NO. 25-7384

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

QUEERDOC, PLLC,

Movant-Appellee,

v.

U.S. DEPARTMENT OF JUSTICE,

Respondent-Appellant.

On Appeal from the U.S. District Court for the Western District of Washington
No. 2:25-MC-00042-JNW
The Honorable Jamal N. Whitehead, U.S. District Court Judge

BRIEF OF AMICI CURIAE WASHINGTON, MASSACHUSETTS, ARIZONA, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, ILLINOIS, MAINE, MARYLAND, MICHIGAN, MINNESOTA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, OREGON, RHODE ISLAND, VERMONT, AND WISCONSIN IN SUPPORT OF MOVANT-APPELLEE QUEERDOC, PLLC

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I. INTRODUCTION AND STATEMENT OF INTERESTS

Washington, Massachusetts, Arizona, California, Colorado, Connecticut, Delaware, the District of Columbia, Illinois, Maine Maryland, Michigan, Minnesota, Nevada, New Jersey, New Mexico, New York, Oregon, Rhode Island, Vermont, and Wisconsin (Amici States) submit this brief in support of Movant-Appellee QueerDoc. Many Amici States are home to medical providers and hospitals who have been targeted by the Department of Justice's sweeping subpoenas based on their provision of lawful transgender health care to young people. In addition to QueerDoc, subpoena recipients in Amici States include Seattle Children's Hospital, Boston Children's Hospital, Children's Hospital Colorado, Children's National Hospital, Children's Hospital of Philadelphia, and the University of Pittsburgh Medical Center. These providers and hospitals provide essential medical care to tens of thousands of people every year, including medically necessary transgender health care to individuals under the age of 19, and that essential medical care is expressly protected by law in many Amici States.

The district court properly quashed the subpoena because it is pretextual and seeks to intimidate medical providers from offering critical, medically necessary health care to transgender youth—one of the most vulnerable populations in Amici States. Indeed, the subpoena places medical providers and hospital administrators in the crosshairs of civil and criminal enforcement, including prosecution, merely for

providing lawful medical care. DOJ's baseless attempt to sweep the routine prescription and administration of medications for off-label use into federal criminal prohibitions in pursuit of its stated goal of "ending" transgender health care will cause profound disruptions across the entire medical field.

Amici have strong interests in regulating the practice of medicine in their jurisdictions, including by licensing doctors and other medical professionals; implementing standards of care for a wide variety of medical procedures and treatments; and enforcing those standards and other related regulations. In this realm, many Amici States have enacted laws safeguarding access to transgender health care and protecting practitioners who lawfully provide or help others access such care. In many Amici States' experience, these laws are necessary to protect the health and well-being of our communities and to uphold the rights and dignity of our transgender residents.

In its opening brief, DOJ attempts to justify its invasion of this traditional sphere of state regulation by pointing to the federal Food, Drug, and Cosmetic Act (FDCA), but its interpretation of that statute is exceedingly broad, disruptive, and untethered to precedent and practice. DOJ's interpretation conflicts with decades of settled precedent concerning medical providers' *use* of approved medications for off-label purposes—something that the law has never been understood to reach. Moreover, DOJ's suggestion here—that the FDCA's prohibitions concerning the

misbranding and mislabeling of drugs should be applied to the provision of routine medical care and to standard communications between doctors and patients—would impose potential criminal liability on a sweeping array of health care practitioners. DOJ offers no limiting principle to its argument; if DOJ's interpretation of the FDCA were accepted, entire fields of medicine could see their practitioners at risk of criminal conviction merely for offering evidence-based treatments in accordance with the prevailing standards of care. If QueerDoc were forced to comply with this unlawful subpoena, such a directive would threaten the health and welfare of the people of Washington and other Amici States, and intrude on Amici States' traditional role as the regulators of medicine.

Finally, DOJ defends its sweeping investigation by arguing that it has carte blanche to choose targets for investigation based solely on their provision of transgender health care, which remains lawful conduct under state and federal law. This argument should be rejected. Controlling U.S. Supreme Court precedent requires this Court to conduct an inquiry into DOJ's motivations for issuing administrative subpoenas and to quash them when, as here, they are principally motivated to coerce targets to cease lawful activity.

For the reasons advanced below and by QueerDoc, this Court should affirm the district court's order quashing the subpoena.

II. ARGUMENT

A. DOJ Seeks to Interfere with Amici States' Authority to Regulate the Practice of Medicine

As sovereigns of their respective territories, States reserve the power to provide for the health, welfare, safety, and security of the people. *See Metro. Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 756 (1985); *see also Hillsborough Cnty., Fla. v. Automated Med. Lab'ys, Inc.*, 471 U.S. 707, 719 (1985); *Linder v. United States*, 268 U.S. 5, 18 (1925). Accordingly, and to avoid encroaching on the practice of medicine, both the Supreme Court and federal agencies, including the Food and Drug Administration (FDA), have historically recognized that the FDCA does not reach the *use* of off-label medications. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001); *see also, e.g.*, Notice of Proposed Rulemaking, *Legal Status of Approved Labeling for Prescription Drugs; Prescribing for Uses Unapproved by the Food and Drug Administration*, 37 Fed. Reg. 16503, 16503 (Aug. 15, 1972). The subpoena in this case—like others recently issued by DOJ—threatens to upend these fundamental principles.

The Tenth Amendment reserves for the States all rights and powers "not delegated to the United States" federal government. U.S. Const. amend. X. Commonly referred to as "traditional state police powers," the rights and powers of the States include the "powers to protect the health and safety of their citizens." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996); *see also Slaughter-House Cases*,

83 U.S. 36, 62 (1872) (describing the police power as extending "to the protection of the lives, limbs, health, comfort, and quiet of all persons . . . within the State"). States have long exercised authority to regulate the practice of medicine. *See Dent v. West Virginia*, 129 U.S. 114, 122 (1889) (states have discretion to set medical licensing requirements as they have done since "time immemorial"). Though Congress may legislate to regulate interstate activities, the Executive may not interpret statutes to invent novel forms of criminal activity in order to disrupt a State's medical regulatory framework. *See Gonzales v. Oregon*, 546 U.S. 243, 269-70 (2006) (holding that the Controlled Substances Act did not prohibit Oregon doctors from prescribing medication for the purpose of medical aid in dying, where such care had been enacted through ballot measure). Courts have upheld a broad set of "state medical practice laws against constitutional challenges, making clear that states are generally authorized to legislate in the medical practice area."[1]

States have exercised their power to regulate medicine in various ways. Perhaps most significantly, states regulate the practice of medicine by defining the

[1] Patricia J. Zettler, *Toward Coherent Federal Oversight of Medicine*, 52 San Diego L. Rev. 427, 448 (2015); *see also Hillsborough Cnty.*, 471 U.S. at 719 ("the regulation of health and safety matters is primarily, and historically, a matter of local concern"); *Watson v. Maryland*, 218 U.S. 173, 176 (1910) (the police power of the states extends to the regulation of certain trades and callings, particularly those which closely concern the public health" and discussing licensing of medical practitioners); *Buckman*, 531 U.S. at 348 (identifying "historic primacy of state regulation of matters of health and safety").

scope and contours of medical practice and requiring medical licenses for practitioners.[2] Since 1895, all states have boards that oversee the licensing of medical professionals practicing in their respective jurisdictions.[3] Fundamental and consistent requirements for obtaining a medical license across states include graduation from an accredited medical school, completing one or more years of residency or fellowship, and passing a licensing examination.[4] Additional requirements may include interviews, a documented lack of criminal history, and medical malpractice insurance coverage.[5] States, through their legislatures and regulatory boards, also regulate medical practice by disciplining licensees who act illegally or unethically and by "enact[ing] laws and regulations that directly circumscribe how licensed practitioners conduct medical practice," such as reporting, disclosure, and timeframe rules.[6]

States have also exercised their police powers to protect vulnerable groups against discrimination and ensure equal access to critical health care. Consistent with state policy judgments about protecting minority populations and prohibiting

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[2] Zettler, *supra* note 1, at 449-50 n.127 (stating that the "cornerstone" of medical practice regulation is states' licensing schemes).

[3] Robert C. Derbyshire, Medical Licensure and Discipline in the United States 8 (1969); Zettler, *supra* note 1, at 450; *see also* Federation of State Medical Boards, *Contact a State Medical Board (n.d.)*, https://www.fsmb.org/contact-a-state-medical-board.

[4] Zettler, *supra* note 1, at 450.

[5] *Id.*

[6] *Id.* at 450-52.

discrimination, many Amici States have enacted civil rights protections for transgender people in education, employment, health care, housing, public accommodations, and other parts of public life.[7] They have also taken specific steps to safeguard access to medical care for transgender people, exercising their sovereign judgment that such safeguards promote public health and wellbeing. For instance, Washington, Massachusetts, and many other Amici States expressly recognize a legal right to transgender health care and have enacted laws intended to protect patients and practitioners in their States who access, provide, or assist with the provision of that care from civil or criminal penalties by out-of-state jurisdictions that outlaw it.[8] Some State licensing boards also instruct licensees that they shall not

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[7] *See, e.g.*, Wash. Rev. Code §§49.60.030(1), 49.60.040(2), 49.60.040(29), 49.60.215; Mass. Gen. Laws ch. 151B, § 4; Mass. Gen. Laws ch. 272, §§92A, 98; Cal. Civ. Code §§51(b), 51(e)(5); Cal. Gov't Code §§12940(a), 12955; Conn. Gen. Stat. §§10-15c, 46a-58 *et seq.*; Del. Code Ann. tit. 6, ch. 45 & 46; Del. Code Ann. tit. 19, ch. 7; D.C. Code §2-1401.01 *et seq.*; Haw. Rev. Stat. §§368-1, 378-2, 489-3, 515-3; 775 Ill. Comp. Stat. 5/1-102(A), 5/1-103(O-1), 5/1-103(Q); Me. Stat. tit. 5, §4551 *et seq.*; Md. Code Ann., State Gov't §§20-606, 20-705; Md. Code Ann., Educ. §26-704; Minn. Stat. §§363A.03, subd. 50; 363A.01 *et seq.*; Nev. Rev. Stat. §§118.100, 284.150(3), 439.994, 449.101(1), 613.330; N.J. Stat. Ann. §§10:5-1 *et seq.*, 17:48-6oo, 18A:36-41; N.Y. Exec. Law §§296, 296-a, 296-b; N.Y. Civil Rights Law §40-c; N.Y. Comp. Codes R. & Regs. tit. 9, §466.13; Or. Rev. Stat. §§659A.006, 659A.030, 659A.403, 659A.421; R.I. Gen. Laws §§11-24-2, 23-17-19, 28-5-5, 28-5.1-12, 28-6-18, 34-37-2, 34-37-4, 34-37-4.3, 34-37-5.2, 34-37-5.3, 34-37-5.4; Vt. Stat. Ann. tit. 9, §§4502, 4503; Vt. Stat. Ann. tit. 21, §495.

[8] *See, e.g.*, Wash. Rev. Code ch. 7.115 *et seq.*; Mass. Gen. Laws ch. 12, §11I1/2(b)-(d); Mass. Gen. Laws ch. 147, §63; Mass. Gen. Laws ch. 276, §13; Cal. Civ. Code §56.109; Colo. Rev. Stat. §§10-16-121(1)(f), 12-30-121, 13-21-133, 16-3-102, 16-3-301; Conn. Gen. Stat. §§19a-17e, 52-146w, 52-146x, 52-571m, 52-571n, 54-155b; 735 Ill. Comp. Stat. 40/28-5, *et seq.*; Me. Stat. tit. 14, §9001, *et seq.*;

withhold or deny care based on a patient's gender identity.[9] Many Amici also cover treatments for gender dysphoria care through their State Medicaid programs,[10] and they prohibit State-regulated health insurance plans from withholding coverage from individuals based on their gender identity or gender dysphoria, thereby ensuring that transgender residents enjoy the same coverage for medically necessary treatment as residents who are not transgender.[11]

Me. Stat. tit. 22, §1508; Md. Code Ann., State Pers. & Pens. §2-312; Minn. Stat. §260.925; N.Y. Exec. Law §837-x; N.Y. Comp. Codes R. & Regs. tit. 10, §405.7(c)(2); Or. Rev. Stat. §§15.430, 24.500, 414.769, 435.210, 435.240; Vt. Stat. Ann. tit. 12, §7301 *et seq*.; N.J. Admin. Code Exec. Order No. 326 (2023).

[9] *See* 244 Code Mass. Regs. §9.03(13); Mass. Bd. of Reg. in Medicine Policy 16-01, *available at* https://www.mass.gov/lists/physician-regulations-policies-and-guidelines.

[10] *See, e.g.*, Wash. Rev. Code §74.09.700; Ill. Admin. Code tit. 89, §§140.413(a)(16), 140.440(h); Md. Code Ann., Health-Gen. §15-151; Gender-Affirming Care Covered by MassHealth, https://www.mass.gov/info-details/gender-affirming-care-covered-by-masshealth; Minn. Stat. §256B.0625, subd. 3a; Nev. Medicaid Servs. Manual § 608, *available at* https://dhcfp.nv.gov/uploadedFiles/dhcfpnvgov/content/Resources/AdminSupport/Manuals/MSM/C600/MSM_600_25-07-30.pdf; R.I. Gender Dysphoria/Gender Nonconformity Coverage Guidelines (Oct. 28, 2015), *available at* https://eohhs.ri.gov/sites/g/files/xkgbur226/files/Portals/0/Uploads/Documents/MA-Providers/MA-Reference-Guides/Physician/gender_dysphoria.pdf.

[11] *See, e.g.*, Wash. Rev. Code §74.09.675; Cal. Code Regs. tit. 10 §2561.2, subd. (a); Colo. Code Regs. §3-702-4, Colo. Code Regs. §4-2-42, 5(A)(1)(o); Del. Code Ann. tit. 18, §2304; 215 Ill. Comp. Stat. 5/356z.60(b); Ill. Admin. Code tit. 50, §2603.35; Me. Stat. tit. 22, §3174-MMM; Md. Code Ann., Ins. §15-1A-22; Mass. Gen. Laws ch. 272, §§92A, 98; Minn. Stat. §62Q.585; N.J. Stat. Ann. §17:48-6oo; N.Y. Comp. Codes R. & Regs. tit. 11, §52.75; Or. Admin. R. 836-053-0441; Vt. Stat. Ann. tit. 8, §§4724, 4088m; Mass. Div. of Ins. Bulls. 2021-11, 2014-03, *available at* https://www.mass.gov/lists/doi-bulletins; R.I. Health Ins. Bull. 2015-03, *available at* https://ohic.ri.gov/sites/g/files/xkgbur736/files/bulletins/Bulletin-2015-3-Guidance-Regarding-Prohibited-Discrimination.pdf.

Similarly, many Amici States have enacted laws that explicitly protect medical providers of transgender health care who act consistent with standards of care from malpractice liability or findings of professional misconduct.[12] Other Amici States, meanwhile, mandate training for health care professionals on trans-inclusive care.[13] Taken together, the above laws and policies reflect Amici States' commitment to preserving the integrity of the medical profession, protecting the equality of all people, and ensuring that people with gender dysphoria are not denied medically necessary health care within Amici States.

Despite no federal law prohibiting medical care to treat gender dysphoria, the clear purpose of DOJ's subpoena to QueerDoc is to "end" gender-affirming care for transgender adolescents in Amici States consistent with the President's Executive Order.[14] *See* Exec. Order 14,187, 90 Fed. Reg. 8771 (Jan. 28, 2025) (cited as

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[12] *See, e.g.*, Wash. Rev. Code §18.130.450; Wash. Rev. Code ch. 7.115; Cal. Bus. & Prof. Code §§850.1, 852, 2253, 2761.1; Conn. Gen. Stat. §§19a-17e, 20-579a, 52-571m; Colo. Rev. Stat. §12-30-121; Mass. Gen. Laws ch. 112, §§5F1/2, 77, 128; Md. Code Ann., Health Occ. §1-227; N.Y. Educ. Law §6531-b; Or. Rev. Stat. §§675.070, 675.540, 675.745, 677.190, 678.138, 685.110, 689.405; 225 Ill. Comp. Stat. 60/22(C). Relatedly, some Amicus States bar medical malpractice insurers from discriminating against medical professionals solely because they provide gender-affirming care. *See, e.g.*, Colo. Rev. Stat. §10-4-109.6(1); Or. Rev. Stat. §676.313.

[13] *See, e.g.*, Cal. Ins. Code §10133.13.

[14] This Executive Order is one of many orders targeting transgender people. On the first day of his second term in office, President Trump issued Executive Order 14,168, which declares that gender identity is a "false" idea and that the United States only recognizes "two sexes, male and female" which are "not changeable." Exec. Order 14,168, 90 Fed. Reg. 8615 (Jan. 20, 2025). "The Administration has

E.O. 14,187) (declaring gender-affirming medical care "a stain on our Nation's history" that "must end"); ER-048, 053 (memo from AG Bondi directing DOJ to bring "the unconscionable ideology behind 'gender-affirming care,'"—described as "a radical ideological agenda" used "to justify the barbaric practice of surgically and chemically maiming and sterilizing children"—"to an end"). DOJ has issued more than 20 subpoenas to providers and hospitals across the country, making sweeping requests for sensitive information—including records of all patients who have received a particular type of medical care.[15] These actions represent a radical departure from DOJ's prior practice and make express the policy goal of the Executive Branch to harm a politically disfavored minority. *See id.*; *see also* ER-008 (order quoting statement by Attorney General Bondi that "[m]edical professionals and organizations that mutilated children in the service of a warped ideology will be held accountable by this Department of Justice").

The federal government's crusade to force a nationwide ban on transgender health care for adolescents further escalated last month, when the Secretary of Health

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issued several other executive orders prohibiting transgender individuals from serving in the military, eliminating federal funding from schools that support 'gender ideology,' and banning transgender women and girls from competing in sports aligned with their gender identity." *In re Admin. Subpoena No. 25-1431-019*, 800 F. Supp. 3d 229, 233 (D. Mass. 2025).

[15] Press Release, Department of Justice Subpoenas Doctors and Clinics Involved in Performing Transgender Medical Procedures on Children (July 9, 2025), https://www.justice.gov/opa/pr/department-justice-subpoenas-doctors-and-clinics-involved-performing-transgender-medical.

and Human Services (HHS), without prior notice or statutory authority, posted on HHS's website an unprecedented "declaration" purporting to declare that transgender health care for youth is "neither safe nor effective as a treatment modality."[16] Significantly, the declaration deems the provision of this care constitutes a "fail[ure] to meet professionally recognized standards of health care[,]" and that providers of such care may be referred to HHS's Office of the Inspector General (OIG) for exclusion from federal health care programs, including Medicare and Medicaid. *Id.*; *see* 42 U.S.C. § 1320a-7(b)(6). The Secretary issued this declaration despite, and in contravention of, Congress's prohibition of the "supervision or control over the practice of medicine" by "any Federal officer." 42 U.S.C. § 1395. Multiple providers in some Amici States—including some of the same children's hospitals who have had their subpoenas from DOJ quashed—have been referred to HHS OIG for providing transgender health care, even though providing such care is legal and protected in these Amici States.[17] Secretary

[16] Declaration of the Secretary of the Department of Health and Human Services re: Safety, Effectiveness, and Professional Standards of Care for Sex Rejecting Procedures on Children and Adolescent (Dec. 18, 2025), available at https://www.hhs.gov/sites/default/files/declaration-pediatric-sex-rejecting-procedures.pdf.

[17] *See, e.g.*, HHS (@hhsgov), X (Dec. 26, 2025, at 11:47 a.m. ET), https://x.com/HHSGov/status/2004640322580578440 (referring Seattle Children's Hospital "to @OIGatHHS for failure to meet professional recognized standards of health care as according to Secretary Kennedy's declaration"); HHS General Counsel Mike Stuart (@HHSGCMikeStuart), X (Dec. 30, 2025, at 4:08 p.m. ET), https://x.com/HHSGCMikeStuart/status/2006110061114851333 (referring

Kennedy's declaration, like the DOJ subpoenas, represents another attempt by the executive branch to unilaterally and unlawfully alter medical standards by fiat.[18]

As reflected in these unrelenting attacks by the federal government on lawful transgender health care, the subpoena to QueerDoc has nothing at all to do with promoting the rule of law. Rather, this extraordinary overreach is an attempt to "end" transgender health care, E.O. 14,187, by subverting the policy and judgment of the states as the traditional regulators of the practice of medicine. As another court explained in quashing a nearly identical subpoena, "[i]t is abundantly clear that the true purpose of issuing the subpoena is to interfere with [states'] right to protect [gender-affirming care] within its borders, to harass and intimidate [providers] to stop providing such care, and to dissuade patients from seeking such care." *In re Admin. Subpoena No. 25-1431-019*, 800 F. Supp. 3d at 239 (quashing subpoena to Boston Children's Hospital); *see also In re 2025 UPMC Subpoena*, No. 2:25-MC-01069-CB, 2025 WL 3724705, at *2 (W.D. Pa. Dec. 24, 2025) (finding that "the United States's investigation tramples the Commonwealth of Pennsylvania's power to police, and legislate, matters of medical care"). The same invidious and unlawful

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Children's Hospital Colorado); HHS General Counsel Mike Stuart (@HHSGCMikeStuart), X (Jan. 15, 2026, at 3:40 p.m. ET), https://x.com/HHSGCMikeStuart/status/2011946547005833419 (referring six additional hospitals, including Boston Children's Hospital).

[18] Amici States have challenged Secretary Kennedy's declaration as unlawful. *See Oregon v. Kennedy*, No. 6:25-cv-02409-MTK (D. Or.) (filed Dec. 23, 2025).

purpose is evident in the identical subpoenas served in Washington and other Amici States. The broadside attack by DOJ on transgender health care undermines the Amici States' sovereign authority in regulating the practice of medicine within our borders and protecting the health and safety of our residents.

B. DOJ Adopts an Overly Expansive—and Unprecedented—Interpretation of the FDCA

DOJ purports to justify its subpoena through a novel and unreasonable interpretation of the FDCA. Contrary to established practice and precedent, DOJ "seeks to transform Congress's regulation of the manufacture, distribution, and labeling of drugs into a vehicle for federal oversight of how physicians diagnose, treat, and counsel child patients." *In re Subpoena No. 25-1431-014*, --- F. Supp. 3d ----, No. MC 25-39, 2025 WL 3252648, at *17 (E.D. Pa. Nov. 21, 2025); *see also Ass'n of Am. Physicians & Surgeons v. U.S. Food & Drug Admin.*, 13 F.4th 531, 534 (6th Cir. 2021) ("Although the Act regulates a manufacturer's distribution of drugs, it does not go further by regulating a doctor's practice of medicine.") (citing *Buckman*, 531 U.S. at 350-51). DOJ's interpretation transforms the statute by sweeping into the statute's prohibitions on distributing misbranded or adulterated drugs, *see* 21 U.S.C. § 331(a), (d), the routine prescribing and dispensing of FDA-approved drugs for off-label purposes by licensed providers, including when accompanied by written communication between providers and their patients about those drugs. Long-settled law holds that the FDCA does not touch these elements of

medical practices or the doctor-patient relationship. The implications of DOJ's reading are thus enormous: Far from being limited to the narrow space of transgender health care, DOJ's interpretation of the FDCA would have widespread and disastrous implications across medicine (with particularly significant harms in some critical areas of care, such as pediatrics and oncology, where off-label use is especially prevalent) and could actively discourage open communication between health care providers and their patients about the medications they receive.

1. Off-label use of approved drugs where medically appropriate is permissible under the FDCA

As part of its regulatory authority, the FDA may approve prescription drugs to be marketed and labeled for certain uses. Within the FDA, the Center for Drug Evaluation and Research (CDER) evaluates prescription drugs' safety and efficacy through premarket approval.[19]

The process by which the FDA approves drugs for particular indications is "not intended to limit or interfere with the practice of medicine nor to preclude physicians from using their best judgment in the interest of the patient" and instead "is intended to ensure that drugs meet certain statutory standards for safety and effectiveness, manufacturing and controls, and labeling[.]" *Weaver v. Reagen*, 886 F.2d 194, 198 (8th Cir. 1989). Consequently, it is well-settled that "[a]s a general

[19] Ryan Abbott & Ian Ayres, *Evidence and Extrapolation: Mechanisms for Regulating Off-Label Uses of Drugs and Devices*, 64 Duke L.J. 377, 383 (2014).

matter, once a drug is approved, physicians may *prescribe* the drug without restriction."[20] The FDA itself has repeatedly made public statements to this effect,[21] including as recently as last year,[22] and its own website specifically says that once the agency "approves a drug, health care providers generally may prescribe the drug for an unapproved use when they judge that it is medically appropriate for their patient."[23] Courts also routinely recognize that the FDCA permits doctors to

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[20] Abbott & Ayres, *supra* note 19, at 387; *see also Buckman*, 531 U.S. at 350 (explaining that "off-label" use of medical devices "is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine").

[21] *See, e.g.*, Abbott & Ayres, *supra* note 19, at 387-88 n.32 (quoting *Promotion of Unapproved Drugs and Medical Devices, Testimony Before the S. Comm. on Labor and Human Res.*, 104th Cong. (1996) (statement of William B. Schultz, Deputy Comm'r for Policy, Food & Drug Admin.) ("The legislative history of the Federal Food, Drug, and Cosmetic Act indicates that Congress did not intend FDA to interfere with the practice of medicine. Thus, once a drug is approved for marketing, FDA does not generally regulate how, and for what uses, physicians prescribe that drug."); FDA, *Final Guidance Document*, *Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices Guidance for Industry* 3 (Jan. 2009) ("[O]ff-label uses or treatment regimens may be important and may even constitute a medically recognized standard of care.").

[22] *See* FDA, *Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products; Questions and Answers; Guidance for Industry* 8-9 (Jan. 2025), https://www.fda.gov/media/184871/download (acknowledging various circumstances in which health care providers may validly prescribe drugs for off-label use) (guidance pending before Office of Management and Budget).

[23] FDA, *Understanding Unapproved Use of Approved Drugs "Off Label"* (Feb. 5, 2018), https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label.

prescribe medications off label. *See, e.g.*, *United States v. Kaplan*, 836 F.3d 1199, 1210-11 (9th Cir. 2016) (explaining "[o]ff-label use allows a physician to use drugs or devices regulated by the FDCA for a purpose not approved by the FDA" "to allow physicians the freedom to manage the care of their patients) (citing *Buckman*, 531 U.S. at 350)); *Wash. Legal Found. v. Henney*, 202 F.3d 331, 333 (D.C. Cir. 2000) ("A physician may prescribe a legal drug to serve any purpose that he or she deems appropriate, regardless of whether the drug has been approved for that use by the FDA."). And DOJ's own Office of Legal Counsel concurs, writing that "[a]s a general matter, [the] FDA does not regulate the practice of medicine, which includes 'off-label' prescribing."[24] As a result, off-label usage of drugs and devices is an important part of the practice of medicine, particularly in certain fields like pediatrics and oncology. *See Planned Parenthood Arizona, Inc. v. Humble*, 753 F.3d 905, 909 (9th Cir. 2014), *abrogated on other grounds by Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215 (2022); *see also infra* Part II.C.

2. DOJ wrongly sweeps off-label prescribing into the FDCA's prohibitions concerning misbranding

DOJ admits, as it must, that "the act of writing a prescription for off-label use would, in and of itself," not "give rise to FDCA liability." Opening Br. at 31.

[24] Steven A. Engel, *Whether the Food & Drug Administration Has Jurisdiction Over Articles Intended for Use in Lawful Executions*, 43 Op. O.L.C. 81, 85 (May 3, 2019).

Recognizing this limitation, DOJ instead improperly characterizes the lawful practice of a clinician prescribing and communicating in writing about FDA-approved drugs for off-label uses as violations of the FDCA's prohibitions concerning the *misbranding* and *mislabeling* of drugs for unapproved uses. Opening Br. at 13, 26. DOJ's reading of the FDCA is wrong, has no basis in law, and, if adopted, would have broad implications far beyond medical care for transgender individuals.

Under the FDCA, a drug or device is deemed "misbranded" if "its labeling is false or misleading in any particular." 21 U.S.C. § 352(a)(1). The FDCA statutory framework bars "the introduction or delivery for introduction into interstate commerce of any food, drug, device . . . that is adulterated or misbranded." 21 U.S.C. § 331(a). Previously, the FDA has construed § 331(a) in the context of misbranding or mislabeling as applying to "firms," *i.e.*, pharmaceutical companies or their paid consultants—not to unaffiliated health care providers.[25]

Yet DOJ now wrongly contends that medical providers could be liable under the FDCA's "misbranding" provision merely by prescribing and explaining an off-label use of an already-approved drug or device to patients. *See* Opening Br. at 13, 26. DOJ observes that the FDCA defines labeling broadly to include material that

[25] *See, e.g.*, FDA, *supra* note 22, at 8-9 (acknowledging various circumstances in which health care providers may validly prescribe drugs for off-label use).

"supplements, explains, or is designed for use with the drug," including things like "promotional materials, advertisements, brochures, flyers, instruction sheets, posters, and similar materials." *Id.* at 6-7. Under DOJ's new and incorrect interpretation of the FDCA, however, if a medical provider were to "mislead" a minor patient and their parents "about the risks and benefits of the use of puberty blockers or cross-sex hormones . . . as a treatment for gender dysphoria" those statements could be "evidence of felony intent" and would, if in "written form, . . . misbrand the drug at issue." *Id.* at 11. DOJ's claim here thus implies that a doctor who merely provides her patient with an instruction sheet explaining the likely side effects or safe administration of the off-label drug she is administering—or, in the case of a telemedicine provider, posts information about the medication on the provider's website for patients to review—could be subject to criminal liability for misbranding under the FDCA. *Id.* at 26, 33.

The construction adopted by DOJ departs both from the typical conduct and typical actors usually considered to be within the scope of § 331(a). Amici are unaware of any instance when DOJ or FDA has extended liability to a medical provider in the circumstances here—that is, where a practitioner was merely prescribing and then providing information about an off-label use of an FDA-approved drug to a patient. *See In re Subpoena No. 25-1431-014*, 2025 WL 3252648, at *18 ("Misbranding liability, as Congress structured it, attaches to those who

design, control, or disseminate a drug's labeling—such as manufacturers and distributors—not to physicians engaged in patient-specific treatment."). Further, the federal government's own past prosecutorial practice demonstrates what the statute, until now, has always been understood to mean. *See, e.g.*, *United States v. Marschall*, 82 F.4th 774, 778 (9th Cir. 2023) (affirming conviction of individual previously enjoined from the unlicensed practice of medicine for introducing misbranded drugs into interstate commerce where the individual mailed drugs that, among other things, did not comply with drug producer registration requirements); *United States v. Chin*, 41 F.4th 16, 19 (1st Cir. 2022) (affirming conviction of supervising pharmacist under § 331(a) involved in shipment of contaminated drugs that resulted in a deadly fungal meningitis outbreak); *United States v. Elmer*, 980 F.3d 1171, 1173 (7th Cir. 2020) (affirming conviction of owner and operator of pharmaceutical company that continued to manufacture and ship drugs the owner knew "contained more or less of their active ingredient than advertised").

The implications of DOJ's adopted construction are considerable. Under this interpretation, if a provider consults with a patient, suggests off-label use of an FDA-approved medication, and then provides the patient with written materials explaining the off-label use of that medication or directs the patient to information on their website on the off-label use, that provider could potentially be subject to FDCA liability for "misbranding" a drug. Opening Br. at 26. Such a broadening of the scope

of the FDCA inserts the government into the doctor-patient relationship to regulate conversations between providers and their patients about possible treatment options, and then allows the federal government to scrutinize and criminalize under the guise of "misbranding" a doctor's written information on that treatment provided to a patient. Not only would this expansion of the statute limit the efficacy of care a medical professional can provide, it would also inhibit a patient's ability to fully understand, safely administer, and give informed consent to certain procedures and medications prescribed off label.

To be clear, even though a medical provider may not be held liable for drug "misbranding" under the FDCA by providing information on an off-label medication to a patient, a provider will not escape consequences for providing inaccurate or incomplete information to their patients in connection with off-label prescriptions. Physicians who do so will risk state medical board disciplinary action and state malpractice claims. *See In re Subpoena No. 25-1431-014*, 2025 WL 3252648, at *13 (explaining how incomplete disclosures or misleading consent forms may implicate state informed-consent or professional-discipline standards, but not how drugs are "labeled, promoted, or distributed in commerce" under the FDCA). Moreover, the Supreme Court recently recognized in *United States v. Skrmetti* that states may ban off-label prescribing of drugs used to treat gender dysphoria if they choose. *See United States v. Skrmetti*, 605 U.S. 495, 506 (2025) (upholding Tennessee's

prohibition of puberty blockers and hormones to treat gender dysphoria); *id.* at 533-34 (Thomas, J., concurring) (recognizing puberty blockers and hormones are often administered "off-label"). But, if a state chooses to allow off-label prescribing of drugs for use in transgender health care by providers within their state, the FDCA does not provide a means for DOJ to investigate or ban physicians for "misbranding" based on the provision of lawful health care services to patients in Amici States. *See id.* ("We afford States 'wide discretion to pass legislation in areas where there is medical and scientific uncertainty.'" (quoting *Gonzales v. Carhart*, 550 U.S 124, 163 (2007)). DOJ's attempt to use the misbranding provision of the FDCA to target providers of transgender health care in Amici States should be rejected as a novel interpretation contrary to well-established law and practice.

C. DOJ's Expansive Interpretation of the FDCA Jeopardizes Entire Fields of Medicine

DOJ's baseless interpretation of the FDCA—that prescribing and providing written information on an off-label drug can constitute unlawful branding—would have devastating and far-reaching effects that go far beyond the narrow field of transgender health care. Recent estimates suggest that between 20 and 50 percent of all prescriptions are for off-label indications.[26] Furthermore, "the prescription of

[26] James M. Beck, *Off-Label Use in the Twenty-First Century: Most Myths and Misconceptions Mitigated*, 54 UIC J. Marshall L. Rev. 1, 25 & n.112 (2021); *see also* Randall S. Stafford, *Regulating Off–Label Drug Use - Rethinking the Role of the FDA*, 358 N. Engl. J. Med. 1427, 1427 (2008) (describing 2003 report showing

drugs for unapproved uses . . . is *ubiquitous* in certain specialties." *Wash. Legal Found.*, 202 F.3d at 333 (emphasis added).

To give one example, providers in oncology units commonly administer a variety of cancer treatments off label, as several cancer-treating medications are effective for more than one type of cancer, and providers often employ combination chemotherapy.[27] As a result, some scholars estimate that 50 to 75 percent of drug use in oncology settings occurs off label.[28] Over time, other fields where off-label use of drugs and medical devices has been particularly prominent have included heart and circulatory disease, AIDS, kidney disease requiring dialysis, osteoporosis, spinal fusion surgery, rare diseases, and psychiatry.[29]

Saliently to the dispute before the Court, off-label prescribing is widespread in pediatrics. Data on the effects of drugs on children is less available than for adults for a variety of reasons, "including unfamiliarity with age-related developmental pharmacology in pediatric patients, ethical considerations with conducting pediatric

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that off-label use for leading drugs in leading drug classes accounted for 21% of prescriptions, with the highest use for anticonvulsants (74%), antipsychotics (60%), and antibiotics (41%)).

[27] *See Nat'l Cancer Inst., Off-Label Drug Use in Cancer Treatment* (rev'd Jan. 13, 2022), https://www.cancer.gov/about-cancer/treatment/drugs/off-label.

[28] Beck, *supra* note 26, at 25-26 & n.113.

[29] James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 Food & Drug L. J. 71, 80 (1998).

research, and a lack of financial incentive for the pharmaceutical industry."[30] This lack of data in turn drives a relative paucity of FDA approvals of drugs for pediatric indications—indeed, many drugs carry a so-called "orphaning clause[]" disclaimer as to pediatric use in light of the absence of sufficient studies.[31] Consequently, some studies estimate that as much as 80 percent of drugs prescribed for children are prescribed for off-label uses.[32]

DOJ's groundless attempt to shoehorn routine parts of off-label prescribing into the FDCA's criminal prohibitions in furtherance of the Administration's stated goal of "ending" gender-affirming care, E.O. 14,187, threatens an enormous range of medical care in a wide variety of fields. While this subpoena to QueerDoc is concerned with transgender health care for adolescents, DOJ's interpretation of the FDCA offers no kind of limiting principle that would cabin it. Rather, DOJ's efforts to apply the FDCA's criminal provisions concerning labeling and branding to

[30] 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. St. Med. Ass'n 776, 777 (2018); *see also* FDA, *Pediatric Ethics* (rev'd Jan. 16, 2024), https://www.fda.gov/science-research/pediatrics/pediatric-ethics; FDA, *Additional Protections for Children* (rev'd Sept. 21, 2015), https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/additional-protections-children.

[31] Lewis A. Grossman, *Criminalizing Transgender Care*, 110 Iowa L. Rev. 281, 310 (2024); Beck & Azari, *supra* note 29, at 80 n.81.

[32] Beck, *supra* note 26, at 25-26 & n.114.

routine off-label prescribing and patient education jeopardizes the availability of medical care for many who need it the most.

The implications and consequences of adopting DOJ's interpretation of the FDCA are even more dire considering the DOJ's threat of strict criminal liability. As DOJ notes, violation of 21 U.S.C. § 331—the criminal provision of the FDCA that, among other things, addresses the misbranding and mislabeling of drugs and medical devices—"are punishable on a strict liability basis without any proof of criminal intent." Opening Br. at 7 (citing *United States v. Park*, 421 U.S. 658, 672-73 (1975)). Read together with DOJ's acknowledgement that it has sent over twenty such subpoenas to providers and children's hospitals across the country, the threat becomes clear: the federal government aims to prosecute medical providers and hospital administrators for federal crimes based on doctors' routine off-label prescribing of medications and written communication with patients about the medical treatments they are receiving. Even the threat of such prosecution flatly contradicts the well-settled notion that the FDCA does not exist to regulate doctors' practice of medicine, *see, e.g.*, *Ass'n of Am. Physicians & Surgeons*, 13 F.4th at 534, and promises to have profound effects on the provision of health care across the country. This Court should reject DOJ's efforts to use the cudgel of criminal liability to intimidate the doctors who provide protected health care services in Amici States.

D. DOJ's Defense of the Misuse of Investigative Power Should Be Rejected

In the last several months, DOJ's novel reading of federal statutes has been consistently recognized for what it is: an attempt to harass and intimidate providers of transgender health care. Yet throughout its brief, DOJ attempts to defend targeting criminal investigations based solely on a person's or entity's provision of lawful medical care that the federal government disfavors. Opening Br. at 3, 10, 27-31. Indeed, DOJ all but concedes that forcing doctors to stop providing transgender health care is its motivation in issuing the subpoena at issue here and dozens of identical ones across the United States. *See* Opening Br. at 27-28 ("The government is simply prioritizing enforcement of federal law in an industry of special concern for policy reasons.").[33] And there can be no doubt that this is the case.[34] Thus, according to DOJ, it can weaponize the criminal justice system and the Court must

[33] *See also* Press Release, *supra* note 15.

[34] On January 28, 2025, President Trump directed DOJ to prioritize enforcement of federal law against providers of transgender health care, declaring this medically necessary care, explicitly protected by law in the Amici States, is "a stain on our Nation's history, and it must end." E.O. 14,187. Attorney General Bondi, on April 22, 2025, relied on this executive order to instruct DOJ's various operational units to prioritize enforcement consistent with President Trump's direction so that "the Department of Justice will bring these practices to an end." ER-053. The subpoena to QueerDoc was issued in explicit conformity with these directives of President Trump and Attorney General Bondi by Assistant Attorney General Brett Shumate. ER-054-056 ("The Civil Division will use all available resources to prioritize investigations of doctors, hospitals, pharmaceutical companies, and other appropriate entities consistent with [the] directives [of President Trump and Attorney General Bondi].").

ignore even obviously improper purposes so long as a subpoena is "facially valid." Opening Br. at 26. That is plainly not the law, as multiple federal courts have now correctly concluded.

Emphasizing DOJ's obvious purpose of using subpoenas to target providers based solely on their provision of lawful transgender health care, a chorus of federal courts nationwide have found these subpoenas "bear little relation to [the] supposed purpose of investigating FDCA violations," *In re: Dept. of Justice Admin. Subpoena No. 25-1431-030*, No. 25-mc-00062-SKC-CYC, 2026 WL 33398, at *6 (D. Colo. Jan. 5, 2026) (report and recommendation of U.S. Magistrate Judge), and go so far beyond the scope of the FDCA as to "carr[y] more than a whiff of ill-intent," *In re: 2025 UPMC Subpoena*, 2025 WL 3724705 at *2; *see* ER-017-018 (district court explaining the mismatch between DOJ's purported investigation and QueerDoc's actual operations). DOJ seeks to collect sweeping information about institutions, their personnel, and their patients, with only "an idle hope of discovering information related to a federal healthcare offense." *In re Subpoena Duces Tecum No. 25-1431-016*, No. 2:25-MC-00041-JHC, 2025 WL 3562151, at *9 (W.D. Wash. Sept. 3, 2025) (citation modified).

The district court's conclusion, that DOJ was attempting to use its "subpoena power to achieve what the Administration cannot accomplish through legislation" (ER-013-014) is thus not "an indefensible and untenable logical leap" (Opening Br.

at 27). It is taking the President and the Attorney General at their word, found credible by multiple district courts considering nearly identical subpoenas issued to other health care providers. *See* ER-017, 019 ("DOJ issued the subpoena first and searched for a justification second"; concluding "the record before the Court establishes that DOJ's subpoena to QueerDoc was issued for a purpose other than to investigate potential violations of the FDCA or FCA," and was instead served to "pressure providers to cease offering gender-affirming care"); *In re 2025 UPMC Subpoena*, 2025 WL 3724705, at *1 (collecting cases); *see also In re Admin. Subpoena No. 25-1431-019*, 800 F. Supp. 3d at 239 (subpoena to Boston Children's Hospital "was issued for an improper purpose, motivated only by bad faith"); *In re Subpoena Duces Tecum No. 25-1431-016*, 2025 WL 3562151, at *13 (quashing subpoena to Seattle Children's Hospital because it "was issued for an improper purpose"); *In re 2025 Subpoena to Children's Nat'l Hosp.*, No. 1:25-cv-03780-JRR, 2026 WL 160792, at *9 (D. Md. Jan. 21, 2026) (quashing subpoena to Children's National Hospital because it "bears no credible connection to an investigation of any statutory violation" and "appears to have no purpose other than to intimidate and harass the Hospital and Movants"); *In re: Dept. of Justice Admin. Subpoena No. 25-1431-030*, 2026 WL 33398, at *7 (report and recommendation recommending that subpoena to Children's Hospital Colorado be quashed; explaining "the 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'").

Where, as here, a subpoena is issued for an improper purpose, it is invalid, and DOJ's self-serving claims for facial validity fall flat. *See* Opening Br. at 26. This is the (heretofore) rare case where DOJ's improper and bad faith objectives were publicly stated and explicitly relied on in issuing the challenged subpoena here (and the other quashed subpoenas around the country). "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." ER-017.

It is emphatically improper for the federal government to target a person or entity for criminal investigation based solely on their engagement in lawful conduct and to coerce them to stop engaging in it. DOJ's defense of its politically motivated investigations should be rejected and the district court should be affirmed.

III. CONCLUSION

Amici States respectfully urge the Court to affirm the district court's order quashing the subpoena directed to QueerDoc.

RESPECTFULLY SUBMITTED this 23rd day of January 2026.

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