UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS, *et al.*, *Plaintiffs*, *v.* DONALD J. TRUMP, in his official capacity as President of the United States, *et al.*, *Defendants*.	Case No. 1:25-cv-12162 Leave to file granted September 21, 2026 Doc No. 144

BRIEF OF PUBLIC HEALTH AND HEALTH LAW SCHOLARS AS *AMICI CURIAE* IN SUPPORT OF PLAINTIFFS AND IN OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION AND STATEMENT OF *AMICI* INTERESTS

Physicians' use of their judgment and expertise to prescribe drugs for purposes other than those approved by the Food and Drug Administration ("FDA")—colloquially known as off-label use—is an indispensable feature of modern medicine. Off-label prescribing is "widely practiced" across medical specialties and especially common in specialties including pediatrics and psychiatry, where patient populations are often excluded from clinical trials. Christopher M. Wittich, Christopher M. Burkle & William L. Lanier, *Ten Common Questions (and Their Answers) About Off-Label Drug Use,* 87 Mayo Clinic Procs. 982, 983 (2012).

The Federal Food, Drug, and Cosmetic Act ("FDCA" or the "Act"), a consumer protection statute passed in 1938, authorizes the FDA's regulation of drugs. Specifically, the Act authorizes the FDA to regulate, through criminal and civil penalties, manufacturers, distributors, and other entities that move drugs into and through the stream of interstate commerce to ensure drugs are safe, effective, and properly labeled.

It is a "long-held understanding that the FDCA generally does not regulate off-label prescribing." Lewis A. Grossman, Nathan G. Cortez & Patricia J. Zettler, *Using FDA Law to Threaten Medical Practice*, 394 N. Engl. J. Med. 524, 524 (2026). The FDA approves drugs as "safe and effective for specific indications." Wittich et al., *supra*, at 982. Once a drug is approved for any indication, prescribing decisions, including whether to prescribe drugs off-label for a patient's particular indication, are left to physicians acting under state law and professional standards. *See id.* at 982, 986–87.[1] Courts and the FDA alike have long affirmed this interpretation. *See, e.g.*, *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350–51 & n.5

[1] The prescribing of drugs for off-label uses is distinct from the *promotion* of drugs for off-label uses, the latter of which the FDA is authorized to regulate. *See* Wittich et al., *supra*, at 988–89.

(2001); *United States v. Facteau*, 89 F.4th 1, 15 (1st Cir. 2023); FDA, *Understanding Unapproved Use of Approved Drugs "Off Label"* (Feb. 5, 2018), https://perma.cc/V29A-ZY3V.

In the EO and Directives at issue in this case,[2] Defendants attempt a sharp expansion of federal authority under the FDCA. In their invocation of the FDCA as an authority to investigate providers engaged in gender-affirming care, Defendants seek to rewrite the Act to license federal government interference into physicians' provision of health care that is legal under Plaintiff States' laws. In passing the FDCA, Congress did not intend for the Department of Justice ("DOJ") to be able to coerce health care providers into abandoning legal, clinically appropriate health care (including off-label prescribing) through the threat of FDCA liability.

Amici Curiae are leading scholars of health, public health, and health law who have published numerous treatises, books, and articles regarding the FDCA and the delivery, regulation, and accessibility of health care more broadly.[3] The signatories and their backgrounds are listed individually in the Motion for Leave to File that accompanies this brief.

Amici have a strong interest in ensuring that the FDCA is interpreted correctly by the Government. Accordingly, they submit this brief in support of Plaintiffs to provide the Court with insight into the Act's text, history, and purpose, from which Defendants' interpretation significantly deviates. This Court should grant Plaintiffs' cross-motion for summary judgment, and in so doing, should reject Defendants' interpretation of the FDCA, which would improperly enable the federal government to interfere with medical practice at large.

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[2] *See* Doc Nos. 1-5, 1-6, and 1-7.

[3] No party's counsel authored this brief in whole or in part. No party or its counsel contributed money intended to fund the preparation or submission of this brief, and no individual or organization other than *Amici* or their counsel contributed money intended to fund the preparation or submission of this brief. The brief's authors acknowledge the contributions of Tai Dinger.

ARGUMENT

I. Off-Label Prescribing is an Essential Part of American Health Care

Off-label prescribing is essential for a wide range of medical specialties and treatment contexts. As FDA law scholars have observed, "off-label prescribing is so prevalent and necessary that much care would grind to a halt without it." Grossman et al., *supra*, at 525. In many cases, off-label uses of medications represent the accepted standard of care or the best available treatment option for a patient. *See* W.A. Meadows & B.D. Hollowell, *'Off-Label' Drug Use: An FDA Regulatory Term, Not a Negative Implication of Its Medical Use*, 20 Int'l J. Impotence Res. 135, 139 (2008). In some cases, "a physician may actually commit malpractice by not prescribing a drug off-label." *Id.*

Oncology provides a salient example. One study estimates that up to 75% of oncology drug use is off-label. Grossman et al., *supra*, at 525. The National Cancer Institute notes that oncologists may prescribe off-label to use approved medications or combinations of approved therapies across various cancers, at different doses, or in children when medications have been approved for adults. Nat'l Cancer Inst., *Off-Label Drug Use in Cancer Treatment* (last updated Jan. 13, 2022), https://perma.cc/3JEH-VU46. Dexrazoxane, for example, is used to reduce heart muscle damage caused by certain chemotherapy drugs. Nat'l Cancer Inst., *Dexrazoxane Protects the Heart Long Term for Kids Being Treated for Cancer* (Mar. 16, 2023), https://perma.cc/V939-WMFM. Although the FDA approved dexrazoxane to reduce chemotherapy-related heart damage in women receiving treatment for metastatic breast cancer, it is also used off-label in children receiving chemotherapy, for whom it is "the only heart-protective drug available." *Id.* When administered before certain types of chemotherapy, dexrazoxane substantially reduces the risk of treatment-related heart problems in adulthood, helping pediatric cancer survivors preserve their cardiac health and quality of life over the long term. *Id.*

Off-label prescribing may also be useful when no approved drug exists for a condition, or if a patient has exhausted all other therapeutic options. FDA, *Understanding Unapproved Use of Approved Drugs, supra*. The need for off-label use is thus even more pronounced for rare cancers, for which drug development is particularly challenging, in large part due to the "difficulty [of] enrolling sufficient number[s] of patients to clinical trials," "decreased financial incentives for drug development," and limitations to conducting randomized control trials "due to small patient numbers or lack of appropriate therapy to use as a comparator." FDA, *OCE Rare Cancers Program* (last updated Jan. 27, 2025), https://perma.cc/A4DE-VJR3.

The widespread use of off-label prescribing in pediatric oncology reflects a broader reality across pediatric medicine. *See* Nat'l Cancer Inst., *supra*; Wittich et al., *supra*, at 982–85. One study estimated that up to 38% of all prescriptions written for children are off-label, and an expert with the Institute for Advanced Clinical Trials for Children noted that off-label medication accounts for 90% of prescriptions for newborns. *See* Patrick Boyle, *The Wish of Pediatricians: More Medications Deemed Safe for Kids*, Ass'n Am. Med. Colls. (June 21, 2022), https://perma.cc/T6UL-HDLU. In large part, the prevalence of pediatric off-label prescribing is the result of lags in FDA approvals for medication use by children, as clinical trials are often not available for pediatric populations. *Id.*; Albert Fung et al., *Off-Label Medication Use in Rare Pediatric Diseases in the United States*, 10 Intractable Rare Disease Res. 238, 238 (2021). Thus, allowing physicians to use their medical judgment in prescribing is a foundational component of pediatric care.

Psychiatry and neurology are also dependent on off-label prescribing. *See* Shariful A. Syed et al., *The Law and Practice of Off-Label Prescribing and Physician Promotion*, 49 J. Am. Academy Psychiatry & L. 53, 54 (2021); *see, e.g.*, Hua Chen et al., *An Epidemiological*

Investigation of Off-Label Anticonvulsant Drug Use in the Georgia Medicaid Population, 14 Pharmacoepidemiol. & Drug Saf. 629, 629–30 (2005). In office-based clinical settings, studies report 31% of all antidepressant, anticonvulsant, and antipsychotic prescriptions are written for off-label indications, and community-based studies suggest that 40% to 80% of patients receiving common psychotropics are treated off-label. Syed et al., *supra*, at 54. Additionally, tricyclic antidepressants, though not FDA-approved for neuropathic pain, are considered first-line treatment for that indication and are used off-label. Wittich et al., *supra*, at 983–85. And, Rituximab—a drug approved for treatment of non-Hodgkin lymphoma and rheumatoid arthritis—is used off-label to manage multiple sclerosis. *See* Tamara Castillo-Trivino et al., *Rituximab in Relapsing and Progressive Forms of Multiple Sclerosis: A Systematic Review*, 8 PLoS ONE e66308 (2013).

As these examples reveal, off-label prescribing is a necessary corollary of the FDA's regulatory process itself. Because FDA approval and labeling processes are time- and resource-intensive and necessarily limited in scope,[4] they cannot realistically encompass every clinically appropriate use of a drug for every patient population, condition, or evolving standard of care. *See* Wittich et al., *supra*, at 985; Katrina Furey & Kirsten Wilkins, *Prescribing "Off-Label": What Should a Physician Disclose?*, 18 Am. Med. Ass'n J. Ethics 587, 588–89 (2016). Physicians therefore routinely rely on emerging evidence, clinical guidelines, and professional judgment to determine when an already approved product is appropriate for a new indication or patient population.

Off-label use also facilitates innovation. "Valid new uses for drugs already on the market are often first discovered through serendipitous observations and therapeutic innovations," and

[4] *See* FDA, *Development & Approval Process (Drugs)* (last updated Aug. 8, 2022), https://perma.cc/5WDD-ZW5C.

"effective and safe treatment options would often be overlooked or never discovered" without off-label use. James Beck, *Off-Label Use in the Twenty-First Century: Most Myths and Misconceptions Mitigated*, 54 UIC J. Marshall L. Rev. 1, 18, 30–31 (2021) (citations omitted).

Off-label prescribing, like most medical interventions, carries risk. *See* Grossman et al., *supra*, at 525. Physicians are therefore obligated under state law to adequately explain the risks, benefits, and reasonable alternatives to a particular course of treatment, and to work with patients to select a treatment plan in the patient's best interest. *See* Furey & Wilkins, *supra*, at 590–92. Where off-label uses are the only treatment option available, those risks must be weighed against the risk of foregoing treatment altogether. *See id.* at 588–90. And, like many areas of medicine, a patient may elect a course of treatment with varied levels of "risk" because it best serves their needs or values. *See id.* at 590–92. Moreover, off-label prescribing is not done without guardrails. Professional practice standards require that such prescribing be grounded in sound scientific evidence and clinical judgment. Am. Med. Ass'n, *Patient Access to Treatments Prescribed by Their Physicians, H-120.988* (2024), https://perma.cc/6XL7-LPRV.

All told, physicians prescribing drugs for off-label uses work in tandem with the FDA's function of safeguarding the drug supply. The FDA evaluates products for safety and efficacy at the product level, while physicians—who are properly regulated by professional standards, applying clinical evidence and operating within state requirements, *see infra* at pp.9–11—translate those determinations into individualized treatment decisions for patients.

II. The FDCA Was Not Designed to Allow the Federal Government to Interfere with Physicians' Clinical Prescribing Decisions

Another significant reason for the prevalence of off-label prescribing is the FDCA itself. The FDCA was not designed and has not been interpreted to allow the federal government to interfere with physicians' clinical decisions to prescribe drugs or devices for off-label uses.

The FDCA is a consumer-protection statute aimed at ensuring that drugs, devices, and other articles entering interstate commerce are safe, effective, and properly labeled. By its text, the FDCA prohibits, with criminal and civil penalties, "the introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded." 21 U.S.C. § 331(a); *see also, e.g.*, 21 U.S.C. § 331(b) (prohibiting the adulteration or misbranding of products in interstate commerce); 21 U.S.C. § 333 (setting out penalties for violations of § 331). A drug is "misbranded" if, among other things, its "labeling"—written, printed, or graphic materials that accompany drugs or devices and provide directions for their use—is false or misleading. 21 U.S.C. § 321(k), (m) (defining "label" and "labeling"); 21 U.S.C. § 352 (defining "misbranded").

None of these provisions authorize the federal government to regulate health care practitioners' clinical judgment to prescribe FDA-approved drugs and devices for off-label uses. This has long gone unquestioned: in addition to the Act's text and Congress's intent, both the FDA and DOJ have historically confirmed this interpretation.

A. Congress Did Not Intend for the FDCA to Interfere with Off-Label Use

The FDCA's sponsors emphasized that, in regulating drugs in interstate commerce, they had no intent to "interfere at all with the ordinary legal practice of the [medical] profession." 79 Cong. Rec. 5019 (1935) (statement of Sen. Royal Copeland during Senate debate on S. 5), *reprinted in A Legislative History of the Federal Food, Drug and Cosmetic Act and Its Amendments*, vol. 4, at 57 (FDA 1979) [hereinafter *Legislative History of the FDCA*]. Congress reaffirmed its understanding in subsequent FDCA amendments. In 1971, Congressman Lawrence H. Fountain stated: "[t]he law, of course, was not intended to regulate the practice of medicine and should not be so used." *New Drugs Used for Nonapproved Purposes (Methotrexate for*

Psoriasis): Hearing Before the Intergovernmental Relations Subcomm. of the H. Comm. on Gov't Operations, 92d Cong. 643 (1971), *reprinted in Legislative History of the FDCA*, app. H, at 643.

The Act's text speaks directly to off-label prescribing. Congress revised the FDCA in 1997 to indicate "[n]othing in [the Act] 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." 21 U.S.C. § 396. The import is clear. A Joint Explanatory Statement of the Committee of Conference responsible for the addition of section 396 to the FDCA noted this provision was:

> intended by the conferees to emphasize that ***the FDA should not interfere in the practice of medicine***. Specifically, the conferees note that the off-label use of a medical device by a physician using his or her best medical judgment in determining how and when to use the medical product for the care of a particular patient ***is not the province of the FDA***.

H.R. Rep. No. 105-399, at 97 (1997) (emphasis added), https://perma.cc/8W7K-APZ6; *see also Judge Rotenberg Educ. Ctr., Inc. v. FDA*, 3 F.4th 390, 395 (D.C. Cir. 2021) ("Section 396 ensures that once the FDA permits a device to be marketed for one use, health care practitioners have the flexibility to draw on their expertise to prescribe or administer the device for any condition or disease, not just the use the FDA approved—in short, to practice medicine.").

In addition to section 396's explicit language regarding off-label use of devices, courts have repeatedly held that the FDCA should not be read to prohibit physicians from prescribing either drugs or devices off-label. Citing section 396, the Supreme Court confirmed "the FDCA expressly disclaims any intent to directly regulate the practice of medicine," quoting scholarship confirming that "[p]hysicians may prescribe drugs and devices for off-label uses." *Buckman*, 531 U.S. at 350–51 & n.5. And, as the First Circuit has reasoned (citing section 396), "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." *Facteau*, 89 F.4th at 15.[5]

B. The FDCA's Protection of Off-Label Use Reflects Congress's Understanding of the Proper Locus of Physician Governance

The legislative history reveals Congress' understanding that protecting physicians' ability to prescribe off-label is essential for at least three reasons: (1) respect for states' regulation of medical practice, (2) the appreciation that physicians are best positioned to evaluate the individual circumstances of their patients, and (3) as discussed above, the importance of off-label prescribing to medical practice.

First, in line with other federal health care statutes,[6] the FDCA respects the longstanding principle that medical practice regulation is quintessentially a matter reserved to states. *See Hillsborough Cnty., Fla. v. Automated Med. Lab'ys, Inc.*, 471 U.S. 707, 720 (1985) ("regulation of health and safety matters is primarily, and historically, a matter of local concern"). "States license physicians and set standards for medical care, often incorporating standards established by the medical profession while allowing broad discretion for physician judgment." *See* Benjamin A. Barsky, Brendan Reid & Christopher Robertson, *Medical Standards by Federal Fiat*, 395 N. Engl. J. Med. 419, 419 (2026). Consistent with this, then-FDA Commissioner George Larrick acknowledged that "the extent to which FDA can rely on the discretion of individual medical practitioners in balancing the advantages and hazards of a drug" "goes to the

[5] Other circuits agree that the FDCA does not prohibit off-label drug prescribing. *See, e.g.*, *Ass'n of Am. Physicians & Surgeons v. FDA*, 13 F.4th 531, 534 (6th Cir. 2021); *In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 240 (3d Cir. 2012); *United States v. Caronia*, 703 F.3d 149, 153 (2d Cir. 2012); *Sigma-Tau Pharms., Inc. v. Schwetz*, 288 F.3d 141, 147–48 (4th Cir. 2002); *Wash. Legal Found. v. Henney*, 202 F.3d 331, 333 (D.C. Cir. 2000).

[6] Congress has likewise limited federal power vis-à-vis medical treatment decisions in other significant ways. *See, e.g.,* 42 U.S.C. § 1395 (starting the Medicare Act by proclaiming that "[n]othing in this subchapter shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine").

heart of the matter of States rights." *Drug Safety: Hearings Before a Subcomm. of the H. Comm. on Gov't Operations*, 88th Cong. 186 (1964) (exchange between Rep. Lawrence H. Fountain and Comm'r Larrick), *reprinted in Legislative History of the FDCA*, app. D, at 180.

Second, Congress understands that individual practitioners—guided by professional standards and clinical evidence and operating within state requirements—are best positioned to evaluate courses of treatment for their patients. As one Senator expressed during the Senate's consideration of the 2013 Drug Quality and Security Act, which amended sections of the FDCA: "I . . . want to clarify that nothing in this legislation will constrain a doctor's options to practice medicine . . . Doctors know their patients best and should have access to accurate information on the safety and quality of the drugs they use." 159 Cong. Rec. S8072 (daily ed. Nov. 18, 2013) (statement of Sen. Lamar Alexander); *see also id.* (statement of Sen. Thomas Coburn) ("I . . . want to express my concern that this legislation should not be used by the FDA to interfere with a doctor's ability to practice medicine and choose the best therapy for his or her patients.").

Third, and perhaps most importantly, Congress understands the distinct importance of off-label prescribing to medical practice. While amending the Act, members of Congress emphasized their understanding of the "tremendous importance [of off-label prescribing] to the patient," citing that "the American Medical Association has estimated that between 40 percent and 60 percent of all prescriptions are for off-label uses of prescription drugs." 143 Cong. Rec. S12244 (daily ed. Nov. 9, 1997) (statement of Sen. William Frist).

Congress' consistent and longstanding decision to limit federal interference with physicians' clinical decisions reflects a core practical consideration: physicians must be able to exercise independent clinical judgment informed by the best-available scientific evidence and standards of care established by state medical boards and professional associations to provide

high-quality, individualized patient care. The FDCA does not provide the federal government authority to interfere with this essential and foundational feature of health care, nor to dictate which of these clinical decisions it favors and which it disfavors.

C. The FDA and DOJ Long Adopted This Understanding

The FDA itself has understood this reading of the FDCA for decades, confirming that the Act does not regulate medical judgment. *See* Legal Status of Approved Labeling for Prescription Drugs; Prescribing for Uses Unapproved by the Food and Drug Administration, 37 Fed. Reg. 16,503 (proposed Aug. 15, 1972) ("Throughout the debate leading to the enactment [of the FDCA], there were repeated statements that Congress did not intend the [FDA] to interfere with medical practice and references to the understanding that the bill did not purport to regulate the practice of medicine as between the physician and the patient.").[7] In a 1974 congressional hearing regarding FDA practice, then-FDA Chief Counsel Peter Barton Hutt put this plainly:

> The legislative history is clear that Congress intended FDA to regulate the shipment of a drug and the labeling for that drug and declined to permit the Food and Drug Administration to regulate the practice of medicine as between the physician and the patient, which is the use of that drug . . . ***Congress denied*** [the FDA] explicitly, both in 1938 and in [the 1962 amendments], ***any authority to regulate the practice of medicine in terms of the use of a drug by a physician once it is lawfully shipped with lawful labeling in interstate commerce***.

Use of Advisory Committees by the Food and Drug Administration: Hearing before a Subcomm. of the H. Comm. on Gov't Operations, 93d Cong. 347–48 (1974), *reprinted in Legislative History of the FDCA,* app. J, at 620–21 (emphasis added). Accordingly, "[f]rom the FDA's perspective, once the FDA approves a drug, healthcare providers generally may prescribe the drug for an

[7] *See also* Labeling Requirements for Systemic Antibacterial Drug Products Intended for Human Use, 68 Fed. Reg. 6071 (Feb. 6, 2003) ("As FDA has long recognized, its role is neither to regulate physician conduct, nor to train physicians.").

unapproved use when they judge that it is medically appropriate for their patient."

Understanding Unapproved Use of Approved Drugs, supra.

Perhaps most telling, DOJ itself agrees. In a 2019 Memorandum Opinion for the Attorney General, DOJ's Office of Legal Counsel wrote:

> As a general matter, FDA does not regulate the practice of medicine, which includes "off-label" prescribing—that is, when physicians prescribe FDA-approved drugs . . . for non-FDA-approved uses … [t]hus, while 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 . . . for unapproved uses.

Steven A. Engel, *Whether the Food & Drug Admin. Has Jurisdiction over Articles Intended for Use in Lawful Executions*, 43 Op. O.L.C. 81, 85 (May 3, 2019) (internal citation omitted).[8]

III. Accepting Defendants' Theories of the FDCA Would Undermine the Act and Cause Harm Across the Health Care Landscape

A. Defendants' Theories Regarding the Scope of Federal Authority under the FDCA Would Threaten Off-Label Prescribing and Affiliated Care

DOJ's declarations that it will "use all available resources to prioritize investigations of doctors [and] hospitals" that provide gender-affirming care, including investigations into possible FDCA violations, Doc No. 1-7 at 3–4, invoke a novel interpretation of the Act that would significantly and harmfully expand federal authority over physicians' clinical decisions. As Defendants have acknowledged, puberty blockers and gender-affirming hormone therapy have been approved by the FDA. *See* Doc No. 124 at 6, 8. That is the end of the analysis under the FDCA: their use by providers, for any indication, is not the province of the federal government under this Act. If Defendants can nonetheless read into the FDCA some authority to investigate and "hold accountable" "medical providers" because they give "advice" or "purchase,

[8] With regard to "limited exceptions," Congress has created a few narrow statutory exceptions where off-label prescribing is itself unlawful. *See, e.g.*, 21 U.S.C. § 333(e) (prohibiting certain off-label uses of human growth hormone). None of these narrow exceptions are applicable here.

store, prescribe, or administer FDA-approved drugs" regarding gender-affirming care (*see* Doc No. 133 at 21 (citing Doc No. 1-6 at 2–3, 5 and Doc No. 87-27 at 9)), this eviscerates legal protections for all off-label prescribing.[9]

In reinforcing the general legality of off-label use, Doc No. 124 at 14, Defendants suggest that the federal government's regulation of gender-affirming care should be treated as unique. Yet, "the arguments [Defendants have] made . . . presage a troubling and drastic expansion of the FDCA into medical practice" beyond this one kind of care. Grossman et al., *supra*, at 524. "By suggesting that physicians may be committing a federal crime under the FDCA when they prescribe or administer a drug for an unapproved use, the [DOJ]—in its effort to deter gender-affirming care—calls into question patients' access to off-label uses of all drugs." *Id.* at 525.

For instance, take Defendants' suggestions that providers may be subject to investigation because of the content of their "advice," Doc No. 1-6 at 3. If Defendants are in any way suggesting that FDCA's labeling and branding requirements should apply to ordinary, oral informed consent discussions between physicians and their individual patients about off-label drug use, this would constitute a dramatic and dangerous expansion of the intended scope and focus of the FDCA. "[T]he FDA has long recognized that . . . clinicians' discussions with patients about these prescriptions" "are generally outside the scope of the statute." Grossman et al., *supra*, at 524.

[9] In their briefing, Defendants suggest the Directives focused on FDCA investigations of manufacturers and distributors, not providers. *See* Doc No. 124 at 14. But again, the Shumate Directive declared DOJ would "use all available resources to prioritize investigations of doctors [and] hospitals," including investigations into possible FDCA violations. And, inescapably, DOJ has since cited this precise language from the Directive in defending the validity of subpoenas it issued to several providers, purportedly to investigate FDCA violations. *See* Appellant's Br. at 12, *In re Administrative Subpoena No. 25-1431-019*, No. 25-2092 (1st Cir. April 15, 2026).

Moreover, to the extent Defendants suggest that any communication from providers to patients that discusses *benefits* of using medications off-label for gender-affirming care would violate federal law, this would violate the First Amendment. As the Supreme Court recently described, government action that prescribes what views a medical provider may or may not express is viewpoint discrimination. *Chiles v. Salazar*, 146 S. Ct. 1010, 1024 (2026).[10]

Similarly dangerous are DOJ's arguments that providers enter the "chain of distribution" under the FDCA by purchasing, storing, or administering puberty blockers. *See* Doc No. 87-27 at 9. FDCA Section 331, which prohibits introducing or delivering adulterated or misbranded drugs in interstate commerce, is directed at actors who place or move drugs in commerce (e.g., drug manufacturers, packers, and distributors), not providers prescribing or administering approved drugs in individual patient care. 21 U.S.C. § 331(a), (b).[11] And "[t]he provision of the FDCA that prohibits 'the causing of' violations has never been read" to find providers prescribing off-label to "cause" drug manufacturers to violate the statute. *See* Grossman et al., *supra*, at 525.

These interpretations of the FDCA would be devastating to care. They would require hospitals and physicians involved in all kinds of off-label prescribing and administration to radically alter their clinical approaches. *See* Barsky et al., *supra*, at 420 (noting "DOJ's theories could be disruptive in situations in which doctors dispense drugs" from a hospital pharmacy or

[10] As the *Chiles* Court reasoned: "History is littered with examples of official efforts to manipulate and control professional speech—including the content of doctor-patient discourse—in ways designed to increase state power, suppress minorities, and muzzle unpopular ideas." *Id.* at 1024–25 (internal citations and quotations omitted). Defendants should not be provided runway to "manipulate and control professional speech—including the content of doctor-patient discourse" to "suppress minorities."

[11] Further, the FDA has amended its regulations regarding the "intended use" of drugs to clarify that a manufacturer "would not be regarded as intending an unapproved new use for an approved drug based solely on that [manufacturer's] knowledge that such drug was being prescribed or used by health care providers for such use." 21 C.F.R. § 201.128.

"infuse drugs, such as oncology and autoimmune products, in their clinics.") In short, DOJ's unprecedented FDCA interpretation would be to the severe detriment of patients and health.

B. Finding Defendants' FDCA Theories to be a Legitimate Justification for these Federal Actions Would Broadly Chill the Practice of Health Care

Given the scope of Defendants' FDCA theories, all kinds of providers reliant on off-label prescribing could be chilled by the threat of federal actions. Moreover, patients reliant on receiving medications for off-label uses, including pediatric and/or oncology, rare disease, and psychiatry and neurology patients, could lose access to lifesaving medication.

Accepting Defendants' theories would enable them to use investigative powers to *de facto* oversee and chill legal medical practice, without Congressional authorization. *See* Barsky et al., *supra*, at 420–21 (federal authority over health care standards "should be established using a proper legal process . . . not by fiat"). Defendants should not be enabled to transform the FDCA into a tool for scrutinizing and deterring the exercise of routine, legal medical judgment. Authorizing Defendants to act in this way would reshape medicine, permitting federal officials to use investigative tools to regulate "off-label prescribing practices that are disfavored by whatever administration is in power, even when these practices are supported by scientific evidence and deemed medically appropriate by doctors." Grossman et al., *supra*, at 525. This Court should not allow the federal government to interfere in routine, evidence-based clinical decisions, on a political whim, in the guise of a statute that was never intended to regulate medical judgment.

CONCLUSION

For the foregoing reasons and those provided in Plaintiff's briefing, this Court should reject Defendants' expansive interpretation of the FDCA, deny Defendants' motion for summary judgment, and grant Plaintiffs' cross-motion for summary judgment.

Dated: September 21, 2026

Respectfully submitted,
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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the CM/ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing and paper copies will be sent to those indicated as non-registered participants as needed.

Dated: September 21, 2026

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