.

Dated: July 24, 2026

/s/ A.D. Sean Lewis
A.D. Sean Lewis
Counsel for Amicus Curiae

CERTIFICATE OF SERVICE

I certify that on July 24, 2026, I caused a true and accurate copy of the foregoing document to be electronically filed with the Clerk of the Court for the United States Court of Appeals for the First Circuit through the CM/ECF system. I further certify that the participants in this case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

/s/ A.D. Sean Lewis

A.D. Sean Lewis

Counsel for Amicus Curiae