EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

IN RE: 2025 UPMC SUBPOENA	Civil Action No. 2:25-mc-01069-CB

BRIEF OF GOVERNOR JOSH SHAPIRO, MASSACHUSETTS, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, THE DISTRICT OF COLUMBIA, ILLINOIS, MARYLAND, MINNESOTA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, RHODE ISLAND, OREGON, VERMONT, WASHINGTON, AND WISCONSIN AS AMICI CURIAE IN OPPOSITION TO "ANONYMIZED" PRODUCTIONS OF PATIENT RECORDS

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INTRODUCTION AND STATEMENT OF INTERESTS

On December 24, 2025, this Court quashed provisions of a subpoena seeking from UPMC "minor patients' personal information, including their names, addresses, social security numbers and complete medical and psychological records," on multiple grounds: that the U.S. Department of Justice lacks statutory authority to compel UPMC to produce any patient data; that patient privacy interests far outweigh DOJ's stated needs; that DOJ's investigation "tramples on the Commonwealth of Pennsylvania's power to police, and legislate, matters of medical care"; and that DOJ's demand for these records "carries more than a whiff of ill-intent." Doc. 52 (incorporating by reference *In re Subpoena No. 25-1431-014*, No. MC 25-39, 2025 WL 3252648 (E.D. Pa. Nov. 21, 2025) ("*In re CHOP Subpoena*")).

Pennsylvania Governor Josh Shapiro, Massachusetts, California, Colorado, Connecticut, Delaware, the District of Columbia, Illinois, Maryland, Minnesota, Nevada, New Jersey, New Mexico, New York, Oregon, Rhode Island, Vermont, Washington, and Wisconsin (Amici) submit this brief in opposition to the motion by DOJ offering to accept an undefined production of purportedly "anonymized" patient records under this same deficient subpoena (Doc. 47). Amici are home to hospitals, such as UPMC, that have provided essential and life-saving care to thousands of people every year, including gender-affirming care 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, including by creating jobs, spurring innovation, improving residents' health, and training the future workforce.

As this Court and courts around the country have already recognized, the subpoena demands highly confidential patient information without legal authority and with questionable

motives.[1] These flaws are not cured by permitting an undefined and purportedly "anonymized" production about a small class of minor patients receiving specialized medical care who have been the subject of significant targeting and discrimination by government actors and the public more broadly. *See* Doc. 52 at 3-5. Medical records contain a wealth of identifying information (well beyond a name or address), and DOJ provides no reason to believe that the records it is willing to accept would not identify (or re-identify) these individual patients and their families.

Accepting DOJ's request and enforcing the subpoena here would allow the government to interfere with the doctor-patient relationship and to erode the confidence patients have that their medical records will be kept private. It would intimidate medical providers from offering critical, medically necessary health care. And it would rest on a flawed legal justification that would intrude on the States' authority to regulate the practice of medicine within their borders. This would place medical providers and hospital administrators in the crosshairs of civil and criminal enforcement mechanisms, including prosecutions, merely for providing essential health care. DOJ's baseless attempt to sweep the routine prescription and administration of medications for off-label use into federal criminal prohibitions, all in pursuit of its stated goal of ending gender-affirming care, will cause profound disruptions across the entire medical field.

As this Court has also recognized, Pennsylvania and 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. But for these efforts

[1] Doc 52; *In re: Dep't of Just. Admin. Subpoena No. 25-1431-030*, No. MC 25-63, 2026 WL 33398, at *3-11 (D. Colo. Jan. 5, 2026) ("*In re Children's Hospital Colorado Subpoena*") (report and recommendation of U.S. Magistrate Judge); *In re CHOP Subpoena*, 2025 WL 3252648, at *10-19, 33-34; *QueerDoc, PLLC v. U.S. Dep't of Just.*, No. MC 25-42, 2025 WL 3013568, at *4-7 (W.D. Wash. Oct. 27, 2025); *In re Admin. Subpoena No. 25-1431-019*, 800 F. Supp. 3d 229, 236-39 (D. Mass. 2025) ("*In re Boston Children's Hospital Subpoena*"); *In re Subpoena Duces Tecum No. 25-1431-016*, No. MC 25-41, 2025 WL 3562151, at *5-13 (W.D. Wash. Sept. 3, 2025) ("*In re Seattle Children's Hospital Subpoena*").

to succeed, patients must have confidence that their private medical records will be kept confidential. Such confidence is essential to protecting the doctor-patient relationship. Permitting DOJ to demand the confidential health information of hundreds of patients based on manufactured justifications would erode the trust between doctors and patients and undermine state efforts to use their regulatory authority to protect that trust.

In its briefing in this matter and related matters across the country, DOJ has attempted to justify its invasion of this traditional sphere of state regulation by citing the federal Food, Drug, and Cosmetic Act (FDCA). But its interpretation of that statute is exceedingly broad, disruptive, and untethered to precedent and practice—and a purportedly "anonymized" production of these patients' records does not correct these errors. DOJ's interpretation conflicts with decades of settled caselaw concerning medical providers' *use* of approved medications for off-label purposes—something that the statute has never been understood to reach. Moreover, DOJ's suggestion—that the FDCA's prohibitions about off-label drugs should be applied to 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: if its interpretation of the FDCA were accepted, entire fields of medicine could see their practitioners at risk of criminal conviction merely for offering evidence-based treatments in accordance with the prevailing standards of care. If UPMC 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 Pennsylvania and other Amici, impede core economic activities of Amici, and encroach on the States' traditional role as the regulators of medicine.

For the reasons advanced below and by the UPMC patient movants, the Court should not permit DOJ to use this subpoena to acquire supposedly "anonymized" patient records.

ARGUMENT

I. Production of patient records under the subpoena would harm the inherent privacy rights of Amici's residents.

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). Underpinning the common welfare is the right to privacy. As Pennsylvania Supreme Court Justice Musmanno said, of "all the precious privileges and prerogatives in the crown of happiness which every American citizen has the right to wear, none shines with greater luster and imparts more innate satisfaction and soulful contentment to the wearer than the golden, diamond-studded right to be let alone." *Commonwealth v. Murray*, 223 A.2d 102, 109 (Pa. 1966) (plurality).

DOJ's subpoena demands that UPMC disclose five years of highly sensitive medical records and personally identifying information about adolescent patients and their families. DOJ cannot dispute that these records "contain intimate facts of a personal nature." *See United States v. Westinghouse Elec. Corp.*, 638 F.2d 570, 577 (3d Cir. 1980). Nor can DOJ dispute that the requested records are the product of the relationship between patient and physician, provided under expectation of confidentiality and in furtherance of personalized medical care. *E.g.*, *Haddad v. Gopal*, 787 A.2d 975, 981 (Pa. Super. 2001) ("Doctors have an obligation to their patients to keep communications, diagnosis, and treatment completely confidential."); 28 Pa. Code § 115.27.

Notwithstanding its absence of statutory authority, Doc. 52 at 2 (incorporating by reference *In re CHOP Subpoena*, 2025 WL 3252648 at *10-19); *see infra* Part III, DOJ now requests "anonymized" (or "redacted") patient records, Doc. 47. Other than noting that it wants the patient's age or year of birth, DOJ offers no explanation about the kind of anonymization or redaction it

expects or how such anonymization or redaction would truly protect these patients' privacy. *Id.* n.1. The records DOJ seeks contain highly sensitive and personal information about patients and their families that cannot be de-identified simply by excluding the patient's name, address, or Social Security number. *See, e.g.*, U.S. HHS Office of Civil Rights, *Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule*, at 12-18, 26-28 (Nov. 26, 2012) (discussing the many context-specific considerations involved with de-identifying medical records under HIPAA, where "de-identifying" means having no reasonable basis to believe that the information can be used to identify an individual).[2] DOJ's failure is particularly stark here because they seek medical records about a small class of patients receiving specialized medical care who have been the subject of significant targeting and discrimination by government actors and the public more broadly. *See* Doc. 52 at 3-5. DOJ's request, therefore, provides no basis to believe that whatever records it is willing to accept could not be used to identify (or re-identify) individual patients and their families.

As this Court recognized, Doc. 52 at 5, it must "weigh[] competing interests" to determine whether such an extraordinary intrusion into individual privacy and the doctor-patient relationship is "justified." *Westinghouse*, 638 F.2d at 578. Pennsylvania's constitutional privacy protections, found in Article I of its Constitution, reflect a centuries-old common understanding that privacy rights are inherent and underscore why the balance tips sharply in favor of rejecting DOJ's request.

The right to privacy is the "most prominent" right secured by Article I of the Pennsylvania Constitution. *Allegheny Reprod. Health Ctr. v. Pa. Dep't of Hum. Servs.*, 309 A.3d 808, 899 (Pa.

[2] https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/coveredentities/De-identification/hhs_deid_guidance.pdf. While HIPAA is not the applicable standard, this guidance is illustrative of the complexity of de-identifying medical records.

2024) (plurality). Pennsylvania courts readily agree that the rights protected by Article I of the Pennsylvania Constitution are "inherent to mankind"—that is, "secured rather than bestowed by the Constitution." *Driscoll v. Corbett*, 69 A.3d 197, 208-09 (Pa. 2013) (discussing how the Pennsylvania Constitution of 1776 was drafted by adherents of natural law philosophers). These inherent rights are "an enumeration of the fundamental human rights possessed by the people of this Commonwealth that are specifically exempted from the powers of Commonwealth government to diminish." *Allegheny Reprod.*, 309 A.3d at 898 (quoting *League of Women Voters v. Commonwealth*, 178 A.3d 737, 803 (Pa. 2018)).

There are at least three components of the right to privacy. *See generally Allegheny Reprod.*, 309 A.3d at 900-05 (summarizing development of privacy jurisprudence). First is "the interest in avoiding disclosure of personal matters," also known as the right to informational privacy, which protects (among other things) "names, addresses, social security numbers, and telephone numbers." *Id.* at 902-03; *see, e.g.*, *Pa. State Educ. Ass'n v. Commonwealth Dep't of Cmty. & Econ. Dev.*, 148 A.3d 142, 158 (Pa. 2016); *Denoncourt v. State Ethics Commission*, 470 A.2d 945, 947-48 (Pa. 1983) (plurality). Second is the "interest in having independence to make certain kinds of important decisions." *Allegheny Reprod.*, 309 A.3d at 900; *see, e.g.*, *Whalen v. Roe*, 429 U.S. 589, 599-600 & n.26 (1977); *Coleman v. W.C.A.B.*, 842 A.2d 349, 354 (Pa. 2004) (linking the common law "right to be free of bodily invasion and to refuse medical treatment" with the "privacy interest in preserving [] bodily integrity"); *Stenger v. Lehigh Valley Hosp. Ctr.*, 609 A.2d 796, 800 (Pa. 1992) (citing *Whalen*); *Denoncourt*, 470 A.2d at 947-48 (same). And third is the "freedom from government intrusion into an individual's bodily integrity." *Allegheny Reprod.*, 309 A.3d at 904-05; *see, e.g.*, *John M. v. Paula T.*, 571 A.2d 1380, 1386 (Pa. 1990).

Information revealed through the doctor-patient relationship implicates all three components: it concerns deeply personal and sensitive topics; it is provided by patients for the purpose of receiving medical advice and making informed decisions about physical and behavioral health needs; and it is derived directly from the patient's physical body.

As a result, courts have long recognized that the right to privacy covers medical records and health information. *See, e.g.*, *Westinghouse*, 638 F.2d at 577 (acknowledging widespread "recognition that information concerning one's body has a special character" that is "well within the ambit of materials entitled to privacy protection"); *Allegheny Reprod.*, 309 A.3d at 906 ("The right to make healthcare decisions related to reproduction is a core important right encompassed by the enmeshed privacy interest protected by our Charter."); *Commonwealth v. Shaw*, 770 A.2d 295, 299 (Pa. 2001) ("The right to privacy extends to medical records of patients."); *Stenger*, 609 A.2d at 800 (in matter involving discovery and records related to blood donation, recognizing that the "well-settled" right of privacy requires the Court "to avoid unjustified intrusions into the private zone of our citizens' lives"); *In re June 1979 Allegheny Cnty. Investigating Grand Jury*, 415 A.2d 73, 77-78 (Pa. 1980) ("Disclosure of confidences made by a patient to a physician, or even of medical data concerning the individual patient could, under certain circumstances, pose such a serious threat to a patient's right not to have personal matters revealed that it would be impermissible under either the United States Constitution or the Pennsylvania Constitution."); *In re "B,"* 394 A.2d 419, 425 (Pa. 1978) (plurality) ("in Pennsylvania … [a] patient's right to prevent disclosure" of sensitive medical information "is constitutionally based").

If enforced, DOJ's request for an undefined tranche of medical records (in the face of significant targeting by government actors and the public) would harm the innate privacy rights minor patients and their families have in their medical records and personal health information—

and ultimately, the privacy rights of all residents in Amici states. Even without the obvious identifiers, DOJ asks this Court to allow an extraordinary intrusion into core health information: documents related to patient intake and to "the clinical indications, diagnoses, or assessments," among other items. But as this Court has already recognized, Doc. 52 at 2 (incorporating by reference *In re CHOP Subpoena*, 2025 WL 3252648 at *30-32), DOJ has offered no credible "need for access" to this deeply personal and sensitive information, *Westinghouse*, 638 F.2d at 578, which could be used to further target these individuals. Instead, as explained below, the subpoena is properly seen as a fishing expedition to substantiate a specious legal theory that would both intrude on rights reserved to the States under the Tenth Amendment and jeopardize the entire practice of medicine.

II. Production of patient records under the subpoena's legal theory would interfere with Amici's authority to regulate the practice of medicine.

As this Court has already recognized, DOJ's investigation into UPMC "tramples the Commonwealth of Pennsylvania's power to police, and legislate, matters of medical care." Doc. 52 at 3. This remains true even if these patient records could be wholly anonymized with no possibility of re-identification.

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." *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 among these powers. *Dent v. West Virginia*, 129 U.S. 114, 122 (1889); *accord* Doc. 52 at 3. Though Congress may regulate

interstate commerce, the Executive may not distort the meaning of federal statutes 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 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."[3]

To avoid encroaching on the practice of medicine, federal agencies, including the Food and Drug Administration, have historically recognized that the FDCA does not regulate the off-label use of 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); *infra* Part III.

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

[3] 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").

[4] Zettler, *supra* note 3, 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)).

that oversee the licensing of medical professionals.[5] Fundamental and consistent requirements for obtaining a medical license across states include graduation from an accredited medical school, completing one or more years of residency or fellowship, and passing a licensing examination.[6] Additional requirements may include interviews, a documented lack of criminal history, and medical malpractice insurance coverage.[7]

In Pennsylvania, the State Boards of Medicine and Osteopathic Medicine are responsible for the licensure, regulation, and discipline of medical and osteopathic physicians and certain other health professionals in the Commonwealth. *See* 63 P.S. §§ 422.1-422.51a; *id.* §§ 271.1-271.19. Medical and osteopathic physicians must be licensed to engage in the practice of medicine in Pennsylvania. *See id.* §§ 422.28, 442.10; *id.* § 271.3. They must meet minimum qualifications for licensure, including education, training, and examination requirements. *See id.* § 422.22; *id.* § 271.6. The Boards seek to ensure that physicians deliver competent, ethical, and legally compliant care throughout the Commonwealth.

To further these duties, the State Board of Medicine is specifically empowered to adopt regulations that "define the accepted standard of care" for the profession. *Id.* § 422.41(8)(ii). Where the Board has not adopted an applicable regulation, the relevant standard of care is "that which would be normally exercised by the average professional of the same kind in [the] Commonwealth under the circumstances." *Id.* The Boards are authorized to discipline any licensed doctor who "provides a medical service at a level beneath the accepted standard of care" or engages

[5] ROBERT C. DERBYSHIRE, MEDICAL LICENSING AND DISCIPLINE IN THE UNITED STATES 8 (1969); Zettler, *supra* note 3, 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.

[6] Zettler, *supra* note 3, at 450 (citing Nadia N. Sawicki, *Character, Competence and the Principles of Medical Discipline*, 13 HEALTH CARE L. & POL'Y 285, 290 (2010)).

[7] Zettler, *supra* note 3, at 450.

in "incompetence, gross negligence, or repeated acts of negligence or incompetence in the practice of medicine or surgery." *Id.* § 422.41; *id.* § 271.15; 49 Pa. Code § 16.61.

Thus, it is the responsibility of these licensing boards—and not the federal government—to determine whether physicians have engaged in conduct that is inconsistent with the standard of care. Doc. 52 at 3. And in making this assessment, the boards look to the practice of medicine in the Commonwealth, rather than dictates from a federal agency. Yet the subpoena rests on a misguided theory that would allow DOJ to dictate the medical standard of care in every state based on its own tortured reading of the FDCA. *See infra* Part III. Such a theory would have sweeping implications beyond gender-affirming care; among others, it would threaten physicians across the country with criminal prosecution for providing care that is entirely permissible in their home state and, in their clinical judgment, in the best interest of their patients.

2. In Pennsylvania—and in all Amici states—gender-affirming care remains legal and accessible. Pennsylvania's licensing boards have never determined that gender-affirming care that is consistent with the standard of care in the Commonwealth is inappropriate in any way. Likewise, the off-label prescription of medicine is permissible, so long as it is done consistently with the appropriate standard of care.

Other states have taken more formal steps to safeguard access to gender-affirming care for transgender people, exercising their sovereign judgment that such safeguards promote public health and wellbeing. For instance, Massachusetts and many other Amici 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.[8] Some State licensing boards—such as the Boards of Registration in Medicine and in Nursing in Massachusetts—also instruct licensees that they shall not withhold or deny care based on a patient's gender identity.[9]

For these reasons, even if the medical records of this targeted community could be de-identified, the subpoena's legal theory and DOJ's investigation still threaten all states' ability to regulate the practice of medicine. It is part of an effort to end a specific type of care for a particularly vulnerable population, even though there is no federal law prohibiting such care. DOJ's sweeping requests for sensitive information—including records of all patients who have received gender-affirming care—is an extraordinary attempt to subvert the policy and judgment of the states as the traditional regulators of the practice of medicine. The broadside attack by DOJ undermines the States' sovereign authority in protecting the health and safety of our residents.

III. DOJ's pretextual interpretation of the FDCA cannot justify the production of patient records, even anonymized.

In its briefing in this matter and related matters across the country, DOJ justifies its subpoena through a novel and unreasonable interpretation of the FDCA. Contrary to established practice and precedent,[10] DOJ now interprets the FDCA to regulate the practice of medicine. It

[8] *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.*; Md. Code Ann., State Pers. & Pens. § 2-312; Minn. Stat. § 260.925; N.Y. Exec. Law § 837-x; N.Y. Comp. Codes R. & Regs. tit. 10, § 405.7(c)(2); Or. Rev. Stat. §§ 15.430, 24.500, 414.769, 435.210, 435.240; Vt. Stat. Ann. tit. 12, § 7301 *et seq.*; 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.

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

[10] *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."); *see, e.g.*, *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."); Steven A. Engel, *Whether the Food & Drug*

does so by reading 21 U.S.C. § 331(a) and (d) to cover both the routine administration of approved drugs for off-label purposes and communications 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: 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 health care providers and their patients about the medications they receive.

In the last several months, this novel reading of federal statutes has been consistently recognized for what it is: an unlawful attempt to harass and intimidate providers of gender-affirming care. *See supra* note 1. Offering to accept "anonymized" patient records cannot (and does not) create authority where it does not exist.

A. Production of "anonymized" records cannot cure a subpoena issued without statutory authority and for an improper purpose.

This Court and courts across the country have found that DOJ's legal theory, *infra* Part III.B-D, does not give it statutory authority to obtain patient records. Doc. 52 at 2 (incorporating by reference *In re CHOP Subpoena*, 2025 WL 3252648 at *10-19); *see also In re Seattle Children's Hospital Subpoena*, 2025 WL 3562151, at *4-9; *In re Boston Children's Hospital Subpoena*, 800 F. Supp. 3d at 237-38; *QueerDoc*, 2025 WL 3013568, at *6. To sidestep the issue of its overreach, DOJ now suggests that it will accept "anonymized" patient records. Even if such anonymization were possible, a modest narrowing of scope is irrelevant where DOJ seeks information beyond the authority granted to it by Congress. DOJ's attempts to end gender-

Administration Has Jurisdiction Over Articles Intended for Use in Lawful Executions, 43 Op. O.L.C. 81, 85 (2019) ("As a general matter, [the] FDA does not regulate the practice of medicine, which includes 'off-label' prescribing.").

affirming care in the States through civil investigation subpoenas clearly fall beyond the bounds of its statutory authority under the FDCA. *Ibid*.; *see infra* Part III.B-D. This alone ends the inquiry.

Nor can anonymization cure an improper purpose. *See Westinghouse*, 788 F.2d 164 at 166-67 ("[I]f a subpoena is issued for an improper purpose, such as harassment, its enforcement constitutes an abuse of the court's process."). This Court joined a chorus of federal courts in finding that the subpoena at issue goes so far beyond the scope of the FDCA as to "carr[y] more than a whiff of ill-intent." Doc. 52, at 3; *see also In re Seattle Children's Hospital Subpoena*, 2025 WL 3562151, at *10-13 (holding that subpoena issues for "improper purpose" where it exceeds statutory authority to investigate); *In re Boston Children's Hospital Subpoena*, 800 F. Supp. 3d at 239 (holding that it was "abundantly clear" subpoena was designed to "harass and intimidate" providers and "motivated only by bad faith"); *QueerDoc*, 2025 WL 3013568, at *7 (finding that subpoena issued to telehealth providers "serves to pressure providers to cease offering gender-affirming care rather than to investigate specific unlawful conduct"); *In re CHOP Subpoena*, 2025 WL 3252648, at *34 (holding that DOJ had no authority to seek confidential patient information under FDCA and, in any event, the patients' privacy interests "far outweigh" DOJ's need for information requested); *In re Children's Hospital Colorado Subpoena*, 2026 WL 33398, at *11 (finding that subpoena was "no faithful execution of the law," but issued for improper purpose of ending gender-affirming care).

The overwhelming contextual evidence "paints a compelling picture illustrating that the government's aim is not actually to investigate FDCA violations, but to use the FDCA as a smokescreen for its true objective of pressuring pediatric hospitals into ending gender-affirming care through commencing vague, suspicionless 'investigations.'" *In re Children's Hospital Colorado Subpoena*, 2026 WL 33398, at *7. Enforcing this subpoena, even with purportedly

"anonymized" data, would permit the federal courts to be a tool of intimidation and harassment and allow an executive agency to act beyond its statutory authority to interfere with the rights of States to regulate the practice of medicine. This Court should not countenance such an abuse of its process.

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

The FDA has regulatory authority to 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.[11] 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.[12] 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."[13]

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," but 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 restriction."[14]

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

[12] Abbott & Ayres, *supra* note 11, at 384.

[13] Abbott & Ayres, *supra* note 11, at 384-85.

[14] Abbott & Ayres, *supra* note 11, at 387; *see also Buckman*, 531 U.S. at 350 (explaining that "off-label" use of medical *devices* "is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine").

The FDA itself has repeatedly made public statements to this effect,[15] including as recently as this year,[16] and its own website specifically says that once the agency "approves a drug, health care providers generally may prescribe the drug for unapproved use when they judge that it is medically appropriate for their patient."[17] Courts also routinely recognize that the FDCA permits doctors to prescribe medications off label. *See, e.g.*, *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."); *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."); *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."[18]

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[15] *See, e.g.*, Abbott & Ayres, *supra* note 11, at 387 n.32 (quoting *Promotion of Unapproved Drugs and Medical Devices, Testimony Before e 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.")).

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

[17] 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.

[18] 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).

As a result, off-label usage of drugs and devices is an important part of the practice of medicine, particularly in fields such as pediatrics and oncology. *See infra* Part III.D.

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

DOJ admits, as it must, that physicians "are permitted to prescribe an FDA-approved drug for an unapproved use." Hsiao Decl. ¶ 12 (Doc. 27-1). Recognizing this limitation, DOJ instead 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 on the *distribution* and *labeling* of drugs for unapproved uses. DOJ's reading of the FDCA is wrong, has no basis in law, and, if adopted, will have broad implications for the practice of medicine.

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 such 'new drug' into interstate commerce without an FDA-approved indication is unlawful," Hsiao Decl. ¶ 22 (Doc. 27-1); *second*, drugs that are used to treat conditions for which they have not been specifically approved "constitute[s] 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 health care 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 highlighted by DOJ as potentially exposing providers to criminal liability are puberty blockers, which are "typically implants or injectables," *id.* ¶ 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 within the meaning of the FDCA. *Contra* Hsiao Decl. ¶ 23 (Doc. 27-1). The suggestion that FDCA liability attaches to anyone who administers an approved device for an unapproved 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, nor 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 such as nursing homes or rehabilitation centers, and certain outpatient treatment centers because such treatment is medically appropriate. Indeed, DOJ's 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 vital, as recognized by the Centers for Medicare and Medicaid Services (CMS).[19]

DOJ's unfounded 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 Schering*, 678 F.3d at 240 ("[P]hysicians may lawfully prescribe drugs for off-label uses."). Indeed, 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 unapproved use, physicians may, with limited exceptions, prescribe and administer FDA-approved drugs and devices for unapproved uses."[20]

2. Practitioners' 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 the

[19] 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.

[20] Engel, *supra* note 18, at 85.

introduction or delivery for introduction into interstate commerce of any food, drug, device … that is adulterated or misbranded." 21 U.S.C. § 331(a). Until this matter, the FDA had construed § 331(a) in the context of misbranding or mislabeling as applying only to "firms," *i.e.*, pharmaceutical companies, or their paid consultants—not to unaffiliated health care providers.[21]

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. *See* Hsiao Decl. ¶¶ 13-16 (Doc. 27-1). 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.

The construction adopted by DOJ thus departs both from the typical conduct and typical actors usually considered to be within the scope of § 331(a). Such a construction is a sharp departure from the federal government's own past practice. Amici are unaware of any instance

[21] *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 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.

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. Such a broadening of the scope of the FDCA inserts the federal government into the examination room to regulate conversations between providers and their patients about possible treatment options. Such conversations are a routine part of care; indeed, the National Cancer Institute (NCI), a part of the National Institutes of Health, notes that off-label use of chemotherapy drugs is "very common" in cancer treatment.[22] Thus, restrictions on the ability to discuss off-label treatments has implications for the efficacy of care a medical professional can provide, inhibits a patient's ability to fully understand and give informed consent to certain procedures and medications prescribed off label, and may ultimately prevent such prescriptions from being offered at all.

D. 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

[22] 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. NCI adds that while there may be drawbacks to off-label prescribing, "if your doctor prescribes a drug for an off-label use to treat your cancer, they are basing the decision on ***knowledge of and experience with the drug***, as well as on research that shows it might be helpful for your stage and type of cancer." (emphasis added).

field of gender-affirming care. Recent estimates suggest that between 20 and 50 percent of all prescriptions are for off-label indications.[23] 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 such as nursing homes or rehabilitation centers for eating disorders; or in certain outpatient treatment centers. And as discussed above, medical devices that must be implanted or inserted by medical professionals, such as chemotherapy ports, knee replacements, or indeed any surgical device, are necessarily 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 (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.[24] As a result, some scholars estimate that 50 to 75 percent of drug use in oncology settings occurs off label.[25] 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.[26]

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[23] 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).

[24] *See* Nat'l Cancer Inst., *Off-Label Drug Use in Cancer Treatment*, supra note 22.

[25] Beck, *supra* note 23, at 25-26 & n.113.

[26] 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).

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 that 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."[27] This lack of data in turn drives a relative paucity of FDA approvals of drugs for pediatric indications[28]—indeed, many drugs carry a so-called "orphaning clause" disclaimer as to pediatric use in light of the absence of sufficient studies.[29] Consequently, some studies estimate that as much as 80 percent of drugs prescribed for children are prescribed for off-label uses.[30]

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, DOJ Mem. at 22 (Doc. 27), 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, the violation of

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[27] 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.

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

[29] Beck & Azari, *supra* note 26, at 80 n.81.

[30] Beck, *supra* note 23, at 25-26 & n.114.

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." Hsiao Decl. ¶ 19 (Doc. 27-1) (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 UPMC, DOJ in turn references those same strict liability provisions as justifying its request for information on the personnel at UPMC responsible for the direction of prescribing and marketing practices. Hsiao Decl. ¶ 35 (Doc. 27-1). 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.[31]

Read 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 threatens profound effects on the provision of health care across the country. The effects would be devastating, particularly in states such as Pennsylvania that see significant economic activity from the health care, biotech, and life sciences

[31] 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").

industries. This Court should reject DOJ's efforts to use the cudgel of criminal liability to intimidate the doctors and administrators who care for our communities.

CONCLUSION

For the foregoing reasons, Amici respectfully ask the Court to deny DOJ's motion.

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