

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF RHODE ISLAND**

In Re: Administrative Subpoena
25-1431-032 to Rhode Island Hospital

Misc. Action No. 1:26-mc-00007-MSM-AEM

**BRIEF OF LAMBDA LEGAL DEFENSE AND EDUCATION FUND, INC.
AS *AMICUS CURIAE* IN SUPPORT OF PLAINTIFF'S
EMERGENCY MOTION TO QUASH SUBPOENA DUCES TECUM**

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INTEREST OF *AMICUS CURIAE*¹

Amicus curiae **Lambda Legal Defense and Education Fund, Inc.** (“Lambda Legal”) is the nation’s oldest and largest legal organization dedicated to achieving full recognition of the civil rights of lesbian, gay, bisexual, transgender, and queer (LGBTQ+) people and everyone living with HIV through impact litigation, education, and policy advocacy. Since its founding in 1973, Lambda Legal has sought to eliminate discriminatory barriers to health care for LGBTQ+ people, particularly transgender people, serving as counsel or *amicus* in cases across the country. *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); *Whitman-Walker Clinic, Inc. v. U.S. Dep’t of Health & Hum. Servs.*, 485 F.Supp.3d 1 (D.D.C. 2020). This includes cases pushing back against the Trump Administration’s defunding of researchers and healthcare entities serving transgender people. *See, e.g., San Francisco AIDS Found. v. Trump*, 786 F.Supp.3d 1184 (N.D. Cal. 2025) (“*SFAF*”); *PFLAG, Inc. v. Trump*, 769 F.Supp.3d 405 (D. Md. 2025) (“*PFLAG*”).

Having long litigated cases involving barriers to gender-affirming medical care, *Amicus* offers perspectives on the Trump Administration’s far-ranging targeting of transgender people and their healthcare providers and on the illegitimacy of investigating medical associations for their clinical guidance and policy statements as the Court considers the improper purpose underlying the administrative subpoenas sent to providers like Rhode Island Hospital.

INTRODUCTION AND SUMMARY OF THE ARGUMENT

In June 2025, the U.S. Department of Justice (“DOJ”) issued substantively identical subpoenas to more than twenty healthcare institutions across the country whose care for their

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.

patients includes gender-affirming medical care to transgender adolescents who need such healthcare. The latest salvo in the Trump Administration's broad-based discriminatory, demeaning campaign against transgender people, the subpoenas were issued to intimidate providers of evidence-based gender-affirming medical care for transgender adolescents and to end this care entirely.

The Administration's attacks on transgender people began on day one of the present term with a mandate to eradicate "gender ideology," the Administration's derogatory term for acknowledging the existence of transgender people. Exec. Order No. 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" gender-affirming medical care 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," and that "it must end." Exec. Order No. 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 not only by the U.S. Departments of Health and Social Services ("HHS") and the U.S. Federal Trade Commission ("FTC"), but also Justice ("DOJ"), culminating in the issuance of investigative demands and subpoenas, including the one to Rhode Island Hospital ("RI Hospital") at issue here.

But the Administration's animus towards transgender people and its rancor towards those who endorse or support the gender-affirming medical care that enables transgender adolescents to live authentically are not lawful bases for any administrative subpoenas. As every court that has considered the issue has concluded, the subpoenas lack a legitimate investigatory basis and were instead issued for the improper purpose of "fulfill[ing] the Executive's well-publicized policy

objective to terminate and block gender affirming healthcare.” See *In Re 2025 Subpoena to Children’s Nat’l Hosp.*, No. 1:25-cv-03780-JRR, 2026 WL 160792 at *8 (D. Md. Jan. 21, 2026), *appeal docketed*, No. 26-1104 (4th Cir. Feb. 2, 2026).²

Notwithstanding that the Subpoena at issue in this case was issued by DOJ attorneys in Washington, DC to RI Hospital, based in Rhode Island, for care provided in Rhode Island, on April 30, 2026, DOJ filed a Petition for Enforcement of the Subpoena in the United States District Court for the Northern District of Texas. See *Pet. for Enforcement of Admin. Subpoena, In Re: Administrative Subpoena 25-1431-032*, No. 4-26MC-006-0 (N.D. Tex. Apr. 30, 2026) (ECF No. 1).³ The district court granted the government’s motion to compel hours later, without any filed opposition, and ordered RI Hospital to “provide all records responsive to each request in the subpoena within 14 days of the entry of this order.” Order, *In Re: Administrative Subpoena 25-1431-032*, No. 4-26MC-006-0 (N.D. Tex. Apr. 30, 2026) (ECF No. 2). Immediately thereafter, seeking to protect the privacy of RI Hospital patients who have sought care for gender dysphoria whose private medical information would be disclosed in RI Hospital’s mandated compliance, the Child Advocate filed the instant action in the venue where the subpoena was served and where the

² See also, e.g., *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 UPMC Subpoena*, No. 2:25-MC-01069-CB, 2025 WL 3724705, at *2 (W.D. Pa. Dec. 24, 2025), (subpoena “carries more than a whiff of ill-intent.”), *judgment entered*, No. 2:25-MC-01069-CB, 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) (subpoena’s “true purpose” is to interfere with “Massachusetts’ right to protect GAC within its borders, to harass and intimidate BCH to stop providing such care, and to dissuade patients from seeking such care.”); *In re Subpoena No. 25-1431-014*, 810 F.Supp.3d 555, at 583 (E.D. Pa. 2025) (DOJ’s asserted concerns “describe policy disagreements about the propriety of medical care,” not a legitimate basis for a subpoena), *appeal docketed*, No. 26-1134 (3d Cir. Jan. 26, 2026); *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) (finding “threadbare” allegations pretextual; true purpose was “to pressure hospitals into ending gender-related care for minors.”).

³ For purposes of this brief, *Amicus* uses “Dkt.” to refer to filings in the instant case and “ECF” to reference filings in other cases.

information and records sought are actually located, challenging the lawfulness of the subpoena and asking the Court to shield their information from disclosure. *See* Dkt. No. 1.

In both actions, DOJ has failed to demonstrate a lawful purpose for the subpoena's issuance. To the contrary, DOJ issued the Subpoena as part of a coordinated campaign by the Trump Administration against transgender people and to eliminate access to the medical care that enables them to live authentically as themselves, namely, medical treatment for gender dysphoria, which is essential and often lifesaving care that is recognized as medically necessary by every major medical association, even where it is expressly protected by state law, as it is in Rhode Island. The Administration has made no secret of its true goal: to end the medical care that many transgender young people need through intimidation, harassment, and the threat of criminal prosecution.

DOJ attempts to tie the Subpoena to purported investigations of healthcare offenses under the Food, Drug, & Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA"), but its allegations regarding off-label use of medications to treat gender dysphoria and patient outcomes bear no resemblance to any offense prohibited by that statute. *See* Gov't Opp. (Dkt. 9) at 14-15; Hsiao Decl. Ex. 3, Dkt. No. 1-3, at ¶ 22.⁴ The same is true of DOJ's argument that it sought information about billing (including detailed requests for financial information far beyond insurance reimbursement claims, including consulting agreements, sponsorships, speaking honoraria and other financial information) because such information may contain probative evidence of alleged "false billing." Gov't Opp. at 14. Both theories are rooted in the Administration's disdainful, inflammatory narrative regarding transgender people and gender-affirming medical care, relying on

⁴ The very same declaration was filed in the petition to enforce the subpoena at issue here in Texas. Hsiao Decl. Ex. 1, *In Re: Administrative Subpoena 25-1431-032*, No. 4-26MC-006-0 (N.D. Tex. Apr. 30, 2026), ECF No. 1-1.

commissioned sources designed to fit that narrative. These manufactured violations and DOJ's evolving framing serve to illustrate that DOJ devised them after the fact to conceal their improper motive for the subpoena rather than serving as a lawful predicate. This gamesmanship, along with DOJ's bald forum shopping, are inextricably tied to the broader attack on transgender people and gender-affirming medical care.

Because the subpoena to RI Hospital is rooted in this improper purpose, this Court should grant the relief sought by the plaintiff.

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 RI Hospital to any legitimate investigation, and, as every court to actually consider objections to DOJ's nearly identical subpoenas to providers of gender-affirming medical care has found, DOJ's subsequent efforts to reframe its purpose as something other than carrying out the Trump Administration's effort to end the provision of gender-affirming medical care to adolescents similarly fail. It is impossible to view the subpoenas in isolation as their issuance is the direct result of the Administration's relentless campaign to erase transgender people from public life and to disavow and disparage the medical care that allows them to live as themselves, *i.e.*, gender-affirming medical care, as well as

its providers and supporters. As courts in the analogous context of civil investigative demands (“CIDs”) by the FTC to medical organizations that support gender-affirming medical care have found, these subpoenas are part of a “systemic targeting of proponents of medical treatment for gender incongruence” that “reasonably appears to be one more step in a multiagency campaign to stamp out dissenters” of the administration’s directives “to put a stop to any acknowledgment of gender dysphoria or that some individuals are transgender.” *Endocrine Soc’y v. Fed. Trade Comm’n*, No. 1:26-cv-00512-JEB, Slip Op. (D.D.C. May 7, 2026) (ECF No. 38), at 4, 26, 31.

DOJ has proffered arguments about the legitimacy of DOJ’s investigation into federal healthcare offenses under the FDCA. But neither the Government’s opposition nor the Hsiao Declaration establishes a proper purpose for the subpoena because the conduct DOJ claims to be investigating is not illegal. Far from ensuring that providers are carrying out the provision of gender-affirming medical care lawfully, DOJ’s filings frame the ordinary practice of medicine in this context as inherently unlawful, whether in terms of prescribing off-label use or providing patients with information about the medications themselves. DOJ’s ever-evolving justifications and its litigation gamesmanship bolster that the subpoena was issued in bad faith and for an improper purpose—to harass RI Hospital and pressure them into ending the provision of gender-affirming medical care to transgender adolescents. This is precisely the type of improper purpose courts have condemned.

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

DOJ’s subpoenas to providers like RI Hospital are a direct result of the Trump Administration’s relentless targeting of transgender people for unequal treatment, including its multifaceted campaign to eliminate the provision of gender-affirming medical care to adolescents. Given the impossibility of extricating the Subpoena from these broader efforts to exclude

transgender people from public life and deny them access to the healthcare that enables them to live authentically, the inexorable conclusion is that the subpoena is imbued with an improper purpose and warrants granting plaintiff's motion to quash.

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

The Trump Administration set the tone on its first day in office by launching its attack on transgender people via the issuance of the Gender EO, a cross-cutting effort to reverse existing protections and deny recognition of transgender people's existence. *See, e.g.*, 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 all agencies to interpret sex-based terms as birth-assigned sex, including with regard to government-issued identification documents and personnel records, § 3(c), (d); rescinded provisions of prior executive orders combating discrimination against LGBTQ people, § 7(b); barred federal funding from being "used to promote gender ideology," § 3(g); mandated housing in accordance with a person's birth-assigned sex in federal prisons and federally-funded shelters, § 4; and directed federal agencies to rescind guidance, forms, and policies acknowledging the existence of transgender people, §§ 3(e), 7(c).

Additional Executive Orders followed, with the Administration using the power of the purse to enforce its erasure of transgender people and its refusal to recognize any form of systemic discrimination; targeting gender-affirming medical care for transgender adolescents through the Denial-of-Care EO; excluding transgender people from military service; threatening federal funding for schools that recognize and affirm transgender students' identities; and barring transgender athletes from school sports. *See, e.g.*, Exec. Order No. 14151, *Ending Radical and Wasteful DEI Programs and Preferencing*, 90 Fed. Reg. 8339 (Jan. 20, 2025); Exec. Order No.

14173, *Ending Illegal Discrimination and Restoring Merit-Based Opportunity*, 90 Fed. Reg. 8633 (Jan. 21, 2025); Exec. Order No. 14183, *Prioritizing Military Excellence and Readiness*, 90 Fed. Reg. 8757 (Jan. 27, 2025) (“Military Ban EO”); Exec. Order No. 14190, *Ending Radical Indoctrination in K-12 Schooling*, 90 Fed. Reg. 8853 (Jan 29, 2025); Exec. Order No. 14201, *Keeping Men Out of Women’s Sports*, 90 Fed. Reg. 9279 (Feb. 11, 2025) (“Sports Ban EO”).

These Executive Orders employ dehumanizing, inaccurate rhetoric to cast transgender people, gender-affirming medical care, 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. Far from mere policy preferences, courts have recognized that these EOs specifically seek to erase transgender people and punish the organizations that provide them necessary services and care. *See, e.g., PFLAG*, 769 F.Supp.3d at 443-44 (The Gender EO “den[ies] the existence of transgender persons altogether;” “[t]he 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*, Slip Op. at 4 (The Executive Orders “exhorted federal agencies to put a stop to any acknowledgment of gender dysphoria or that some individuals are transgender.”).

Federal agencies took immediate action to carry out the Gender and Denial-of-Care EOs’ campaign against transgender people and their medical providers. For example, within days of the Gender EO, Secretary of State Rubio ordered State Department staff “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) (internal quotations omitted). Contemporaneously, the Bureau of Prisons (“BOP”) initiated transfers of transgender women to men’s prisons, paused access to gender-affirming medical care, and discontinued access to gender-affirming clothing and toiletries. *See Doe v. McHenry*, 763 F.Supp.3d 81, 84 (D.D.C. 2025) (granting TRO to prohibit imminent transfers); *Kingdom v. Trump*, No. 1:25-CV-691-RCL, 2025 WL 1568238, at *1 (D.D.C. June 3, 2025) (granting PI to protect access to gender-affirming medical care and social accommodations). *See also* Bureau of Prisons, *Management of Inmates with Gender Dysphoria*, No. 5260.01 (Feb. 19, 2026), <https://tinyurl.com/3cwbfxxh> (instructing BOP providers to medically de-transition patients, and to treat gender dysphoria symptoms solely with talk therapy and psychotropics).

The Office of Personnel Management instructed federal agencies to “take down all outward facing media (websites, social media accounts, etc.) that inculcate or promote gender ideology.” U.S. Off. of Pers. Mgmt., *Initial Guidance Regarding President Trump’s Executive Order Defending Women* (Jan. 29, 2025), <https://tinyurl.com/243c49d6>. HHS did so. The Office of Management and Budget also promised to stop the use of federal funds to promote “transgenderism.” Matthew J. Vaeth, Off. of Mgmt. & Budget, *Temporary Pause of Agency Grant, Loan, and Other Financial Assistance Programs* (Jan. 27, 2025), <https://tinyurl.com/3zpchy7r>. Within days, 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>.

Similarly, the National Institutes of Health terminated hundreds of research grants relating to LGBTQ+ people because the research related to “transgender issues” and, according to the Administration, “research based on gender identity ... do[es] nothing to enhance the health of many Americans” and “ignore[s] biological realities.” *Am. Ass’n of Physicians for Hum. Rts., Inc. v. Nat’l Insts. of Health*, 795 F.Supp.3d 678, 688, 696-97 (D. Md. 2025). In this regard, the termination of such research pulls back the curtain on the Administration’s discriminatory motives and improper purpose: The Administration is not concerned with the evidence base relating to gender-affirming medical care (or truth or facts, for that matter), but rather with the ultimate demise of the essential medical care that enables transgender people to live authentically.

The breadth of these executive actions is breathtaking and has a dramatic chilling effect on the speech and activity of organizations and individuals that acknowledge the existence of transgender people and aim to support them.

B. The Administration’s Endgame is to Eliminate Gender-Affirming Medical Care, Particularly for Adolescents.

The sharpest tip of the Administration’s attacks against transgender people is aimed at transgender adolescents, their families and supporters, their medical providers, and the professional associations that express affirming viewpoints about gender-affirming medical care.

The executive’s statements about transgender people and gender-affirming medical care providers are “provocative and unabashedly so.” *In re 2025 UPMC Subpoena*, 2025 WL 3724705, at *2; *see also Endocrine Soc’y*, Slip Op. at 1 (“Members of the Executive Branch, including the President, have expressed vehement disagreement with, criticism of, and vitriol toward th[e] message” that “individuals can experience gender incongruence between their biological sex and their gender identity and that gender-affirming care can treat that incongruence.”). DOJ has characterized gender-affirming medical care as “a radical ideological agenda”; an “infect[ion]

visited upon] an entire generation”; the work of “politically captured profiteers”; “barbaric practice[s]” that “maim and steriliz[e] children”; and as “genital mutilation.” *In re 2025 UPMC Subpoena*, 2025 WL 3724705, at *2 (quoting DOJ statements). The President has characterized gender-affirming medical care for adolescents as child abuse and “barbaric,” 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>. As courts have found, such “rhetoric regarding gender-affirming care reflects callous indifference, if not abject cruelty.” *In re 2025 UPMC Subpoena*, No. 2:25-MC-01069-CB, 2026 WL 570419, at *2 (W.D. Pa. Mar. 2, 2026) (“*UPMC Subpoena II*”).

As directed by the Denial-of-Care EO, multiple other agencies have taken action to enforce the Administration’s singular viewpoint opposing gender-affirming medical care and to punish entities that take an opposing view. For example, HHS published a report allegedly reviewing “the existing literature on best practices for promoting the health of children” with gender dysphoria. 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/yxjdbud7> (“HHS Report”). However, the HHS Report has been criticized for “its extensive violations of scientific norms, misrepresentations of science, and wanton disregard of the expert standard of care for [transgender and gender diverse] TGD youth,” as well as “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 *The Journal of Adolescent Health* 342-345 (2025), <https://tinyurl.com/5ecbdbf9>; see also Susan J. Kressly, *AAP Statement on HHS Report Treatment for Pediatric Gender Dysphoria*, *Am. Academy Pediatrics* (May 1, 2025), <https://tinyurl.com/478yckca>.

The HHS Report was lambasted by the medical establishment as “misrepresent[ing] the current medical consensus and fail[ing] to reflect the realities of pediatric care. Susan J. Kressly, *AAP Statement on HHS Report Treatment for Pediatric Gender Dysphoria*, Am. Academy Pediatrics (May 1, 2025), <https://tinyurl.com/478yckca>.⁵ Indeed, multiple studies and systematic reviews have found gender-affirming medical care 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 the widespread critiques of the HHS Report, HHS notified healthcare providers of the Report’s findings and requested detailed information about gender-affirming medical care for minors from providers. See U.S. Dept. of Health & Hum. Servs., *Urgent Review of Quality Standards and Gender Transition Procedures* (May 28, 2025), <https://tinyurl.com/4j2bt2zd>.

In December 2025, HHS Secretary Kennedy went further and sought by fiat to unilaterally establish that *any* provision of gender-affirming medical care 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/4uyrafyf>. The same day, HHS published proposed

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://doi.org/10.1007/s13178-025-01221-5> (condemning “the political motivations leading to the publication of the HHS review without consulting pediatric gender care experts and organizations” and “the review’s misrepresentation of the evidence surrounding the benefits of supporting and affirming TGNB youth.”); Nadia Dowshen, et al., *A Critical Scientific Appraisal of the Health and Human Services Report on Pediatric Gender Dysphoria*, 77 The Journal of Adolescent Health 342-345 (2025), <https://doi.org/10.1016/j.jadohealth.2025.06.002> (“The HHS report, with its extensive violations of scientific norms, misrepresentations of science, and wanton disregard of the expert standard of care for TGD youth, is a dangerous incursion of politics into science and medicine.”); Phie Jacobs, *Researchers slam HHS report on gender-affirming care for youth*, Science (May 2, 2025), <https://tinyurl.com/326md8yf>.

⁶ See, e.g., 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>; Dopp, 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>.

rules (1) barring Medicaid and Children’s Health Insurance Program funds from paying for gender-affirming medical care,⁷ (2) prohibiting hospitals from providing gender-affirming medical care as a condition of participation in Medicare and Medicaid,⁸ and (3) excluding gender dysphoria from disability-based antidiscrimination protections.⁹ HHS’s General Counsel also publicized his referrals of children’s hospitals providing gender-affirming medical care to HHS’s Office of Inspector General “for failing to meet ‘recognized standards of health care,’ citing Kennedy’s declaration.”¹⁰ HHS’s sweeping contemporaneous actions confirm HHS’s intent to operationalize a categorical, nationwide prohibition of gender-affirming medical care by sub-regulatory pronouncement.¹¹

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 gender-affirming medical care and “revise [its] medical guidelines and guidance that advise medical professionals to provide these procedures to minors.” *E.g.*, 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

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) (to be codified at 42 C.F.R. pt. 441, 457).

⁸ *Medicare and Medicaid Programs; Hospital Condition of Participation: Prohibiting Sex-Rejecting Procedures for Children*, 90 Fed. Reg. 59463-01 (proposed Dec. 19, 2025) (to be codified at 42 C.F.R. pt. 482).

⁹ *Nondiscrimination on the Basis of Disability in Programs or Activities Receiving Federal Financial Assistance*, 90 Fed. Reg. 59478-01 (proposed Dec. 19, 2025) (to be codified at 45 C.F.R. pt. 84).

¹⁰ Orion Rummier, *Three hospitals are under investigation for providing gender-affirming care to trans youth*, The 19th (Jan. 7, 2026), <https://tinyurl.com/3muuawv7>.

¹¹ Other agencies have also taken steps to carry out these mandates. For example, the Federal Trade Commission held a workshop on the purported on “dangers” of gender-affirming medical care to minors and has sought public comment relating to gender-affirming medical care with the goal of exploring unprecedented enforcement against gender-affirming medical care providers under the guise that the provision of such care constitutes an unfair or deceptive trade practice. *See* Fed. Trade Comm’n, *The Dangers of “Gender-Affirming Care” for Minors*, <https://www.ftc.gov/news-events/events/2025/07/dangers-gender-affirming-care-minors>; Fed. Trade Comm’n, *Request for Public Comment Regarding “Gender-Affirming Care” for Minors*, Document No. FTC-2025-0264-001 (Jul. 27, 2025), <https://tinyurl.com/5x69775u>.

Information (Dec. 30, 2025), at 1, <https://tinyurl.com/2czkqp42>. HHS further threatened that if they did not do so, HHS “will use all authority under the law ... to aggressively pursue any medical organization that participates in” gender-affirming medical care for youth. *Id.* at 2. HHS officials publicly 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 then continued to publicly refer non-compliant hospital groups for investigation by the HHS Office of Inspector General. *See* HHS General Counsel Mike Stuart (@HHSGCMikeStuart), X (Feb. 3, 2026, at 5:25 PM CT), <https://x.com/HHSGCMikeStuart/status/2018828343144010025>.

The Kennedy Declaration has since been found to unlawful, both procedurally and substantively, with the court noting that in issuing the declaration, HHS Secretary Kennedy exhibited an “unserious regard for the rule of law” that, “tragically, ... is one of a long list of examples of how a leader’s wanton disregard for the rule of law causes very real harm to very real people,” and noting that in so doing HHS Secretary Kennedy had “act[ed] with cruelty.” *Oregon v. Kennedy*, No. 6:25-CV-02409-MTK, 2026 WL 1048354, at *1 (D. Or. Apr. 18, 2026). The court thus ultimately held that “[t]he Kennedy Declaration exceeded Defendants’ statutory authority, flouted applicable notice and comment rulemaking procedures, and impeded [States’] rights to regulate the medical profession and their discretion to design their own statutorily-compliant Medicaid plans.” *Id.* at *16-17; *see also id.* at *18 (granting plaintiffs’ motion for injunctive relief and ordering that, “Defendants lack the authority to unilaterally establish standards of care that supersede professionally recognized standards of care for provision of gender-affirming care recognized in the Plaintiff States. Defendants also lack the authority to exclude providers from federal healthcare programs based on their provision of gender-affirming care in a manner and quality consistent with the professionally recognized standards of care in the Plaintiff States.”).

C. The Subpoenas to Healthcare Providers Like RI Hospital Are a Component of DOJ's Implementation of the Administration's Mission to Discriminate Against Transgender People and End Access to Gender-Affirming Medical Care.

The Denial-of-Care EO imposed specific obligations on DOJ to explore legal avenues for limiting or ending the provision of gender-affirming medical care. Attorney General Pam Bondi diligently took on these mandates, with federal law enforcement entities publicly pronouncing their intent to target transgender people and medical care providers. *See, e.g.*, FBI (@FBI), X (June 2, 2025), <https://x.com/FBI/status/1929587710894739567?s=20> (“Help the FBI protect children. 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 at 1-800-CALL-FBI or <http://tips.fbi.gov>.”).

In April 2025, Attorney General 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.’”¹² The Civil Division announced it would do so, issuing a June 2025 memorandum committing to prioritizing these investigations.¹³ The subpoenas followed immediately.

Immediately thereafter, DOJ issued subpoenas to more than twenty healthcare institutions across the country whose care for their patients includes gender-affirming medical care. *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>. Every court to consider these subpoenas has

¹² Off. of Att’y Gen., *Memorandum: Preventing the Mutilation of American Children* (Apr. 22, 2025), <https://www.justice.gov/ag/media/1402396/dl> (“Apr. 22, 2025, Att’y Gen. Memo”).

¹³ Off. of Assistant Att’y Gen., *Memorandum: Civil Division Enforcement Priorities* (June 11, 2025), <https://www.justice.gov/civil/media/1404046/dl>.

determined that they were issued for the improper purpose of “fulfill[ing] the Executive’s well-publicized policy objective to terminate and block gender affirming healthcare.” *In Re 2025 Subpoena to Children’s Nat’l Hosp.*, 2026 WL 160792 at *8; *see also In re Dep’t of Just. Admin. Subpoena No. 25-1431-030*, 2026 WL 33398, at *7 (“government’s . . . true objective [is] pressuring pediatric hospitals into ending gender-affirming care through commencing vague, suspicionless ‘investigations.’”); *In re 2025 UPMC Subpoena*, 2025 WL 3724705, at *2; *In re Admin. Subpoena No. 25-1431-019*, 800 F.Supp.3d 229, 237, 239 (D. Mass. 2025) (subpoena’s “true purpose” is to interfere with “[states’] right to protect GAC within its borders, to harass and intimidate [hospitals] to stop providing such care, and to dissuade patients from seeking such care.”), *appeal docketed*, No. 25-2092 (1st Cir. Nov. 14, 2025); *In re Subpoena No. 25-1431-014*, 810 F.Supp.3d at 583 (DOJ’s asserted concerns “describe policy disagreements about the propriety of medical care,” not a legitimate basis for a subpoena); *QueerDoc, PLLC v. U.S. Dep’t of Justice*, 807 F. Supp. 3d 1295, 1303 (W.D. Wash. 2025) (“No clearer evidence of improper purpose could exist than the Government’s own repeated declarations that it seeks to end the very practice it claims to be merely investigating.”), *appeal docketed*, No. 25-7384 (9th Cir. Nov. 24, 2025); *In re Subpoena Duces Tecum No. 25-1431-016*, 2025 WL 3562151, at *10-11 (true purpose was “to pressure hospitals into ending gender-related care for minors.”).

The Government’s Opposition and the Hsiao Declaration illustrate the subpoenas’ purpose of carrying out the Denial-of-Care EO and the Administration’s broader aims. The Hsiao Declaration filed in connection with this Subpoena mirrors the Bondi memo. *Compare* Apr. 22, 2025, Att’y Gen. Memo at 4 (“the promotion of off-label uses of hormones . . . run afoul of the FDA’s prohibitions on misbranding and mislabeling”) *with* Hsiao Decl. ¶ 22 (“[T]o the extent these drugs are intended to treat gender dysphoria in minors, they constitute unapproved new drugs

under federal law, and their distribution for that unapproved indication violates the FDCA and is a federal crime.”). It also relies on the HHS Report’s erroneous determination that gender-affirming medical care lacks robust evidence to support its efficacy. Hsiao Decl. ¶ 24. Lastly, it attests that the government has committed significant resources to this investigation, including “several veteran, career prosecutors” and FBI “agents and analysts to assist with various field activities and is employing advanced data analytics to identify prescribing, potential off-label promotion, and patterns in reimbursement.” Hsiao Decl. ¶ 45. There can be no plainer evidence that the subpoena to RI Hospital was issued for the improper purpose of fulfilling the Administration’s mission of ending access to gender-affirming medical care as part of its broad attacks on transgender people.

II. DOJ’S UNFOUNDED ALLEGATIONS OF HEALTHCARE OFFENSES AGAINST PROVIDERS LIKE RI HOSPITAL WHO PROVIDE GENDER-AFFIRMING MEDICAL CARE ILLUSTRATE THE SUBPOENA’S IMPROPER PURPOSE.

Not only is the issuance of the subpoena to RI Hospital inextricable from the Administration’s targeting of transgender people and the gender-affirming medical care they need, as well as the providers who prescribe it, but DOJ’s attempts to justify it betray the pretextual nature of its actions. Specifically, the Hsiao Declaration’s unfounded allegation that a physician’s prescription of an approved medication for off-label use constitutes an FDCA violation or other federal healthcare offense shows that the subpoenas are part of a legally meritless fishing expedition designed to end the provision of evidence-based, widely established care, rather than a routine mechanism to collect information reasonably relevant to a genuine investigation. Hsiao Decl. ¶ 22.

And while in its opposition to Plaintiff’s motion, DOJ seems to walk away from the clear statement contained in the Hsiao Declaration DOJ submitted in support of its petition to enforce in the Northern District of Texas by now stating that “Rhode Island Hospital’s potential FDCA

liability in no way depends on physicians merely writing prescriptions for off-label use.” Gov’t Opp. at 19. As explained herein, DOJ cannot explain how unredacted patient records and personal health information (PHI) relates to an investigation purportedly about misbranding and promotion of medications.

Simply put, the lack of foundation for the supposed legal violations DOJ is investigating and DOJ’s ever-changing tactics and statements of purpose undermine their claim that this has always been about a legitimate investigation.

A. Off-label Prescription of Medications as Part of Gender-Affirming Medical Care Does Not Violate the FDCA or Otherwise Constitute a Healthcare Offense.

From the outset of this matter, DOJ has portrayed the alleged violation the Subpoena purported to investigate in terms drawn directly from the DOJ Memos implementing the applicable Executive Orders: “whether off-label promotion and/or unlawful dispensing of puberty blockers and cross-sex hormones for use by minors violated” the FDCA. *See* Bondi Memo. In so doing, the Government wrongfully implied that a doctor who issues an off-label prescription of an otherwise lawful medication violates the FDCA. Through the Hsiao Declaration, DOJ doubled down and expanded upon this theory, misleadingly suggesting that prescribing “off-brand” (*i.e.*, for an “unapproved” use) is either unlawful in itself, or at least is evidence of some other illegal activity: “FDA’s approval of a drug for one or more particular uses does not mean that the drug is safe and effective for unapproved uses, nor does approval mean that the labeling provides adequate directions for unapproved uses. While physicians are permitted to prescribe an FDA-approved drug for an unapproved use, such prescribing may warrant investigation because it may provide evidence of FDCA violations by others. Also, depending on the circumstances, prescribing for unapproved uses can itself involve FDCA violations—for example, where the physician is engaged in the distribution or labeling of an unapproved drug.” Hsiao Decl. ¶ 12.

Contrary to the Government's suggestion, however, 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 by regulating a doctor's practice of medicine. The Act thus does not prohibit doctors from prescribing an FDA-approved drug (say, a chemotherapy drug approved to treat leukemia) for an 'off-label' use (say, treatment of other cancers). 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) (internal citations omitted). Moreover, 18 U.S.C. § 24 defines "Federal health care offenses," but "off-label" prescribing is not enumerated among them.

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 (meaning usage "for some other purpose than that for which it has been approved by the FDA) 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 Supreme 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." *Buckman* at 351. As Beck and Azari noted,

It 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. Even so, the public (and an occasional court) mistakenly presumes that all off-label treatment is investigational or experimental and that physicians therefore should inform their patients of this whenever an off-label use is proposed.

Beck & Azari, *supra*, at 72.¹⁴

Further, the FDA’s own website expressly identifies the medically legitimate and perfectly lawful reasons a doctor might prescribe off-label and makes clear that that providers may exercise their clinical judgment to prescribe a medication for a reason other than that for which the FDA has granted approval:

From the FDA perspective, once the FDA approves a drug, healthcare providers generally may prescribe the drug for an unapproved use when they judge that it is medically appropriate for their patient. You may be asking yourself why your healthcare provider would want to prescribe a drug to treat a disease or medical condition that the drug is not approved for. One reason is that there might not be an approved drug to treat your disease or medical condition. Another is that you may have tried all approved treatments without seeing any benefits. In situations like these, you and your healthcare provider may talk about using an approved drug for an unapproved use to treat your disease or medical condition.¹⁵

DOJ is simply wrong to suggest that off-label prescribing is illegal or evidence of some other unlawful act.

Longstanding medical practice bears this out. Contrary to DOJ’s position, off-label use of medications in pediatric patients is a common practice,”¹⁶ particularly in light of “paediatric drug testing barriers,”¹⁷ including ethical concerns.¹⁸ Off-label use is often necessary to deliver the best evidence-based care.¹⁹ These principles apply equally in the context of gender-affirming medical

¹⁴ See also *United States v. Caronia*, 703 F.3d 149, 153 (2d. Cir 2012); *Chaney v. Heckler*, 718 F.2d 1174, 1180 (D.C. Cir. 1983), *rev’d on other grounds*, 470 U.S. 821 (1985).

¹⁵ FDA, *Understanding Unapproved Use of Approved Drugs “Off Label”* (Feb. 5, 2018), <https://tinyurl.com/pd6ff88v>.

¹⁶ 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/>.

¹⁷ *Paediatric off-label prescribing in the USA*, *Reactions Weekly* 1773, 10 (2019), <https://doi.org/10.1007/s40278-019-68767-y>.

¹⁸ 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>.

¹⁹ 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> (in some circumstances, “a physician’s failure to prescribe the medical product for such an unapproved use can constitute medical malpractice”).

care. The prescription of puberty blockers and hormone therapy to treat an adolescent's gender dysphoria despite the FDA approval of those medications having been for other conditions does not make them "unapproved new drugs." *In Re: Administrative Subpoena* 25-1431-032, No. 4-26MC-006-0, ECF No. 1 (N.D. Tex. Apr. 30, 2026). To the 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). And a lack of labeling should not be confused with a finding of contraindication or unsafety. *Id.* To suggest otherwise is erroneous and contravenes common medical practice.

DOJ's attempt to shoehorn a healthcare provider's entirely lawful practice of exercising their clinical judgment to prescribe FDA-approved medications to treat a patient's gender dysphoria into a violation of the FDCA or other healthcare offense illustrates the subpoena's lack of legitimate purpose. Because RI Hospital's off-label prescribing is plainly authorized, the justification set forth in the Hsiao Declaration submitted in connection with the enforcement of this very Subpoena is pretextual.

B. Informing Patients About the Off-Label Use of Puberty Blockers and Hormone Therapy to Treat Gender Dysphoria Does Not Violate the FDCA or Otherwise Constitute a Healthcare Offense.

Seemingly recognizing that their focus on off-label use in and of itself cannot establish a health care offense, DOJ's opposition focuses on their allegation that the information that RI Hospital provides to its patients regarding gender-affirming medical care constitutes "misbranding" under the FDCA or that RI Hospital may have "violated the FDCA by causing distribution of misbranded drugs." Gov't Opp. at 17. The former was set forth in the Hsiao Declaration as well, alleging "A drug is also misbranded if its labeling is false or misleading in any particular. [sic] 21 U.S.C. § 352(a)." Hsiao Decl. ¶ 14. Hsiao further emphasized that gender-affirming care presents "serious potential for harm." *Id.* at ¶ 31. And DOJ provides no explanation

as to how the PHI and the health records of minor patients relates to the distribution and branding of medications by distributors and manufacturers.

DOJ halfheartedly asserts that “patient medical records can reveal the scope of potential violations, permit identification of billing patterns, provide powerful evidence of intent to misbrand and to conceal violations of federal law by falsely coding diagnoses, identify adverse health outcomes that are directly relevant to prosecutions for healthcare offenses, and generate leads for further investigation.” Gov’t Opp. at 20. But by all accounts, including DOJ’s (Gov’t Opp. at 17), though the present investigation purportedly relates to FDCA violations, DOJ provides no explanation how billing or health outcomes relate to such violations. As such, DOJ’s relevance argument reveals the Subpoena’s true purpose: a fishing expedition meant to chill the provision of gender-affirming medical care for minor adolescents, even in states where it is lawful and protected, like Rhode Island.

DOJ’s continuous shift in tactics²⁰ and the baselessness of its initial argument, as set forth in the declaration it submitted in Texas in relation to this Subpoena, underscore the improper purpose of the Subpoena rather than its legitimacy. 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., In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 240 (3d Cir. 2012) (noting “asymmetry” between doctors and manufacturers in regulation of off-label uses; physicians may lawfully prescribe off-label uses, but FDCA bans manufacturers from marketing such uses to doctors); *UFCW Loc. 1776 v. Eli Lilly & Co.*, 620 F.3d 121, 127 (2d

²⁰ *See* Part II.C., *infra*. One court considering another subpoena noted that 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,” concluding that DOJ’s “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.

Cir. 2010) (“off-label prescriptions are permitted within a physician’s discretion,” while manufacturers are barred from promoting a drug’s off-label uses). As noted *supra*, the FDCA was never intended to interfere with the practice of medicine, 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 overboard interpretation of “misbranding” is similarly nonsensical. Even Attorney General Bondi’s memo from which these subpoenas directly flow only authorizes investigations of potential FDCA violations by drug manufacturers and distributors and not by providers, as DOJ has conceded. In creating out of whole cloth this alleged violation by a physician providing information to patients about an off-label use of FDA-approved medication to treat their gender dysphoria, DOJ cannot claim that the subpoena is legally authorized.

Second, DOJ’s claims that RI Hospital’s representations regarding the risks and benefits of gender-affirming medical care are “potentially false and misleading” flow directly from the Administration’s campaign against this care rather than from science or research. Despite that these treatments have long been recognized by the medical establishment 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), the Hsiao Declaration and DOJ’s petition reflect the Administration’s opposition of gender-affirming medical care in their portrayal of RI Hospital’s assessments in this light. Hsiao Decl. ¶ 22-24.

Specifically, DOJ points to one government source for their position that “these interventions are untested, unsafe, unnecessary, and unethical,” both of which were created as a result or in implementation of the Denial-of-Care EO’s mandates to undermine longstanding recognition of the medical necessity of these treatments and to use every tool available to end the provision of gender-affirming medical care. Denial-of-Care EO, §§ 1, 3, 5. The DOJ relies on the HHS Report, claiming that it alone “determined that that the evidence for the safety and efficacy of these drugs for the treatment of gender dysphoria in minors is weak;” that they “carry risk of significant harms” and “regret;” and that the quality of evidence supporting their use is “very low.” Hsiao Decl. ¶ 24. But, as discussed supra, this Report, with a predetermined outcome, is highly flawed.

C. DOJ’s Gamesmanship Bolsters the Illegitimacy of its Issuance and Enforcement of the Subpoena to RI Hospital.

The gamesmanship in DOJ’s litigation tactics also undercuts the alleged legitimate purposes underlying the subpoena, highlighting that they are pretext for the Administration’s discriminatory targeting of transgender people and their medical providers. DOJ has engaged in two kinds of gamesmanship as it has attempted to effectuate these subpoenas. First, DOJ’s evolving explanations for the alleged legitimacy of its fishing expeditions against providers of gender-affirming medical care show that they are post-hoc and pretextual. Second, DOJ’s attempt to enforce this subpoena in the Northern District of Texas despite that forum utterly lacking jurisdiction over RI Hospital or any nexus to the information sought through the subpoena further underscores the illegitimacy of DOJ’s effectuation of the Trump Administration’s campaign against transgender people and gender affirming medical care.

In its earliest attempts to defend a subpoena like the one received by RI Hospital, DOJ first took the position that the subpoenas related to an investigation of providers’ promotion and

prescription of puberty blockers and hormone therapy for the off-label use of treating gender dysphoria. *See* Resp. in Opp’n to Mot. to Quash, *In re: Administrative Subpoena No. 25-1431-019*, 800 F.Supp.3d 229 (D. Mass. 2025) (No. 25-mc-91324-MJJ), ECF No. 21. After the district court granted Boston Children’s Hospital’s motion to quash that subpoena, concluding both that DOJ had failed to show a proper purpose for the investigation in simply asserting that “BCH is an acknowledged provider of the type of health care services under investigation,” and that the subpoena was really issued for improper purposes, *In re: Administrative Subpoena No. 25-1431-019*, 800 F.Supp.3d at 237-39, DOJ changed its tune (as it has here). In seeking to alter that judgment, DOJ sought to justify the subpoena’s legitimacy in investigating false billing codes and “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*, 800 F.Supp.3d 229 (No. 25-mc-91324-MJJ), (D. Mass. filed Oct. 7, 2025) ECF No. 36.

DOJ did a similar about-face in attempting to defend the nearly identical subpoena to QueerDoc, initially framing it as simply an effectuation of the Bondi and Shumate Memos, Gov’t Opp’n to Mot. to Seal Docket, *QueerDoc, PLLC, v. U.S. Dep’t of Justice*, Case No. 2:25-mc-00042 (W.D. Wash. filed July 17, 2025) (ECF No. 8), two months later as investigating the mere prescription of a drug for off-label use, *see* Gov’t’s Praecept to file Additional Document, *QueerDoc, PLLC, v. U.S. Dep’t of Justice*, Case No. 2:25-mc-00042 (W.D. Wash. filed Sept. 26, 2025) (ECF No. 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 No. 25.1. DOJ’s justifications continued to diverge across the cases seeking to

quash these nearly identical subpoenas, offering an investigation into “the distribution, promotion, and sale of puberty blockers and cross-sex hormones in minors for the treatment of gender dysphoria—uses that the FDA has never approved and that raise grave safety concerns” in its Response in Opposition to the Motion to Quash in *In re 2025 Subpoena To Children’s National Hospital*, 800 F.Supp.3d 229 (Case No. 25-cv-03780-JRR), (D. Md. filed Dec. 15, 2025) (ECF No. 15, and into “off-label promotion and/or unlawful dispensing of puberty blockers and sex hormones for use by minors” in the Hsiao Declaration filed with its Response in Opposition to the Motion to Quash in *In re Dep’t of Justice Admin. Subpoena No. 25-1431-030*, Case No. 1:25-mc-00063 (D. Colo. filed Aug. 29, 2025) (ECF No. 10-1).

And now they have offered that this subpoena to RI Hospital is part of an investigation into “on- or off-label use by manufacturers and distributors of drugs, including puberty blockers and sex hormones, or any other drug used to facilitate a child’s so-called ‘gender transition.’” Hsiao Decl., *In Re: Administrative Subpoena 25-1431-032*, No. 4-26MC-006-0 (N.D. Tex. Apr. 30, 2026) (ECF No. 1-3). DOJ also offers that it is investigating both RI Hospital itself and manufacturers or distributors, and is also looking at false billing codes, misbranding, off-label promotion, and monitoring patients’ health outcomes, Gov’t Opp. at 17—a veritable buffet of the different investigations alleged to support the proper purposes of these subpoenas.

Rather than bolstering the proper purpose of the subpoena to RI Hospital, these changing justifications show that none of the proffered “legitimate” bases are real. They are pretext, “put forward to conceal a true purpose or object.” *Ronda-Perez v. Banco Bilbao Vizcaya Argentaria--Puerto Rico*, 404 F.3d 42, 45 (1st Cir. 2005). 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). These “inconsistent, ever-shifting arguments resemble bad faith ‘gamesmanship.’” *Gryglak v. HSBC Bank USA, N.A.*, 2023 WL 3243998, at *3 (9th Cir. May 4, 2023).

As other courts have held, “DOJ issued the subpoena[s] first, and searched for a justification second.” *QueerDoc, PLLC*, 807 F.Supp.3d at 1303. Such post hoc rationalizations are simply pretextual, supporting the conclusion that the actual motive was improper. *See Mariani Giron v. Acevedo Ruiz*, 834 F.2d 238, 239 (1st Cir. 1987); *see also Santiago-Ramos v. Centennial P.R. Wireless Corp.*, 217 F.3d 46, 56 (1st Cir. 2000) (showing that a litigant’s alleged proper purposes “were after-the-fact justifications, provided subsequent to the beginning of legal action” establishes pretext).

Additionally, DOJ’s attempt to enforce its subpoena in a jurisdiction that has a) no personal jurisdiction over, b) no connection to the subpoena issued to, and c) no connection to the information sought from RI Hospital further illustrates DOJ’s bad faith targeting of providers of gender-affirming medical care at all costs. After a wave of district court rulings quashing or limiting these nearly identical subpoenas because of their improper purpose, *see supra*, and despite RI Hospital’s ongoing engagement with DOJ since receipt of the subpoena in July 2025, *see* Emergency Mot. to Stay Pending Appeal, *In re Administrative Subpoena 25-1431-032*, No. 4:26-MC-0006-O (N.D. Tex. filed May 6, 2026), ECF No. 7, DOJ sought out what it considered to be a more hospitable forum to enforce the RI Hospital subpoena. It did so despite a total lack of any nexus between this subpoena, RI Hospital, and that jurisdiction, *see id.*, perhaps based on that district’s jurisprudence rejecting protections for transgender people. *See, e.g., Texas v. Cardona*, 743 F. Supp. 3d 824 (N.D. Tex. 2024); *Carroll Indep. Sch. Dist. v. U.S. Dep’t of Educ.*, 741 F.Supp.3d 515 (N.D. Tex. 2024); *Franciscan All., Inc. v. Burwell*, 227 F.Supp.3d 660 (N.D. Tex.

2016).²¹ Indeed, the subpoenas were issued by DOJ attorneys in Washington, DC and, as attorneys representing another hospital have noted, all the “calls and meetings were attended exclusively by attorneys at Main Justice.” Br. in support of Mot. to Confirm Jurisdiction, *In re Subpoena No. 25-1431-014*, No. MC 25-39 (E.D. Pa. filed May 6, 2026) (ECF No 47-1), at 1-2. Indeed, it appears that no attorney for any United States Attorney’s Office, including the Northern District of Texas, has participated in meetings or calls pertaining to the subpoenas at issue. *Id.*

“[F]orum-shopping is a concern where parties purposely file an action in a district with improper venue simply to take advantage of the forum’s” more favorable law, procedure, or approach to the party’s interests. *Lafferty v. St. Riel*, 495 F.3d 72, 78 (3d Cir. 2007) (cleaned up). “[W]hen a litigant is playing fast and loose with the courts,” and when such gamesmanship “is being used as a means of obtaining unfair advantage,” *Patriot Cinemas, Inc. v. Gen. Cinemas Corp.*, 834 F.2d 208, 212 (1st Cir. 1987), those efforts should be seen as bad faith, underscoring DOJ’s improper motivations and tactics in targeting providers of gender-affirming medical care. *See Realtime Adaptive Streaming LLC v. Netflix, Inc.*, 41 F.4th 1372, 1379–80 (Fed. Cir. 2022) (when a litigant “impermissibly and unjustifiably engaged in forum-shopping in attempt to avoid or delay an adverse ruling,” such “blatant gamesmanship ... constitutes a willful action for an improper purpose, tantamount to bad faith.”) (cleaned up); *RainSoft v. MacFarland*, 350 F. Supp. 3d 49, 56 n.4 (D.R.I. 2018) (Court will not tolerate the types of gamesmanship procedural rules are designed to prevent). At the end of the day, these bad faith actions reflect DOJ’s “playing fast and loose” regarding this subpoena, starting with its issuance.

²¹ Thus far, DOJ’s gambit has paid off, with that court granting DOJ’s motion to enforce within hours of its filing and without providing RI Hospital with any opportunity to respond, whether to challenge that court’s jurisdiction or venue or to address the unlawfulness of the subpoena. *See Order, In re Administrative Subpoena 25-1431-032*, No. 4:26-MC-0006-O (N.D. Tex. filed Apr. 30, 2026), ECF No. 2. RI Hospital has now filed an appeal and sought a stay pending appeal of the enforcement order. *See Emergency Mot. to Stay Pending Appeal, In re Administrative Subpoena 25-1431-032*, No. 4:26-MC-0006-O (N.D. Tex. filed May 6, 2026), ECF No. 7.

CONCLUSION

In light of the inextricable throughline from the Administration’s discriminatory targeting of transgender people to the Subpoena and that DOJ’s baseless claims of RI Hospital’s purported wrongdoing do not actually allege violations of the FDCA or otherwise constitute healthcare offenses, the Court should recognize the subpoena for what it is: 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, PLLC*, 807 F.Supp.3d at 1304.

The Administration’s disdain for transgender people and the gender-affirming medical care that enables them to live authentically cannot legitimize the use of DOJ’s subpoena authority to bully law-abiding doctors into conforming to its policy preferences or expose patients’ deeply personal medical information. This Court should grant the Motion to Quash.

Respectfully submitted,

Dated: May 8, 2026

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CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system on May 9, 2026. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

s/ Sonja L Deyoe