UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

In re: Department of Justice Administrative Subpoena No. 25-1431-030	Civil Action No. 25-mc-00063-SKC-CYC

BRIEF OF COLORADO, MASSACHUSETTS, CALIFORNIA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, HAWAIʻI, ILLINOIS, MAINE, MARYLAND, MICHIGAN, MINNESOTA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, OREGON, RHODE ISLAND, VERMONT, WASHINGTON, AND WISCONSIN AS AMICUS CURIAE IN SUPPORT OF PETITIONER'S MOTION TO QUASH SUBPOENA

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INTRODUCTION AND STATEMENT OF INTERESTS

Over the summer, the Department of Justice served numerous subpoenas across the country on medical providers, including Children's Hospital Colorado ("Children's Hospital"), that serve no legitimate investigatory purpose, are overly broad, harassing, and intrusive, and undermine the States' sovereign interest to regulate the practice of medicine in their jurisdictions. Accordingly, the States of Colorado, Massachusetts, California, Connecticut, Delaware, District of Columbia, Hawai'i, Illinois, Maine, Maryland, Michigan, Minnesota, Nevada, New Jersey, New Mexico, New York, Oregon, Rhode Island, Vermont, Washington, and Wisconsin ("Amici States") submit this brief in support of Children's Hospital's Motion to Quash. ECF No. 1. Notably, two federal district courts recently quashed similar improper subpoenas issued to other providers as part of DOJ's campaign against gender-affirming care. *See In re Administrative Subpoena No. 25-1431-0019*, 25-mc-91324-MJJ, 2025 WL 2607784 (D. Mass. Sep. 9, 2025), *mot. to alter judgment pending and 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.

The Court should quash the subpoena because it is pretextual and seeks to intimidate medical providers from offering critical, medically necessary health care to transgender youth, a highly vulnerable population in Amici States. The subpoena places medical providers and hospital administrators in the crosshairs of

enforcement mechanisms, including criminal prosecutions, merely for providing essential healthcare. DOJ's baseless attempt to sweep the routine prescription and administration of medications for off-label use into federal criminal prohibitions and civil liability in pursuit of its stated goal of "ending" gender-affirming care in the United States will cause profound disruptions across the entire medical field.

As with the cases filed elsewhere, DOJ now presents to this Court a post hoc and pretextual justification of its invasion into a traditional sphere of state regulation by pointing to the federal Food, Drug, and Cosmetic Act ("FDCA").[1] However, DOJ's interpretation of that statute is exceedingly broad, disruptive, and untethered to 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 here—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 to those who administer a sweeping array of health care. DOJ offers no limiting principle to

[1] DOJ has sought, but has not yet been granted, leave to file additional FDCA-premised arguments. *See* Gov't Mot. for Leave to File Surreply, ECF No. 18. Amici agree with Children's Hospital that this tactic is procedurally improper. *See* Children's Hospital Opp., ECF No. 20. Further, DOJ's extensive and untimely briefing only bolsters the conclusion that its purported justifications are post hoc and pretextual. Nevertheless, in the interest of judicial economy, this brief responds to DOJ's original opposition brief and its proposed surreply.

its argument; if DOJ's interpretation of the FDCA were accepted, entire fields of medicine could see their practitioners at risk of criminal prosecution merely for offering evidence-based treatments in accordance with the prevailing standards of care. If Children's Hospital is forced to comply with this subpoena and DOJ prevails in its interpretation of the FDCA, it would threaten the health and welfare of the people of Colorado 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-affirming medical care.

Amici States are home to preeminent hospitals and medical facilities, like Children's Hospital, that provide essential and life-saving care to thousands of people every year, including, but not limited to, gender-affirming care to individuals under the age of 19. These hospitals are at the forefront of biomedical and technological research on a variety of fronts, 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 gender-affirming health care services and protecting people who lawfully provide or help

others to access such care. In many Amici States' experience and sovereign judgment, 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 gender-affirming care 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 below and by Children's Hospital, Amici States respectfully ask the Court to grant Children's Hospital's 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); *Berman v. Parker*, 348 U.S. 26, 32 (1954); *Hillsborough County v. Automated Med. Lab'ys, Inc.*, 471 U.S. 707, 719 (1985); *see also Anaya v. Crossroads Managed Care Sys., Inc.*, 195 F.3d 584, 590–91 (10th Cir. 1999) (citing *Pino v. Higgs*, 75 F.3d 1461, 1467 (10th Cir. 1996) and *Keystone Bituminous Coal Ass'n v. DeBenedictis*, 480 U.S. 470, 479, 503 (1987)).

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 (proposed 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.[2] 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."[3] Since at least 1889, the authority to regulate the practice of medicine has been among these powers.[4] 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. 243, 269–70 (2006) (holding that Controlled Substances Act could not prohibit Oregon doctors from prescribing medication for the purpose of medical aid in dying, consistent with care enacted through state ballot measure). In keeping

[2] U.S. Const. amend. X.

[3] 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").

[4] *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").

with the states' sovereign authority, 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."[5]

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.[6] Since 1895, all states have boards that oversee the licensing of medical professionals.[7] 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

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[5] 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 (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'" (citing *Medtronic*, 518 U.S. at 485)).

[6] Zettler, *supra* note 4, at 449–50 (citing Robert I. Field, *Health Care Regulation in America: Complexity, Confrontation, and Compromise* 19 (2007) (the "cornerstone" of medical practice regulation is states' licensing schemes).

[7] Robert C. Derbyshire, *Medical Licensing and Discipline in the United States* 8 (1969); Zettler, *supra* note 5, at 450; *see also* , *Contact a State Medical Board*, Fed'n of State Med. Bds., https://www.fsmb.org/contact-a-state-medical-board (last visited on Dec. 1, 2025) (on file with the Colorado Attorney General's Office).

examination.[8] Additional requirements may include interviews, a documented lack of criminal history, and medical malpractice insurance coverage.[9] 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.[10]

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 discrimination, many Amici have enacted civil rights protections for transgender people in education, employment, health care, housing, public accommodations, and other parts of public life.[11] They have also taken steps to safeguard access to

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[8] Zettler, *supra* note 4, at 450 (citing Nadia N. Sawicki, *Character, Competence and the Principles of Medical Discipline*, 13 Health Care L. & Pol'y 285, 290 (2010).

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

[10] *Id.* at 450–52.

[11] *See, e.g.*, Colo. Rev. Stat. §§ 24-34-402, 24-34-502, 24-34-601; 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; 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. Civ. Rights Law § 40-c; N.Y. Comp. Codes R. & Regs. tit.

gender-affirming care for transgender people, exercising their sovereign judgment that such safeguards promote public health and wellbeing. For instance, Colorado and many other Amici States expressly recognize a legal right to gender-affirming care and have enacted laws intended to protect people 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.[12] Many Amici also cover gender-affirming care through their State Medicaid programs,[13] and they prohibit State-regulated

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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; Wash. Rev. Code §§ 49.60.030(1), 49.60.040(2), 49.60.040(29), 49.60.215.

[12] *See, e.g.*, Colo. Rev. Stat. §§ 10-16-121(1)(f), 12-30-121, 13-21-133, 16-3-102, 16-3-301; 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; 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 Shield Laws for Reproductive and Gender-Affirming Health Care: A State Law Guide*, UCLA Sch. of Law Williams Inst., https://williamsinstitute.law.ucla.edu/publications/shield-laws-fact-sheets (Aug. 2024) (on file with the Colorado Attorney General's Office).

[13] *See, e.g.*, Colo. Rev. Stat. § 10-16-104(30)(b), (d); Seth Klamann *Amid federal restrictions, Colorado Law Now Enshrines Access to Gender-Affirming Care*, Denver Post (May 23, 2025), https://www.denverpost.com/2025/05/23/colorado-gender-affirming-care-jared-polis/ (on file with the Colorado Attorney General's Office); *Gender-Affirming Care Covered by MassHealth*, Mass Health, https://www.mass.gov/info-details/gender-affirming-care-covered-by-masshealth (last visited on Dec. 1, 2025) (on file with the Colorado Attorney General's Office); Md. Code Ann., Health-Gen. § 15-151; 89 Ill. Adm. Code

health insurance plans from withholding coverage from individuals based on their gender identity or gender dysphoria, ensuring that these residents enjoy the same access to medically necessary treatment as residents who are not transgender.[14]

Similarly, many Amici States have enacted laws that exclude the provision of gender-affirming care 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 gender-affirming care.[15] Other Amici States, meanwhile, mandate training for health care

§§ 140.413(a)(16), 140.440(h); Minn. Stat. § 256B.0625, subd. 3a; Nev. Medicaid Servs. Manual § 608 (July 29, 2025), https://bit.ly/NVMedicaid; R.I. Gender Dysphoria/Gender Nonconformity Coverage Guidelines (Oct. 28, 2015), https://bit.ly/RI-Guidelines.

[14] *See, e.g.*, 3 Code Colo. Regs. §702-4, Reg. 4-2-42, §5(A)(1)(o); Mass. Gen. Laws ch. 272, §§92A, 98; Cal. Code Regs. tit. 10 §2561.2, subd. (a) (2012); 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 (Sep. 9, 2021), https://coag.gov/app/uploads/2025/12/Mass-Bulletin-2021-11.pdf; 2014-03 (June 20, 2014), https://coag.gov/app/uploads/2025/12/Mass-Bulletin-2014-3.pdf; R.I. Health Ins. Bull. 2015-03, https://bit.ly/RI-2015-03.

[15] *See, e.g.,* Colo. Rev. Stat. § 12-30-121; 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; 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.

professionals to ensure that patients who identify as transgender, gender diverse, and intersex receive trans-inclusive care.[16]

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 health care. In the experience of many Amici States, these laws and policies are essential to address long-standing inequities in the health care 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 Children's Hospital is to end gender-affirming care for adolescents. *See* Mot. to Quash, ECF No. 1 at 10–11. 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 make express the "policy goal" of the Executive Branch to harm a politically disfavored minority. *See In re Boston Children's Hospital Subpoena*, 2025 WL 2607784 at *7 ("It is abundantly clear that the true purpose of issuing the subpoena

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

is to interfere with the Commonwealth of Massachusetts' right to protect [gender-affirming care] 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 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. This broadside attack, though here brought by DOJ in the context of gender-affirming care, if allowed to go forward, would undermine 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,[17] 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 such off-label use of 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

[17] *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)).

limited to the narrow space of gender-affirming care, DOJ's interpretation of the FDCA would have widespread and disastrous implications across the field of medicine (with particularly significant harms in 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.

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. The FDA evaluates the drugs' safety and efficacy through premarket approval.[18] Premarket approval is a multistep process, involving multiple applications and stepped authorizations, that results in approval of a drug to be marketed and sold for a particular indication (use) in a specific population.[19] FDA approval also includes an approved drug label, which summarizes "the evidence supporting the safe and effective use of the drug."[20]

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

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

[19] Abbott & Ayres, *supra* note 18, at 384.

[20] Abbott & Ayres, *supra* note 18, at 384–85.

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 matter, once a drug is approved, physicians may *prescribe* the drug without restriction."[21] The FDA itself has repeatedly made public statements to this effect,[22] including as recently as this year,[23] and its own website says that once the agency "approves a drug, healthcare providers generally may prescribe the drug for an unapproved use when they judge that it is medically appropriate for their patient."[24] Courts also routinely recognize that the FDCA permits doctors to

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[21] Abbott & Ayres, *supra* note 18, at 387 (2014) (emphasis added); 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").

[22] *See, e.g.*, Abbott & Ayres, *supra* note 18, at 387 n.32 (quoting *Promotion of Unapproved Drugs and Medical Devices, Testimony Before the S. Comm. on Labor and Human Res.*, 104th Cong. 1 (1996) (statement of William B. Schultz, Deputy Comm'r for Policy, Food & Drug Admin.) ("The legislative history of the [FDCA] 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.").

[23] *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://coag.gov/app/uploads/2025/12/Unapproved-Uses-QA.pdf (acknowledging various circumstances in which health care providers may validly prescribe drugs for off-label use).

[24] FDA, *Understanding Unapproved Use of Approved Drugs "Off Label"* (Feb. 5, 2018), https://www.fda.gov/patients/learn-about-expanded-access-and-other-

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) ("[I]t 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 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 ("OLC") concurs, writing that "[a]s a general matter, [the] FDA does not regulate the practice of medicine, which includes 'off-label' prescribing."[25] As a result, off-label usage of drugs and devices is a well-settled part of the practice of medicine, particularly in 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.

In its proposed surreply papers, DOJ admits, as it must, that it is "possible" for physicians "to prescribe an FDA-approved drug for an unapproved use" but

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treatment-options/understanding-unapproved-use-approved-drugs-label (on file with the Colorado Attorney General's Office).

[25] Whether the Food & Drug Administration Has Jurisdiction Over Articles Intended for Use in Lawful Executions, 43 Op. O.L.C. 81, 85 (2019).

nevertheless maintains that "prescriptions for unapproved uses may involve violations of the FDCA." Proposed Hsiao Decl. ¶ 12.[26] The limitations of this argument become evident in the examples that follow, however, where the DOJ improperly characterizes the lawful practice of a clinician prescribing and communicating about FDA-approved drugs for off-label uses as violations 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, would have broad implications far beyond the administration of gender-affirming care.

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, multistep interpretation of the

[26] DOJ's motion for leave to file appends as Exhibit A its proposed surreply (ECF No. 18-1), which itself contains multiple embedded documents. Exhibit A-1 to ECF No. 18-1 is the District of Massachusetts order quashing the subpoena issued to Boston Children's Hospital. ECF No. 18-1 at pp. 18–31. Exhibit A-2 contains the government's memorandum in support of a motion to alter that ruling (ECF No. 18-1 at pp. 33–46), as well as a declaration from Lisa K. Hsiao that was submitted in support (ECF No. 18-1 at pp. 47–62). And finally, Exhibit A-3 is a new declaration from Ms. Hsiao submitted in support of the proposed surreply now before this Court. ECF No. 18-1 at pp. 63–84. Because the two Hsiao declarations differ in some respects, the remaining discussion cites to the most recent declaration as the "Proposed Hsiao Decl."

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 indication is unlawful"; *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"; *third*, that "distribution for that unapproved indication violates the FDCA and is a federal crime"; and *finally*, that health care providers who "purchase, store, and administer the drug . . . [are] in the chain of distribution of that drug." Proposed Hsiao Decl. ¶¶ 22–23. 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," Proposed Hsiao Decl. ¶ 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, Proposed Hsiao Decl. ¶ 23, within the meaning of the FDCA. The suggestion that FDCA liability attaches to anyone who administers an approved device for an off-label but medically indicated purpose is thus 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); *Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1344 (10th Cir. 2015) (stating in reference to off-label protections in the FDCA, "Congress added this language aware that experiments with off-label uses often prove vital to patients and wary about granting the federal government the power to deny doctors and patients the freedom to use approved devices in any way they think might help improve health or extend life."). 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 contravenes 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.[27] 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."); *Caplinger*, 784 F.3d at 1344. Indeed, the DOJ Office of Legal Counsel has noted that the FDCA's prohibitions on distribution generally are not applicable to providers, observing that "while the FDCA bars a

[27] 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, *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 (on file with the Colorado Attorney General's Office).

manufacturer or distributor from selling any drug or device for an unapproved use, physicians may, with limited exceptions, prescribe and administer FDA-approved drugs and devices for unapproved uses."[28]

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 health care providers.[29]

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[28] 43 Op. O.L.C. at 85..

[29] *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, *supra* note 23, at 8–9 (acknowledging various circumstances in which health care 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.

Yet DOJ now 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. Proposed Hsiao Decl. ¶¶ 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.* ¶ 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.[30]

The construction adopted by DOJ in this matter thus 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 secured liability to a practitioner in the circumstances here—that is,

[30] DOJ specifically suggests that statements on Children's Hospital's websites about the effects of puberty blockers "could be considered 'labeling' in certain circumstances, which could form the basis of [a] federal healthcare offense" under the FDCA. Proposed Surreply at 10.

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. Such a broadening of the scope of the FDCA would insert the government into the exam room to regulate conversations between providers and their patients about possible treatment options. Not only does this 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 misbranding—would have devastating and far-reaching effects far beyond the narrow field of gender-affirming care. Recent estimates suggest that between 20 and 50 percent of all prescriptions are for off-

label indications.[31] Providers in all medical fields regularly purchase and administer drugs at their place of practice: in hospitals, 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 providers, such as chemotherapy ports, knee replacements, or 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 Found.*, 202 F.3d at 333. 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.[32] As a result, some scholars estimate that 50 to 75 percent of drug use in oncology settings occurs off label.[33] Over time, other fields where off-label use of drugs and

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[31] 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).

[32] *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 (on file with the Colorado Attorney General's Office).

[33] Beck, *supra* note 30, at 25–26 & n.113.

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.[34]

Salient to the dispute now before this Court, one area where off-label prescribing is 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."[35] This lack of data in turn drives a relative paucity of FDA approvals of drugs for pediatric indications[36]—indeed, many drugs carry a so-called "orphaning clause" disclaimer as to pediatric use in light of the absence of sufficient studies.[37] Some studies estimate that as much as 80 percent of drugs prescribed for children are prescribed for off-label uses.[38]

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[34] 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).

[35] 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), https://pmc.ncbi.nlm.nih.gov/articles/PMC6677268/; *see also* FDA, *Pediatric Ethics* (Jan. 16, 2024), https://www.fda.gov/science-research/pediatrics/pediatric-ethics (on file with the Colorado Attorney General's Office); Additional Safeguards for Children in Clinical Investigations of FDA-Regulated Products, 66 Fed. Reg. 20589 (Apr. 14, 2001).

[36] Lewis A. Grossman, *Criminalizing Transgender Care*, 110 Iowa L. Rev. 281, 310 (2024).

[37] Beck & Azari, *supra* note 33, at 80 n.81.

[38] Beck, *supra* note 30, at 25–26 & n.114.

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" gender-affirming care threatens an enormous range of medical care in a wide variety of fields. While this subpoena is concerned with gender-affirming care 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 DOJ's allusions to 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 distribution and labeling of drugs and medical devices—"is punished as a strict liability misdemeanor without any proof of criminal intent." Proposed Hsiao Decl. ¶ 19 (citing *United States 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 subpoenas, DOJ in turn references those same strict liability provisions as justifying its request for information on hospital personnel responsible for the direction of prescribing and marketing practices. Proposed Hsiao Decl. ¶ 43. The implication is clear: under DOJ's reading 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.[39]

Considered together with its expansive view of the FDCA, DOJ's invocation of the *Park* doctrine reads like a 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 health care 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 for our communities.

CONCLUSION

For the foregoing reasons, Amici States respectfully encourage the Court to grant Children's Hospital's Motion to Quash.

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[39] 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.) (Nov. 2023 update); *see also id.* at § 8:5 (discussing doctrine's "potential for abuse, using criminal threats as leverage to demand extrastatutory remedies").

Dated: December 4, 2025

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