UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF RHODE ISLAND

IN RE ADMINISTRATIVE SUBPOENA 25-1431-032 to Rhode Island Hospital	No. 1:26-mc-00007-MSM-AEM

[PROPOSED] AMICUS BRIEF OF RHODE ISLAND, MASSACHUSETTS, ARIZONA, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, THE DISTRICT OF COLUMBIA, ILLINOIS, MAINE, MARYLAND, MICHIGAN, MINNESOTA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, OREGON, VERMONT, WASHINGTON, AND WISCONSIN AS *AMICI CURIAE* IN SUPPORT OF PETITIONER'S EMERGENCY MOTION TO QUASH SUBPOENA DUCES TECUM

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TABLE OF CONTENTS

INTRODUCTION AND STATEMENT OF INTERESTS

In the summer of 2025, the Department of Justice ("DOJ") served numerous subpoenas across the country on medical providers of transgender healthcare for minors, including Rhode Island Hospital ("RI Hospital"). The subpoenas serve no legitimate investigatory purpose, are overly broad, harassing, and intrusive, jeopardize the health and welfare of State residents, and threaten to undermine the States' sovereign interest in regulating the practice of medicine in their jurisdictions. Accordingly, the States of Rhode Island, Massachusetts, Arizona, California, Colorado, Connecticut, Delaware, Illinois, Maine, Maryland, Michigan, Minnesota, Nevada, New Jersey, New Mexico, New York, Oregon, Vermont, Washington, Wisconsin, and the District of Columbia ("Amici States") submit this brief in support of the Child Advocate for the State of Rhode Island's Emergency Motion to Quash. ECF No. 1. Notably, five federal district courts have quashed six similar subpoenas issued to other providers as part of DOJ's campaign against transgender healthcare. *See In re Subpoena Duces Tecum No. 25-1431-016*, No. 2:25-mc-00041, 2025 WL 3562151 (W.D. Wash. Sep. 3, 2025), *mot. to alter judgment denied*, Apr. 23, 2026; *In re Administrative Subpoena No. 25-1431-0019*, 25-mc-91324-MJJ, 2025 WL 2607784 (D. Mass. Sep. 9, 2025), *appeal filed*, Nov. 7, 2025 ("*In re Boston Children's Hospital Subpoena*"); *Queerdoc, PLLC v. U.S. Dep't of Just.*, 2:25-mc-00042-JNW, 2025 WL 3013568 (W.D. Wash. Oct. 27, 2025), *appeal filed*, Nov. 21, 2025; *In re Subpoena No. 25-1431-014*, Misc Action No. 25-39, 2025 WL 3252648 (E.D. Pa. Nov. 21, 2025), *appeal filed*, Jan. 16, 2026; *In re 2025 UPMC Subpoena*, 2:25-mc-01069-CB, 2025 WL 3724705 (W.D. Pa. Dec. 24, 2025),

appeal filed, Feb. 20, 2026; *In Re: 2025 Subpoena to Children's National Hospital*, No. 1:25-cv-03780, 2025 WL 160792 (D. Md. Jan. 21, 2026), *appeal filed*, Jan. 28, 2026.[1]

The subpoena served by DOJ on RI Hospital is pretextual and seeks to intimidate medical providers out of offering critical, medically necessary healthcare 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 mechanisms, including prosecutions, merely for providing this 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 healthcare will cause profound disruptions across the entire medical field.

As with the cases filed elsewhere, DOJ presented the Texas court with a post hoc and pretextual justification for intruding into this traditional sphere of state regulation by pointing to the federal Food, Drug, and Cosmetic Act ("FDCA"). However, DOJ's interpretation of the FDCA is exceedingly broad, disruptive, and breaches its own precedent and practice. Indeed, DOJ's interpretation appears to conflict 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 in the Hsiao Declaration—that the FDCA's prohibitions concerning the distribution and labeling of off-label 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 those who administer a sweeping array of healthcare. DOJ offers no limiting principle to its argument; if DOJ's interpretation of

[1] Additionally, a United States Magistrate Judge recommended granting Colorado Children's Hospital's motion to quash a similar, improper subpoena. *Department of Justice Administrative Subpoena No. 25-1431-030*, No. 1:25-mc-00063-SKC-CYC, 2026 WL 33398 (D. Colo. Jan. 5, 2026).

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 RI Hospital were forced to comply with this subpoena and DOJ were to prevail in its interpretation of the FDCA, it would threaten the health and welfare of the people of Rhode Island and other Amici States, impede core economic activities of Amici States, and encroach on Amici States' traditional role as the regulators of medicine, both within and outside of the context of transgender medicine.

Amici States are home to hospitals, like RI Hospital, that provide essential and life-saving care to thousands of people every year, including transgender healthcare to individuals under the age of 19. These hospitals are at the forefront of biomedical and technological research, and they fuel the economies of Amici States, including by creating jobs, spurring innovation, improving residents' health, and training the future workforce. 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 healthcare services and protecting people who lawfully provide or help others access such care. In many Amici States' experience, these laws are necessary to uphold the rights and dignity of our transgender residents and the health and well-being of our communities. And while this dispute arises within the context of transgender healthcare to individuals under the age of 19, DOJ's FDCA arguments implicate even more sweeping and expansive questions than just those presented by this immediate matter.

For the reasons advanced by the Child Advocate of the State of Rhode Island and for the reasons discussed below, the Court should grant the emergency motion to quash.

ARGUMENT

I. 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 Linder v. United States*, 268 U.S. 5, 18 (1925); *Bergman v. Parker*, 348 U.S. 26, 32 (1954); *Hillsborough Cnty., Fla. v. Automated Med. Lab'ys, Inc.*, 471 U.S. 707, 719 (1985). To avoid encroaching on the practice of medicine, 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). Recent actions by DOJ, including the subpoena at issue in this case, seek 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 "power to protect the health and safety of their citizens." U.S. Const. amend. X; *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996); *see also Slaughterhouse Cases*, 83 U.S. 36, 62 (1873) (describing the police power as extending "to the protection of the lives, limbs, health, comfort, and quiet of all persons…within the State"). Since at least 1889, the authority to regulate the practice of medicine has been recognized as among these powers. *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 adopt novel interpretations of statutes in order to disrupt a State's medical regulatory framework by inventing novel forms of criminal activity. *See Gonzales v. Oregon*, 546 U.S. 240, 269–70 (holding that 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."[2]

States have exercised their power to regulate medicine in various ways. Perhaps most significantly, states regulate the practice of medicine by defining the scope and contours of medical practice and requiring medical licenses for practitioners.[3] Since 1895, all states have boards that oversee the licensing of medical professionals.[4] 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

[2] Patricia J. Zettler, *Toward Coherent Federal Oversight of Medicine*, 52 SAN DIEGO L. REV. 427, 448 (2015); s*ee also Hillsborough Cnty.*, 471 U.S. at 719 (stating "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); *Gonzales v. Carhart*, 550 U.S. 124, 157 (2007) ("Under our precedents it is clear the State has a significant role to play in regulating the medical profession."); *Barsky v. Bd. of Regents*, 347 U.S. 442, 451 (1954) (indicating that the state has "legitimate concern for maintaining high standards of professional conduct" in the practice of medicine); *Buckman*, 531 U.S. at 348 (identifying "historic primacy of state regulation of matters of health and safety").

[3] Zettler, *supra* note 2, at 449-50 (citing ROBERT I. FIELD, HEALTH CARE REGULATION IN AMERICA: COMPLEXITY, CONFRONTATION, AND COMPROMISE 19 (2007) (stating that the "cornerstone" of medical practice regulation is states' licensing schemes).

[4] Robert C. Derbyshire, MEDICAL LICENSING AND DISCIPLINE IN THE UNITED STATES 8 (1969); Zettler, *supra* note 2, 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.

examination.[5] Additional requirements may include interviews, a documented lack of criminal history, and medical malpractice insurance coverage.[6] 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.[7]

States have also exercised their police powers to protect vulnerable groups against discrimination and ensure equal access to critical healthcare. Consistent with state policy judgments about protecting minority populations and prohibiting discrimination, many Amici have enacted civil rights protections for transgender people in education, employment, healthcare, housing, public accommodations, and other parts of public life.[8] They have also taken steps to safeguard access to transgender healthcare, exercising their sovereign judgment that such safeguards promote public health and wellbeing. For instance, Rhode Island and many other Amici States expressly recognize a legal right to transgender healthcare and have enacted laws intended to protect people in their States who access, provide, or assist with the provision of

[5] Zettler, *supra* note 2, at 450 (citing Nadia N. Sawicki, *Character, Competence and the Principles of Medical Discipline*, 13 HEALTH CARE L. & POL'Y 285, 290 (2010).

[6] *Id*.

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

[8] *See, e.g.*, R.I. Gen. Laws §§ 11-24-2, 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; 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; Md. Code Ann., Educ. § 26-704; Conn. Gen. Stat. §§ 10-15c, 46a-58 *et seq*.; Del. Code tit. 6, ch. 45 & 46; Del. Code 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. Rev. Stat. tit. 5, § 4551 *et seq*.; Md. Code Ann., State Gov't §§ 20-606, 20-705; Mich. Comp. Laws § 37.2202(1)(a); 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; Vt. Stat. Ann. tit. 9, §§ 4502, 4503; Vt. Stat. Ann. tit. 21, § 495; Wash. Rev. Code §§ 49.60.030(1), 49.60.040(2), 49.60.040(29), 49.60.215.

that care from civil or criminal penalties by out-of-state jurisdictions that outlaw it.[9] Many Amici, including Rhode Island, also cover transgender healthcare 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] These protective measures include efforts to preserve confidentiality of patient records. In Rhode Island, for instance, healthcare providers may only disclose confidential healthcare information in the context of a judicial proceeding if the individual whose records are being sought is served with a copy of the subpoena; upon receipt, the individual may independently move to quash within twenty days. R.I. Gen. Laws § 5-37.3-6.1. It is far from clear that patients have been given an opportunity to exercise these rights under Rhode Island law.

Similarly, many Amici States have enacted laws that exclude the provision of transgender

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[9] *See, e.g.*, Mass. Gen. Laws ch. 12, § 11I½(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. Rev. Stat. tit. 14, § 9001, *et seq.*; Me. Rev. Stat. tit. 22, §§ 1508; Md. Code Ann., State Pers. & Pens. § 2-312; 2023 Minn. Laws ch. 29; 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.*; Wash. Rev. Code § 7.115 *et seq.*; N.J.A.C. Executive Order No. 326 (2023); *see also* UCLA Sch. of Law Williams Inst., *Shield Laws for Reproductive and Gender-Affirming Health Care: A State Law Guide*, https://williamsinstitute.law.ucla.edu/publications/shield-laws-fact-sheets.

[10] *See, e.g.,* R.I. Gender Dysphoria/Gender Nonconformity Coverage Guidelines (Oct. 28, 2015), *available at* https://bit.ly/RI-Guidelines; Gender-Affirming Care Covered by MassHealth, https://www.mass.gov/info-details/gender-affirming-care-covered-by-masshealth; Md. Code Ann., Health-Gen. § 15-151; 89 Ill. Adm. Code §§ 140.413(a)(16), 140.440(h); Medicaid State Plan, § 3.1, Supp. to Attachment 3.1-A, pp. 15-15a.1, *available at* https://www.mdch.state.mi.us/dch-medicaid/manuals/MichiganStatePlan/MichiganStatePlan.pdf; Minn. Stat. § 256B.0625, subd. 3a; Nev. Medicaid Servs. Manual § 608, *available at* https://bit.ly/NVMedicaid.

[11] *See, e.g.*, R.I. Health Ins. Bull. 2015-03, *available at* https://bit.ly/RI-2015-03; Mass. Gen. Laws ch. 272, §§92A, 98; Cal. Code Regs. tit. 10 §2561.2, subd. (a) (2012); 3 Code Colo. Regs. §702-4, Reg. 4-2-42, §5(A)(1)(o); Del. Code tit. 18, §2304; 215 Ill. Comp. Stat. 5/356z.60(b); 50 Ill. Adm. Code §2603.35; Me. Rev. Stat. tit. 22, §3174-MMM; Md. Code Ann., Ins. §15-1A-22; 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.

healthcare from the definition of "professional misconduct" and that shield medical providers from facing professional discipline based solely on an out-of-state conviction or adverse license action resulting from the provision of transgender healthcare.[12] Other Amici States, meanwhile, mandate training for healthcare professionals to ensure that patients who identify as transgender, gender diverse, and intersex receive trans-inclusive care.[13]

Taken together, the above laws and policies reflect many 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 healthcare. In the experience of many Amici States, these laws and policies are essential to address long-standing inequities in the healthcare system. The laws and policies discussed above adhere to medical standards of care and respect the doctor-patient relationship, thereby preserving the integrity and ethics of the medical profession. More importantly, these laws result in better health outcomes for transgender adolescents, safeguarding their physical, emotional, and financial wellbeing.

Despite no federal law prohibiting such care, the clear purpose of DOJ's subpoena to RI Hospital is to end transgender healthcare for adolescents. *See* Mot. to Quash, ECF No. 1 at 23–26. As federal courts across the country have held, DOJ's sweeping requests for sensitive information—including records of all patients who have received a particular type of medical care—appear to represent a radical departure from its prior practice and makes express the "policy goal" of the Executive Branch to harm a politically disfavored minority. *See In re*

[12] *See, e.g.,* R.I. Gen. Laws § 5-37.8-1; Mass. Gen. Laws ch. 112, §§ 5F½, 77, 128; 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; 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 transgender healthcare. *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.

Boston Children's Hospital Subpoena, 2025 WL 2607784 at *7 (D. Mass. Sep. 9, 2025) ("It is abundantly clear that the true purpose of issuing the subpoena is to interfere with the Commonwealth of Massachusetts' right to protect [transgender healthcare] within its borders, to harass and intimidate BCH to stop providing such care, and to dissuade patients from seeking such care."). The subpoena has nothing at all to do with promoting the rule of law. Rather, this extraordinary overreach is an attempt to subvert the policy and judgment of the states as the traditional regulators of the practice of medicine. The broadside attack by DOJ on transgender healthcare undermines the Amici States' sovereign authority in protecting the health and safety of our residents.

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

DOJ attempts to justify its subpoena through a novel and unreasonable interpretation of the FDCA. Contrary to established practice and precedent, *see, e.g., Ass'n of Am. Physicians & Surgeons v. U.S. Food & Drug Admin.*, 13 F.4th 531, 534 (6th Cir. 2021) (citing *Buckman.*, 531 U.S. at 350-51) ("Although the Act regulates a manufacturer's distribution of drugs, it does not go further by regulating a doctor's practice of medicine."), DOJ now interprets the FDCA to regulate the practice of medicine. It does so by sweeping into the statute's prohibitions, 21 U.S.C. § 331(a), (d), the routine administration of approved drugs for off-label purposes and communication between providers and patients about those drugs—medical practices and elements of the doctor-patient relationship that long-settled law says the Act does not touch. The implications of this reading are enormous: Far from being limited to the narrow space of transgender healthcare, DOJ's interpretation of the FDCA will have widespread and disastrous implications across the field of 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 healthcare providers and their patients about the medications they receive.

A. 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.[14] Premarket approval is a multi-step process (involving multiple applications and stepped authorizations) that ultimately results in approval of a drug to be marketed and sold for a particular indication (use) in a specific population.[15] The FDA's approval also includes an approved drug label, which is "a summary of the evidence supporting the safe and effective use of the drug."[16]

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.3d 194, 198 (8th Cir. 1989). Consequently, it is well-settled that "[a]s a general matter, once a drug is approved, physicians may *prescribe* the drug without

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

[15] *Id*. at 384.

[16] *Id*. at 384-85.

restriction."[17] The FDA itself has repeatedly made public statements to this effect,[18] including as recently as last year,[19] and its own website specifically says that once the agency "approves a drug, healthcare providers generally may prescribe the drug for unapproved use when they judge that it is medically appropriate for their patient."[20] Courts also routinely recognize that the FDCA permits doctors to prescribe medications off label. *See, e.g.*, *In re Zofran (Ondansetron) Prods. Liab. Litig.*, 541 F. Supp. 3d 164, 173 (D. Mass. 2021), *aff'd*, 57 F.4th 327 (1st Cir. 2023) ("It is generally lawful for physicians to prescribe medications for purposes for which they have not been FDA-approved."); *In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 240 (3d Cir. 2012) ("Because the FDCA does not regulate the practice of medicine, physicians may lawfully prescribe drugs for off-label uses."); *Wash. Legal Foundation 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 ("OLC") concurs, writing that "[a]s a general matter, [the] FDA does not regulate the practice of medicine, which includes

[17] *Id*. at 387 (2014); *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").

[18] *See, e.g.*, *id*. at 387 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. A physician may prescribe a drug for uses or in treatment regimens or patient populations that are not listed in the FDA-approved labeling.").

[19] *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 healthcare providers may validly prescribe drugs for off-label use).

[20] 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.

'off-label' prescribing."[21] 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 infra* Part II.C.

B. DOJ wrongly sweeps off-label prescribing and dispensing into the FDCA's prohibitions concerning distribution and promotion of unapproved drugs.

DOJ advances its novel interpretation of the FDCA in a declaration from Lisa K. Hsiao, the Acting Director of the Enforcement and Affirmative Litigation Branch of the DOJ's Civil Division ("Hsiao Declaration"). The Hsiao Declaration admits, as it must, that physicians "are permitted to prescribe an FDA-approved drug for an unapproved use." ECF No. 1-3 ¶ 12. Recognizing this limitation, DOJ instead improperly characterizes the lawful practice of a clinician prescribing and communicating with a patient about FDA-approved drugs for off-label uses as a violation of the FDCA's prohibitions concerning the *distribution* and *labeling* of drugs for unapproved uses. *See id.* ¶¶ 13–16 (labeling); *id.* ¶¶ 17–18 (distribution). DOJ's reading of the FDCA is wrong, has no basis in law, and, if adopted, will have broad implications far beyond the administration of transgender healthcare.

1. Purchasing, storing, and administering approved medications does not give rise to criminal liability under the FDCA.

DOJ wrongly claims, without support, that the FDCA subjects hospital staff and medical providers to criminal liability when they purchase, store, and administer an approved drug for a purpose other than that approved by the FDA. To get to that conclusion, DOJ offers an elaborate, multi-step interpretation of the FDCA, which would (for the first time) make providers criminally liable for purchasing, storing, and administering a drug for an off-label use. It says, *first,* that "introducing a 'new drug' into interstate commerce without an FDA-approved

[21] 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 (2019).

indication is unlawful," ECF No. 1-3 ¶ 22; *second*, that since drugs used to treat gender dysphoria in minors have not been specifically approved for that indication, "[those drugs] constitute unapproved new drugs under federal law," *id.*; *third*, that "distribution for that unapproved indication violates the FDCA and is a federal crime," *id.*; and *finally*, that healthcare providers who "purchase, store, and administer the drug … [are] in the chain of distribution of that drug," *id.* ¶ 23. The government's tortured analysis is at odds with explicit statutory language as well as accepted practice and precedent, and would make hospital pharmacies, hospital departments, and even retail pharmacies liable for routine parts of their practice.

The specific drugs DOJ asserts potentially expose providers to criminal liability are puberty blockers, which are "typically implants or injectables," ECF No. 1-3 ¶ 23, that are administered by medical providers at their offices. Implanted puberty blockers are devices under 21 U.S.C. § 321(h)(1), which the FDCA explicitly allows providers to administer to patients for off-label uses. *See* 21 U.S.C. § 396 ("Nothing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship."). Contrary to DOJ's interpretation, providers who are purchasing, storing, and administering such implants or injectables for an off-label use in their places of practice are thus not unlawfully "distributing" the drug or device, *see* ECF No. 1-3 ¶ 23, within the meaning of the FDCA. The suggestion that FDCA liability attaches to anyone who administers an approved device for an unapproved but medically indicated purpose is therefore belied by the statutory framework. *See* 21 U.S.C. § 396.

Moreover, the prescription or administration of an approved medication or device off label by a medical provider does not render it a "new drug" for purposes of the FDCA or render

it "unapproved." Rather, it is well established that "medical professionals may lawfully prescribe and administer a device for an off-label use as long as that device has received [FDA] clearance for any intended use." *United States v. Facteau*, 89 F.4th 1, 15 (1st Cir. 2023), cert. denied, 145 S. Ct. 137 (2024). If this were not so, virtually all drugs in common use across the United States would be deemed in violation of the statute if prescribed for any purpose other than what is specified on the label.

Finally, the idea that a provider becomes an unlawful "distributor" if the provider purchases, stores, and administers a drug to a patient is in tension with the widely accepted and permissible off-label dispensing of drugs. Providers regularly purchase, store, and administer drugs for off-label uses in hospital settings, residential facilities like nursing homes or rehabilitation centers, and certain outpatient treatment centers because such treatment is medically appropriate. Indeed, DOJ's erroneous interpretation would virtually upend oncology practices, where the purchase, storage, and on-site administration of chemotherapeutic drugs for off-label uses is not only extremely common but also recognized as vital by CMS.[22] DOJ's misplaced theory of provider liability would endanger these routine and widespread methods of care and would effectively nullify the longstanding recognition of the propriety and legality of off-label prescribing by duly licensed medical professionals. *See, e.g., In re Celexa & Lexapro Mktg. & Sales Pracs. Litig.*, 915 F.3d 1, 5 (1st Cir. 2019) ("The FDCA . . . does not prohibit doctors from prescribing drugs for off-label uses."). Indeed, the DOJ OLC has noted that the FDCA's prohibitions on distribution generally are not applicable to providers, observing that "[w]hile the FDCA bars a manufacturer or distributor from selling any drug or device for an

[22] Coleen Klasmeier, *FDA, Medical Communications, and Intended Use-A New Challenge to First and Fifth Amendment Constraints on Government Power*, 78 FOOD & DRUG L.J. 263, 271 (2023); *see* CMS, *Article: Off-Label Use of Drugs and Biologicals for Anti-Cancer Chemotherapeutic Regimen* (rev'd Nov. 16, 2023), https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=58113.

unapproved use, physicians may, with limited exceptions, prescribe and administer FDA-approved drugs and devices for unapproved uses."[23]

2. The provision of information about off-label uses does not subject medical providers to liability for misbranding.

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 "[t]he 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 healthcare providers.[24]

Yet in its attempts to enforce this subpoena, DOJ suggests that medical providers could be liable under the FDCA's prohibition on distributing "misbranded" medications merely for explaining an off-label use of an already-approved drug or device to patients. *See* ECF No. 1-3 ¶¶ 13-16. DOJ observes that the FDCA defines labeling broadly to include material that "supplements, explains, or is designed for use with the drug," including things like flyers or instruction sheets. *Id.* ¶ 15. It then extrapolates that if a person "distributes (or causes the distribution of) an approved drug with false or misleading labeling for an unapproved use, [they] could possibly be charged with misbranding the drug or distributing a misbranded drug." *Id.*

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[23] Engel, *supra* note 21, at 85.

[24] *See, e.g.*, 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 healthcare providers may validly prescribe drugs for off-label use). (Note that although this guidance is final, it is "not for current implementation," as it is currently before the Office of Management and Budget for approval of information collection provisions. *See id.* at 29.) Moreover, even in circumstances involving paid promotional activity (which is, again, not at issue here), where the "communications" between the pharmaceutical company and provider are truthful, the FDA has recognized that there are First Amendment constraints on their ability to charge such communications as "misbranding." *See, e.g.*, FDA, *Addendum to Jan 2017 FDA Memo—Additional and Updated Considerations Related to Manufacturer Communications Re Unapproved Uses of Approved or Cleared Medical Products* (Jan. 2025), https://www.regulations.gov/document/FDA-2016-N-1149-0107.

¶ 16. Together with its assertion that a medical provider who stores or administers such a drug is in the chain of distribution, DOJ's claim here thus implies that a doctor who provides her patient with an instruction sheet explaining the off-label drug she is administering could be subject to criminal liability for misbranding under the FDCA.

The construction adopted by DOJ in this matter departs both from the typical conduct and typical actors usually considered to be within the scope of § 331(a). Such a construction appears to be a sharp departure from the federal government's own past practice. Amici are unaware of any instance when DOJ or FDA has extended liability to a practitioner in the circumstances here—that is, when, with no connection to any firm-supported promotional activity (such as paid peer-to-peer presentations), the practitioner merely prescribes and provides information about an off-label drug to a patient.

The implications of DOJ's adopted construction are considerable. Under this interpretation, if a provider consults with a patient, suggests off-label use of a medication, and provides the patient with materials explaining the off-label use of that medication, that provider could potentially have "distributed" a "misbranded" drug. Not only does such a broadening of the scope of the FDCA have implications for the efficacy of care a medical professional can provide, it also would inhibit a patient's ability to fully understand and give informed consent to certain procedures and medications prescribed off label.

C. DOJ's expansive interpretation of the FDCA jeopardizes entire fields of medicine.

DOJ's baseless interpretation of the FDCA—that off-label administration of a drug can constitute unlawful distribution, and providing instructions for an off-label drug can constitute unlawful branding—would have devastating and far-reaching effects that go far beyond the narrow field of transgender healthcare. Recent estimates suggest that between 20 and 50 percent

of all prescriptions are for off-label indications.[25] Further, providers in all medical fields regularly purchase and administer drugs at their place of practice: in hospitals, where providers dispense medication in emergency departments, inpatient units, and oncology units; in residential facilities like nursing homes or rehabilitation centers for eating disorders; or in certain outpatient treatment centers. And as discussed above, in the case of medical devices that must be implanted or inserted by medical professionals, such as chemotherapy ports, knee replacements, or indeed any surgical device, those must be purchased and stored on-site. DOJ's interpretation of the FDCA would lead to sweeping criminalization of providers in all these settings who purchase, store, prescribe, dispense, and explain medication to patients for routine off-label use.

Furthermore, "the prescription of drugs for unapproved uses … is *ubiquitous* in certain specialties." *Wash. Legal Foundation*, 202 F.3d at 333 (emphasis added). To give one example, providers in oncology units very 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.[26] As a result, some scholars estimate that 50 to 75 percent of drug use in oncology settings occurs off label.[27] 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.[28]

Salient to the dispute now before this Court, one area where off-label prescribing is

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[25] 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).

[26] *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.

[27] Beck, *supra* note 25, at 25–26 & n.113.

[28] 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).

especially widespread is 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 research, and a lack of financial incentive for the pharmaceutical industry."[29] This lack of data in turn drives a relative paucity of FDA approvals of drugs for pediatric indications[30]—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 the off-label prescription and administration of medications into the FDCA's criminal prohibitions in pursuit of its stated goal of "ending" transgender healthcare threatens an enormous range of medical care in a wide variety of fields. While this subpoena is concerned with transgender healthcare for adolescents, nothing about DOJ's interpretation of the FDCA offers any kind of limiting principle that would cabin its criminalizing effect. Rather, DOJ's efforts to apply the FDCA's criminal provisions concerning distribution and branding to routine off-label prescribing 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 allusions to strict criminal liability. As DOJ notes, the violation of 21 U.S.C. § 331—the criminal provision of the FDCA that, among other things,

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[29] 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.

[30] Lewis A. Grossman, *Criminalizing Transgender Care*, 110 IOWA L. REV. 281, 310 (2024).

[31] Beck & Azari, *supra* note 28, at 80 n.81.

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

addresses the distribution and labeling of drugs and medical devices—"is punished as a strict liability misdemeanor without any proof of criminal intent." ECF No. 1-3 ¶ 19 (citing *U.S. v. Park*, 421 U.S. 658, 672-73 (1975)). Under what is referred to as the *Park* doctrine, this liability is extended to corporate officers. *Park*, 421 U.S. at 672–73. In addressing the particulars of its subpoena to RI Hospital, DOJ in turn references those same strict liability provisions as justifying its request for information on the personnel at RI Hospital responsible for the direction of prescribing and marketing practices. ECF No. 1-3 ¶ 41. The implication is clear: under DOJ's read of the FDCA and the *Park* doctrine, it intends to hold hospital administrators, doctors, and other providers strictly liable for perceived criminal violations of the statute.[33]

Considered together with its expansive view of the distribution and labeling provisions of the FDCA, DOJ's invocation of the *Park* doctrine reflects a shocking threat: the federal government aims to prosecute medical providers and hospital administrators for federal crimes based on their routine prescription and administration of medication and communication with patients about the 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 healthcare across the country. This Court should reject DOJ's efforts to use the cudgel of criminal liability to intimidate the doctors and administrators who provide lawful care to our communities.

[33] Indeed, some critics of the *Park* doctrine "have suggested that the concept of liability for chief executives may become merely a 'hostage' rule under which criminal sanctions against individual executives are used as leverage to exact strict compliance with FDA requirements with a minimal expenditure of government resources." James T. O'Reilly & Katherine A. Van Tassel, eds., 1 *Food and Drug Admin.* § 8:4 (4th ed.) (Westlaw Nov. 2023 update); *see also id.* at § 8:5 (discussing doctrine's "potential for abuse, using criminal threats as leverage to demand extrastatutory remedies").

CONCLUSION

For the foregoing reasons, Amici States respectfully encourage the Court to grant the Child Advocate's Emergency Motion to Quash the subpoena directed to RI Hospital.

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