**No. 26-1568**

**IN THE UNITED STATES COURT OF APPEALS**
**FOR THE FIRST CIRCUIT**

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*In re*: Motion to Quash Administrative Subpoena to Rhode Island Hospital —

**CHILD ADVOCATE FOR RHODE ISLAND, ET AL.,**
*Petitioners-Appellees*,

v.

**UNITED STATES OF AMERICA,**
*Respondent-Appellant*.

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On Appeal from the United States District Court for the
District of Rhode Island
Case No. 1:26-mc-00007-MSM-AEM

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# BRIEF OF *AMICI CURIAE* AMERICAN SOCIETY OF CLINICAL ONCOLOGY AND BLOOD CANCER UNITED, JOINED BY 18 MEDICAL PROFESSIONAL SOCIETIES AND PATIENT ADVOCACY ORGANIZATIONS, IN SUPPORT OF APPELLEES AND AFFIRMANCE

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## CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1 and Local Rule 26.1, the American Academy of Family Physicians, American Cancer Society Cancer Action Network, American College of Physicians, American Geriatrics Society, American Nurses Association, American Society for Clinical Pathology, American Society of Clinical Oncology, American Society of Health-System Pharmacists, American Urological Association, Blood Cancer United, Cancer Nation, Children's Cancer Cause, Crohn's & Colitis Foundation, Hematology/Oncology Pharmacy Association, Lupus Foundation of America, Muscular Dystrophy Association, National Alliance on Mental Illness, National Comprehensive Cancer Network, National Multiple Sclerosis Society, and NCODA each state that they have no parent corporation and no corporation or publicly held company owns 10% or more of each entity's stock.

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## STATEMENT OF IDENTITY AND INTEREST OF *AMICI CURIAE*

*Amici curiae* are medical professional societies, patient advocacy organizations, and healthcare nonprofits whose members and constituents depend on the lawful off-label prescribing of medications approved by the Food and Drug Administration ("FDA"). Off-label prescribing is the standard of care across their respective fields. *Amici* are united in their position that the Government's legal theories, if adopted, would criminalize routine medical practice and threaten patient access to evidence-based care.

The American Society of Clinical Oncology ("ASCO"), founded in 1964, is the world's leading professional organization for physicians and other professionals who care for people with cancer. A charitable, educational, and scientific organization classified under Section 501(c)(3) of the Internal Revenue Code, ASCO's network comprises more than 50,000 oncology professionals across medical, radiation, and surgical oncology and every oncology subspecialty. ASCO promotes the highest-quality cancer care through clinical research, education, and the development of evidence-based clinical practice guidelines on which oncologists nationwide—including within the First Circuit—rely.

Blood Cancer United, founded in 1949 and known until 2025 as the Leukemia & Lymphoma Society, is the largest global nonprofit focused on blood cancer patient support, research, and advocacy. Its mission is to cure blood cancer and improve the quality of life of patients and their families affected by more than 100 types of blood

cancer, including leukemia, lymphoma, myeloma, myelodysplastic syndromes, and myeloproliferative neoplasms. Blood Cancer United brings together researchers, healthcare professionals, volunteers, and advocates to help patients access the care they need.

*Amici* also include the following organizations: American Academy of Family Physicians, American Cancer Society Cancer Action Network, American College of Physicians, American Geriatrics Society, American Nurses Association, American Society for Clinical Pathology, American Society of Health-System Pharmacists, American Urological Association, Cancer Nation, Children's Cancer Cause, Crohn's & Colitis Foundation, Hematology/Oncology Pharmacy Association, Lupus Foundation of America, Muscular Dystrophy Association, National Alliance on Mental Illness, National Comprehensive Cancer Network, National Multiple Sclerosis Society, and NCODA. Descriptions of each organization are in the Appendix.

None of the *amici* was formed to provide or advocate for the patient care at issue in this case, but all are deeply concerned that the Government's legal theories—if accepted—would introduce criminal liability for off-label prescribing and distribution of treatments on which their members and patients routinely depend.

No party's counsel authored this brief in whole or in part, and no party or party's counsel contributed money intended to fund preparing or submitting this brief. No person other than *amici curiae*, their members, or their counsel contributed money to fund this brief.

Counsel for all parties have consented to the filing of this brief.

## INTRODUCTION AND SUMMARY

The Government concedes that writing an off-label prescription does not, "'in and of itself, give rise to FDCA liability.'" Brief for Appellant at 35, *In re Motion to Quash Administrative Subpoena to Rhode Island Hosp.*, No. 26-1568 (1st Cir. June 17, 2026) ("Gov't Br."); *see also* Brief for the United States as Amicus Curiae Supporting Petitioners, *Hikma Pharms. USA Inc. v. Amarin Pharma, Inc.*, No. 24-889 (U.S. filed Feb. 25, 2026), 2026 WL 582226, at *9 ("The FDCA does not prohibit doctors or pharmacists from prescribing or dispensing a drug 'off-label'—*i.e.*, for uses other than those for which FDA has determined that the drug is safe and effective[.]"). But the district court, concerned about the implications of the Government's theory, explained that if accepted, hospitals which dispense or administer FDA-approved drugs for off-label uses would participate in a "distribution chain" that places "misbranded" drugs into commerce, and "any party in the distribution chain who helped place that drug in commerce—including a hospital whose physicians wrote the prescriptions," would face criminal liability for providing treatment that is often the standard of care. *In re Admin. Subpoena 25-1431-032 to Rhode Island Hosp.*, No. CV 1:26-MC-0007, 2026 WL 1392565, at *6 (D.R.I. May 14, 2026). On appeal, the Government advances two alternative theories: first, that a hospital "conspired with manufacturers and distributors who were misbranding drugs"; and second, that a hospital "engaged in misbranding by altering a drug's labeling, such as by providing false or misleading 'written, printed, or graphic matter . . . accompanying' the drug."

Gov't Br. at 36–37 (quoting 21 U.S.C. § 321(m)). These theories remain equally troubling. The Government's rationale cannot be distinguished from the off-label prescribing that is central to modern healthcare.

*Amici* make three points. *First*, the FDCA does not regulate the practice of medicine. Off-label prescribing is protected by statute and by this Court's decisions in *United States v. Facteau*, 89 F.4th 1, 15 n.4 (1st Cir. 2023), *cert. denied*, 145 S. Ct. 137 (2024), and *In re Celexa & Lexapro Mktg. & Sales Pracs. Litig.*, 915 F.3d 1, 11 (1st Cir. 2019). Federal law draws a clear line between lawful physician prescribing and unlawful manufacturer promotion—a line the Government's theory ignores. The district court correctly applied these precedents. *Second*, off-label prescribing is critical to patient care where adequate alternatives do not exist. Off-label use of prescription medication is often the standard of care in oncology, pediatrics, neurology, rheumatology, gastroenterology, urology, psychiatry, geriatrics, and other specialties. The Government's theory would criminalize routine treatment across medicine—from pediatric and geriatric oncology to multiple sclerosis, inflammatory bowel disease, lupus, muscular dystrophy, and mental health conditions. *Third*, the federal government itself reimburses off-label drug use. The Centers for Medicare & Medicaid Services ("CMS") recognizes approved compendia as authoritative sources for Medicare coverage. The Government cannot criminalize practices it actively reimburses.

## ARGUMENT

### I. THE FDCA DOES NOT REGULATE THE PRACTICE OF MEDICINE

The law is clear: the FDCA does not regulate the practice of medicine. Section 396 expressly provides that "[n]othing 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." 21 U.S.C. § 396. Although Section 396 addresses devices by its terms, courts have consistently applied the same principle to drugs. *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."). Moreover, the statute separately exempts prescription drugs dispensed pursuant to a licensed practitioner's prescription from the misbranding requirements on which the Government's theory depends. *See* 21 U.S.C. § 353(b)(2) (subject to certain exceptions, exempting from Section 352's requirements any drug "dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug"). Off-label prescribing falls squarely within that protected zone. As the Supreme Court has recognized, off-label prescribing "is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350

(2001). Off-label prescribing—the use of an FDA-approved drug for an indication, dosage, dosage form, or patient population not included in the approved labeling—is a part of the practice of medicine that is protected by statute and binding precedent. The Government's theory finds no support in the cited case law or regulatory framework.

### A. Off-Label Prescribing Is Protected by Statute and Binding Precedent

This Court's precedents are equally unambiguous in holding that the FDCA does not prohibit off-label prescribing. In *Facteau*, this Court held 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." 89 F.4th at 15 (citing *Buckman*, 531 U.S. at 350; *Judge Rotenberg Educ. Ctr., Inc. v. U.S. Food & Drug Admin.*, 3 F.4th 390, 395 (D.C. Cir. 2021)). And *In re Celexa* confirmed that "[t]he FDCA . . . does not prohibit doctors from prescribing drugs for off-label uses." 915 F.3d at 5 (citing *Lawton ex rel. United States v. Takeda Pharm. Co.*, 842 F.3d 125, 128 n.4 (1st Cir. 2016)). Other circuits have reached the same conclusion. *See, e.g.*, *In re Schering Plough Corp.*, 678 F.3d at 240; *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."). There is no contrary authority.

Even the Government's own Office of Legal Counsel ("OLC") agrees. OLC has concluded that the "FDA does not regulate the practice of medicine, which

includes 'off-label' prescribing," and that "physicians may, with limited exceptions, prescribe and administer FDA-approved drugs and devices for unapproved uses." *Whether the Food & Drug Administration Has Jurisdiction Over Articles Intended for Use in Lawful Executions*, 43 Op. O.L.C. 81, 85 (2019). The Government now asks this Court to reject a principle that every relevant authority—including its own—has affirmed.

### B. The Government's Theory Finds No Support in the Regulatory Framework or Case Law

The Government's regulatory argument fares no better than its statutory arguments. It contends that "intended use" under 21 C.F.R. § 201.128 can change after a drug enters interstate commerce, exposing hospitals and other healthcare facilities to misbranding liability. *See* Gov't Br. at 5–8. But that regulation defines "intended use" by reference to "the persons legally responsible for the labeling of an article"—i.e., the manufacturers and distributors, not treating physicians. A hospital or clinic administering or dispensing a prescription for an individual patient is delivering medical care within the context of a provider-patient relationship, not introducing drugs into commerce. Every case cited by the Government involved sellers or distributors who marketed products with promotional literature for unapproved purposes. *Kordel v. United States*, 335 U.S. 345 (1948); *United States v. Urbuteit*, 335 U.S. 355 (1948); *United States v. 47 Bottles, More or Less*, 320 F.2d 564 (3d Cir. 1963). None involved a hospital, clinic, pharmacy, or physician dispensing or prescribing FDA-approved drugs for patient care.

The Government's enforcement examples are equally inapposite. *See* Gov't Br. at 7–8. In *United States v. Cephalon*, for example, the Information alleged that the manufacturer trained its sales force to promote drugs for unapproved uses, directed sales representatives to coach physicians on diagnostic codes to ensure reimbursement for off-label prescriptions, and funded continuing medical education programs to push unapproved uses. *See* Information ¶¶ 12–18, *United States v. Cephalon, Inc.*, No. 2:08-cr-00598 (E.D. Pa. Sept. 29, 2008) (Dkt. 1). In *Eli Lilly*, the manufacturer directed sales representatives to send unsolicited letters promoting unapproved uses. Press Release, U.S. Dep't of Just., *Eli Lilly and Company to Pay U.S. $36 Million Relating to Off-Label Promotion* (Dec. 21, 2005), https://perma.cc/2Y64-FUK5. And *United States v. Marschall* did not even involve FDA-approved drugs, and so is wholly inapposite to the issue of prescribing off-label. Even so, the case involved a repeat FDCA violator who marketed unapproved products directly to consumers, shipped them through the U.S. mail, and included false informational sheets he authored claiming the products could treat COVID-19. 82 F.4th 774, 776–78 (9th Cir. 2023). Each case involved promotional conduct—sales outreach, promotional materials, or direct-to-consumer marketing—by parties who introduced drugs or products into commerce. None involved a physician or hospital exercising clinical judgment within the context of a provider-patient relationship. The Government cites no case—and *amici* are aware of none—extending FDCA liability to a hospital, pharmacy, or provider for the acts of dispensing, administering, or prescribing. Indeed, its cases

prove the rule: FDCA enforcement targets those who market drugs, not those who dispense or prescribe them. This Court's decision in *Facteau* draws precisely this line. 89 F.4th at 15 (citing *Buckman*, 531 U.S. at 349–50).

The Government cannot construct a conspiracy or aiding-and-abetting theory merely based on a physician's lawful act of prescribing a drug to a patient for an off-label use. The statute confirms the point: the FDCA exempts any drug "dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug" from Section 352's labeling requirements, subject to limited exemptions. 21 U.S.C. § 353(b)(2). No court has extended FDCA misbranding liability to a hospital, pharmacy, or physician for prescribing or dispensing an FDA-approved drug for an off-label use within a provider-patient relationship.

## II. OFF-LABEL PRESCRIBING IS PREVALENT ACROSS MEDICINE, AND THE GOVERNMENT'S THEORY WOULD CRIMINALIZE ROUTINE CLINICAL CARE

Off-label prescribing is a widespread, medically necessary practice. Recent estimates suggest that between 21–50% of all prescriptions nationwide are for off-label indications. *See* 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). The practice is especially prevalent in oncology, where up to 50–75% of oncology drug use is estimated to be off-label, and in pediatrics, where up to 80% of drugs prescribed are for off-label uses; the same is true in cardiology, psychiatry, rare diseases, and HIV/AIDS treatment. *See id.* at 25–26 & nn.112–114. The FDA itself has stated that

"once [it] 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." FDA, *Understanding Unapproved Use of Approved Drugs "Off Label"* (last updated Feb. 5, 2018), https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label. Indeed, "[p]rescribing for so-called off-label uses can be accepted medical practice, often reflecting cutting-edge clinical expertise." Cong. Rsch. Serv., *Off-Label Use of Prescription Drugs*, Summary (Feb. 23, 2021).

Off-label prescribing is critical to medical care for several reasons. Obtaining FDA approval for a drug is expensive and time-consuming, requiring additional investments for each indicated use. It is often impractical for manufacturers to conduct the studies required for FDA approval for all currently available and known effective therapeutics—doing so would slow innovation and delay access to evidence-based advances in treatment. As a result, off-label prescribing is often the only means to provide evidence-based, life-saving care for numerous diseases.

### A. Entire Patient Populations Are Excluded from Clinical Trials

Entire patient populations are systematically excluded from premarketing trials and are thus excluded from the indicated uses: children, older adults with multiple comorbidities, pregnant women, and patients with rare diseases. The FDA itself has acknowledged this gap, recognizing that "some eligibility criteria have become commonly accepted over time . . . sometimes excluding certain populations from trials

without strong clinical or scientific justification." FDA, *Enhancing Participation in Clinical Trials — Eligibility Criteria, Enrollment Practices, and Trial Designs: Guidance for Industry* 4 (Rev. 1, Dec. 2025). Pediatric trials "present unique challenges, including small and heterogeneous patient populations," compounded by "[e]thical and feasibility concerns." Rylee McGonigle et al., *Pediatric Studies and Labeling Additions Required by the U.S. FDA for Novel Drugs Approved from 2011 to 2023*, 22 PLOS MED. e1004651, at 11 (2025). Older adults "are underrepresented in cancer clinical trials" despite accounting for an increasing share of the patient population. FDA, *Inclusion of Older Adults in Cancer Clinical Trials: Guidance for Industry* 2 (Mar. 2022). "During clinical development of most drugs and vaccines, pregnant women are actively excluded from trials." FDA, *Postapproval Pregnancy Safety Studies: Guidance for Industry* 2 (May 2026). And for rare diseases, only about 5% of nearly 10,000 identified rare diseases have FDA-approved treatments, in part because drug sponsors find it difficult to recruit a sufficient number of participants for clinical trials. Government Accountability Office, *Rare Disease Drugs: FDA Has Steps Underway to Strengthen Oversight*, at 1–2 (Nov. 2024).

The disparity is especially stark in pediatric gastroenterology. While adults with inflammatory bowel disease (IBD) have 13 FDA-approved advanced therapies spanning six mechanistic targets, children have access to only four, three of which have the same mechanistic target. Two of these medications were approved within the last year, more than a decade after they had been FDA-approved for use in adult IBD.

Children with ulcerative colitis continue to have access to only one class of medication on-label.[1] Drugs like vedolizumab are effective for adult IBD and have been safely prescribed off-label for pediatric IBD for over a decade. Despite a significant body of real-world evidence demonstrating efficacy in children, the FDA has yet to approve vedolizumab for pediatric use. Conducting the large-scale pediatric trials required for IBD approval is difficult: enrolling enough children takes years, and once a drug is available off-label, families are understandably reluctant to enroll in trials where they might receive a placebo or the less-effective treatment. The Government's theory threatens to expose pediatric gastroenterologists to potential criminal liability for delivering the standard of care—chilling evidence-based prescribing and leaving children without access to effective treatment.

### B. Off-Label Use Is the Standard of Care Across Specialties

The prevalence of off-label prescribing underscores the resounding effect of the Government's theory. In oncology, an estimated 50–75% of all drug use is off-label. Beck, *supra*, at 25–26 & n.113. The National Cancer Institute confirms that off-label use is "very common in cancer treatment" because many drugs work across cancer types and combination chemotherapy routinely includes drugs not individually

[1] *See* Benjamin Sahn et al.*, Children With Inflammatory Bowel Diseases Are Disadvantaged by Current Drug Approval Policie*s, CROHN'S & COLITIS 360 (2025) (describing the disparity between FDA-approved therapies for adults and children with IBD)*; see also* FDA-approved prescribing information for infliximab, adalimumab, golimumab, and ustekinumab.

approved for the cancer being treated; indeed, "[t]he FDA usually does not approve combinations of chemotherapy" because "[t]here are so many of them that it would not be practical to approve each combination." Nat'l Cancer Inst., *Off-Label Drug Use in Cancer Treatment* (last updated Jan. 13, 2022), https://perma.cc/E8BX-JLKC. Drugs like oxaliplatin—approved only for colorectal cancer—are used to treat gastroesophageal adenocarcinoma, pancreatic cancer, small bowel adenocarcinoma, and biliary tract cancers, often as the preferred regimen. Similarly, capecitabine—approved for limited gastrointestinal indications—is the only therapy used in adjuvant settings for biliary tract cancers, a setting with no FDA-approved indication. In many rare cancers, such as small bowel adenocarcinoma, no prospective clinical trials have been conducted at all; clinicians prescribe FOLFOX and FOLFIRI regimens based on extrapolated data and real-world evidence, thereby offering their patients the chance at treatment that would not be possible if off-label medicine becomes harder to access. Nat'l Comprehensive Cancer Network ("NCCN"), Clinical Practice Guidelines in Oncology: Biliary Tract Cancers (Ver. 1.2026); Esophageal and Esophagogastric Junction Cancers (Ver. 3.2026); Pancreatic Adenocarcinoma (Ver. 2.2026); Small Bowel Adenocarcinoma (Ver. 2.2026).

In pediatrics, off-label prescription rates range from 3.2–95%. *See* 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 (2018) (citing 31 studies). Earlier research found that 78.7% of hospitalized children were discharged

on at least one off-label medication. Samir S. Shah et al., *Off-Label Drug Use in Hospitalized Children*, 161 ARCH. PEDIATRICS & ADOLESCENT MED. 282 (2007). The American Academy of Pediatrics has confirmed that off-label use of medications in children "does not imply improper, illegal, contraindicated, or investigational use." Am. Acad. of Pediatrics, Policy Statement, *Off-Label Use of Drugs in Children*, 133 PEDIATRICS 563 (2014).

For these patients, off-label prescribing is not a workaround—it is the standard of care. Without it, many pediatric patients—whether facing cancer, autoimmune diseases, or other serious conditions—would have no treatment at all. In geriatric medicine, older adults with multiple chronic conditions are routinely excluded from the trials that establish FDA-approved dosing. In appropriate clinical contexts, the American Geriatrics Society advises clinicians to start medications at lower doses and adjust for kidney function—in practice, these doses may be considered off-label due to the change in the labeled dose. Judith L. Beizer, *Pharmacotherapy*, in Geriatrics Review Syllabus: A Core Curriculum in Geriatric Medicine 73 (Jessica L. Colburn et al. eds., 12th ed. 2025). In cardiology, psychiatry, and rare-disease medicine, the picture is similar: labeling lags practice, and physicians prescribe based on the best available clinical evidence.

The treatments that the Government's theory threatens to criminalize are saving lives. Concomitant chemoradiotherapy—adding chemotherapy to radiation for locally advanced head and neck cancer—improves five-year survival by 6.5%, with

platinum-based regimens showing the greatest benefit; yet many of these life-saving combinations remain off-label. Benjamin Lacas et al., *Meta-analysis of Chemotherapy in Head and Neck Cancer (MACH-NC): An Update on 107 Randomized Trials and 19,805 Patients*, 156 RADIOTHERAPY & ONCOLOGY 281 (2021). Carboplatin is labeled only for ovarian cancer, yet decades of evidence have established it as standard of care for lung cancer, head and neck cancer, and pediatric neuroblastoma. NCCN, Clinical Practice Guidelines in Oncology: Small Cell Lung Cancer (Ver. 1.2027); Head and Neck Cancers (Ver. 2.2026); Neuroblastoma (Ver. 2.2026). Carboplatin is frequently substituted for cisplatin in patients with impaired kidney function or hearing loss, a safer option that is not included in the FDA label. *See* NCCN, NCCN Drugs and Biologics Compendium ("NCCN Compendium"). Donepezil is approved only for Alzheimer's disease, yet a randomized, placebo-controlled trial demonstrated significant improvement in patients with Lewy body dementia. Etsuro Mori et al., *Donepezil for Dementia with Lewy Bodies: A Randomized, Placebo-Controlled Trial*, 72 ANNALS OF NEUROLOGY 41 (2012). Methylphenidate is FDA-approved only for ADHD and narcolepsy, yet it is used with antidepressants to treat geriatric depression—a regimen validated by double-blind trials. Helen Lavretsky et al., *Citalopram, Methylphenidate, or Their Combination in Geriatric Depression: A Randomized, Double-Blind, Placebo-Controlled Trial*, 172 AM. J. PSYCHIATRY 561 (2015). Used off-label, olanzapine—a drug approved as an atypical antipsychotic—prevents nausea and vomiting for patients receiving highly emetogenic chemotherapy, enabling them to remain on treatment and

improving their quality of life. *See* Paul J. Hesketh et al., *Antiemetics: ASCO Guideline Update*, 38 J. CLINICAL ONCOLOGY 2782 (2020). These are not fringe practices; they are the standard of care.

The same pattern holds in hematologic malignancy, where drugs at the core of curative protocols are administered off-label as a matter of routine. Daunorubicin, etoposide, and mitoxantrone are used off-label in acute myeloid leukemia; prednisone and dexamethasone in acute lymphoblastic leukemia; vincristine, cyclophosphamide, ifosfamide, and etoposide in Ewing sarcoma. *See* NCCN Compendium. Many of the most widely used blood-cancer therapies—rituximab, methotrexate, cyclophosphamide, vincristine—are FDA-approved for one malignancy yet administered for others, consistent with the NCCN Compendium. Additional examples illustrate the breadth of off-label use: cabozantinib is FDA-approved for medullary thyroid cancer but is recommended for kidney cancer and certain types of non-small cell lung cancer; brentuximab vedotin is approved for Hodgkin lymphoma but recommended off-label for mycosis fungoides and Sézary syndrome; carfilzomib is approved for relapsed multiple myeloma but listed for Waldenström's macroglobulinemia; regorafenib is approved for colorectal cancer, GIST, and hepatocellular carcinoma but is recommended for second-line biliary tract cancers; and pomalidomide is approved for multiple myeloma but is listed and recommended for systemic light chain ("AL") amyloidosis. *See id.* Because these drugs are given by IV infusion, hospitals, cancer centers, and infusion clinics must purchase, store, and

administer them on-site—precisely the conduct the Government would recast as criminal "distribution."

The same principle applies beyond cancer care. In neurology, the FDA has approved more than 20 disease-modifying therapies to treat multiple sclerosis ("MS"), yet providers also prescribe off-label medications to manage the MS disease process. Rituximab—one of the blood-cancer therapies mentioned above—was first approved by the FDA specifically for treating cancer but is now often used off-label for MS. Several clinical trials have demonstrated that rituximab is effective in reducing clinical relapses and limiting new inflammation in the central nervous system and may even limit the progression or worsening of MS symptoms. *See* Nat'l Multiple Sclerosis Soc'y, *Off-Label Use of Disease-Modifying Therapies*, https://perma.cc/6PXY-984T; Tamara Castillo-Trivino et al., *Rituximab in Relapsing and Progressive Forms of Multiple Sclerosis: A Systematic Review*, 8 PLOS ONE e0066308 (2013). Rituximab thus illustrates how off-label use crosses not only cancer types but disease categories entirely—and how the Government's theory would reach routine neurological care.

Pediatric oncology presents a particularly stark illustration. Dexrazoxane is a cytoprotective medication primarily used to prevent or reduce heart muscle damage (cardiomyopathy) caused by anthracycline chemotherapy drugs like doxorubicin. While its adult label is limited to metastatic breast cancer, dexrazoxane is widely used off-label—and frequently recommended in pediatric oncology protocols—to protect the developing hearts of children undergoing treatment for leukemias and solid

tumors. Many children receiving chemotherapy are at risk for cardiac late effects, and clinicians must mitigate the known toxicities of harsh chemotherapies. Although dexrazoxane carries an FDA label restriction stating it is not indicated for pediatric patients, it is widely utilized and supported by clinical evidence and pediatric oncology guidelines. *See* Children's Oncology Grp., *Long-Term Follow-Up Guidelines for Survivors of Childhood, Adolescent, and Young Adult Cancers* (Ver. 6.0 2023), https://perma.cc/2UYA-NVZB. If the Government's theory prevailed, pediatric oncologists administering this cardioprotective therapy would face criminal liability for protecting children's hearts.

### C. The Government's Theory Would Criminalize Evidence-Based Care

Under the Government's theory, any entity that administers or dispenses an FDA-approved drug for an off-label indication—even one supported by randomized controlled trials and professional guidelines—could be cast as a criminal "distributor" of a "misbranded" drug. The same would be true of any retail or specialty pharmacy that fills an off-label prescription. In oncology, that means a hospital or cancer center administering cisplatin to a patient with a cancer type not on the label faces criminal exposure. In neurology, a clinician administering donepezil for Lewy body dementia —a use supported by clinical trial evidence—faces the same risk. In rheumatology, a physician prescribing rituximab for lupus or mycophenolate for autoimmune conditions faces identical exposure. The same is true across psychiatry,

gastroenterology, urology, and every other specialty where off-label use is the standard of care.

The consequences extend beyond provider liability. If hospitals, cancer centers, infusion centers, clinics, physician offices, and pharmacies face prosecution for administering or dispensing off-label drugs, providers will curtail well-supported regimens to avoid legal risk. In pediatric oncology, geriatric medicine, rare diseases, neonatal care, and psychiatry, patients will suffer—or lose their lives.

## III. THE FEDERAL GOVERNMENT AFFIRMATIVELY REIMBURSES OFF-LABEL DRUG USE

CMS has long recognized off-label prescribing as reasonable and necessary. Medicare reimburses off-label uses listed in approved compendia, and, since 2008, CMS has recognized the NCCN Compendium as one of the sources for determining whether an off-label cancer indication qualifies as a medically accepted indication. *See* CMS, *Medicare Benefit Policy Manual*, Pub. 100-02, ch. 15, § 50.4.5.B. (rev. 151, Nov. 18, 2011), https://perma.cc/9DRV-9GLE. By establishing this framework, Congress and CMS have affirmatively endorsed the very practice of off-label prescribing the Government now seeks to criminalize. The Government's position is internally incoherent: one arm of the federal government reimburses off-label prescribing while another seeks to criminalize it.

The practical operation of this framework underscores the Government's incoherence. Medicare covers off-label uses listed in approved compendia, and the

NCCN Compendium alone contains more than 10,000 entries—a substantial portion of which are off-label because it would not be practical for the FDA to approve every indication. Many involve generic drugs where manufacturers have no financial incentive to seek label expansion, yet the drugs remain essential to patient care. In urology, off-label intravesical therapy drugs are routinely prescribed for bladder cancer and reimbursed by Medicare when listed with at least 2A-level evidence in the NCCN Compendium. *See* CMS, *Medicare Benefit Policy Manual*, ch. 15, § 50.4.5. These are not marginal treatments; they are how patients survive.

The FDA agrees. In guidance issued in January 2025, the agency acknowledged that healthcare providers may prescribe drugs for off-label use "when they judge that the unapproved use is medically appropriate for their particular patient." FDA, *Communications from Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products: Guidance for Industry* 8 (Jan. 2025). The Government cannot criminalize conduct that another arm of the federal government has explicitly authorized and what the FDA itself has affirmed as lawful medical practice.

## CONCLUSION

The district court's order quashing the administrative subpoena should be affirmed. The Government's legal theories would criminalize the standard of care across multiple medical specialties. The judgment below protects not only Rhode

Island Hospital and its physicians, but the many patients who depend on off-label care and the hospitals, cancer centers, clinics, pharmacies, and physicians who serve them.

Respectfully submitted,

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# APPENDIX

## APPENDIX: ORGANIZATIONAL *AMICI CURIAE*

In addition to the American Society of Clinical Oncology and Blood Cancer United, *amici curiae* include the following medical professional societies and patient advocacy and disease-focused organizations:

Founded in 1947, the **American Academy of Family Physicians** ("AAFP") is one of the largest national medical organizations, representing over 124,000 family physicians and medical students nationwide. AAFP seeks to improve the health of patients, families, and communities by advocating for the health of the public and by supporting its members in providing continuous comprehensive health care to all.

The **American Cancer Society Cancer Action Network** ("ACS CAN") advocates for evidence-based public policies to reduce the cancer burden for everyone. ACS CAN believes everyone should have a fair and just opportunity to prevent, detect treat and survive cancer. Many cancer patients require off label drug use for survival or quality of life, so evidence based administration of these drugs should not risk criminal liability.

The **American College of Physicians** is the largest medical specialty organization and the second-largest physician membership organization in the United States, representing 163,000 internal medicine physicians, related subspecialists, and medical students. Internal medicine physicians apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum of health and disease.

The mission of the **American Geriatrics Society** ("AGS"), a nationwide, not-for-profit society of geriatrics healthcare professionals, is to improve the health, independence, and quality of life of all older people. AGS's 6,000-plus members include geriatricians, geriatrics nurse practitioners, social workers, family practitioners, physician associates, pharmacists, and internists who are pioneers in serious illness care for older individuals. AGS works to advance high-quality, person-centered care that is informed by geriatrics principles, free of ageism, and focused on our health, safety, and independence as we age. AGS has a strong interest in ensuring that older Americans have access to medications that are safe and prescribed in accordance with their needs. Our members and the older adults they serve depend on lawful, evidence-based off-label prescribing as part of routine medical practice and patient care.

The **American Nurses Association** ("ANA") is a national, not-for-profit organization founded in 1896. ANA represents the interests of the nation's 5 million registered nurses. ANA advances the nursing profession by fostering high standards

of nursing practice, promoting a safe and ethical work environment, bolstering the health and wellness of nurses, and advocating on health care issues that affect nurses and the public. ANA also provides continuing education and professional development for nurses, including advanced nurses, and publishes guidelines for the profession, including the Code of Ethics for Nurses and Nursing: Scope and Standards of Practice.

The **American Society for Clinical Pathology** ("ASCP") is the world's largest professional membership organization for pathologists and laboratory professionals. Uniting more than 100,000 members, comprised of anatomic and clinical pathologists, medical laboratory professionals, residents, and students, ASCP has guided the application and evolution of the pathology and laboratory medicine specialty to improve patient care since 1922. ASCP members provide excellence in patient care through the practice of pathology and laboratory medicine, which forms the foundation of modern healthcare.

The **American Society of Health-System Pharmacists** ("ASHP ") is the largest association of pharmacy professionals in the United States. ASHP advocates and supports the professional practice of pharmacists in hospitals, health systems, ambulatory care clinics, and other settings spanning the full spectrum of medication use. For over 80 years, ASHP has championed innovation in pharmacy practice; advanced education and professional development; and served as a steadfast advocate for members and patients.

Founded in 1902 and headquartered near Baltimore, Maryland, the **American Urological Association** ("AUA") is a leading advocate for the specialty of urology and has more than 26,000 members throughout the world. The AUA is a premier urologic association, providing invaluable support to the urologic community as it pursues its mission of fostering the highest standards of urologic care through education, research, and the formulation of health policy. The AUA has a strong interest in this case because its members and the patients they serve depend on lawful, evidence-based off-label prescribing as part of routine urologic practice and patient care.

**Cancer Nation**, formerly known as the National Coalition for Cancer Survivorship, is a patient advocacy organization founded in 1986. Its community includes more than 18 million cancer survivors, patients, caregivers, and advocates across the United States. Cancer Nation's mission is to advocate for quality cancer care for all people touched by cancer. Through advocacy training, policy engagement, and survivorship education, Cancer Nation works to advance whole person cancer care, survivorship care planning, and financial protections for people living with,

through, and beyond cancer. Cancer Nation has a strong interest in this case because its constituents depend on lawful, evidence-based off-label prescribing as part of routine medical practice and patient care.

The **Children's Cancer Cause** ("CCC"), established in 1999, was founded to ensure the needs and perspectives of children with cancer, survivors, and their families are integrated into federal health care, research, and cancer policy. For more than twenty-five years, CCC has worked to accelerate anti-cancer drug development so that the more than 16,000 children diagnosed each year can achieve access to less toxic and more effective therapies for children with cancer. CCC leads efforts to ensure that the needs and perspectives of children with cancer and the country's 521,000 childhood cancer survivors are integrated into the highest level deliberations on health care and policy. CCC has a strong interest in this case because our community depends on safe and effective therapies and lawful, evidence-based off-label prescribing as part of routine medical practice and patient care.

The **Crohn's & Colitis Foundation** is a non-profit, volunteer-fueled organization dedicated to finding cures for Crohn's disease and ulcerative colitis, and improving the quality of life of children and adults affected by these diseases.

The **Hematology/Oncology Pharmacy Association** ("HOPA") is a non-profit professional association for hematology/oncology pharmacy practitioners founded in 2004. HOPA is comprised of over 4,000 members working in hospitals, clinics, physicians' offices, community pharmacies, and home health across the United States. HOPA's mission is to optimize the care of individuals affected by cancer through the support, promotion, and advancement of hematology/oncology pharmacy practice. HOPA is the leading oncology pharmacy association focused on maintaining quality and safety in cancer care in interdisciplinary, collaborative practice settings. Through education, research, advocacy, professional standards, and other activities, HOPA works to ensure that all patients have access to safe and high-quality cancer treatments that meet their needs. HOPA has a strong interest in this case because its members rely on lawful, evidence-based off-label prescribing to ensure that all patients have access to potentially life-saving treatments.

The **Lupus Foundation of America** ("LFA") is the nation's leading organization dedicated to solving the mystery of lupus while improving the quality of life for all people affected by the disease. Through research programs, patient education, support services, advocacy, and efforts to increase participation in clinical research, the Foundation serves individuals and families impacted by lupus in communities across the United States. LFA has a strong interest in this case because people living with lupus depend on lawful, evidence-based off-label prescribing as part of routine

medical practice and patient care. Patients and clinicians have long relied on medications originally developed for other indications, and many lupus treatment regimens continue to include therapies used off-label despite years of clinical experience supporting their utility.

The **Muscular Dystrophy Association** ("MDA") is the #1 voluntary health organization in the United States for people living with muscular dystrophy, ALS, and over 300 other neuromuscular conditions. For over 75 years, MDA has led the way in accelerating research, advancing care, and advocating support and inclusion of families living with neuromuscular disease. MDA's mission is to empower the people we serve to live longer, more independent lives.

**National Alliance on Mental Illness** ("NAMI") is the nation's largest grassroots mental health organization, dedicated to building better lives for the millions of Americans affected by mental illness. NAMI is an alliance of more than 650 affiliate organizations that work in communities in all 50 States to raise awareness, provide support and education, and advocate for policy change. NAMI has a strong interest in this case because of our long history of working to ensure people with mental health conditions can access necessary treatment including evidence-based off-label prescribing.

The **National Comprehensive Cancer Network®** ("NCCN®") is a not-for-profit alliance of 34 leading cancer centers devoted to patient care, research, and education. NCCN is dedicated to defining and advancing quality, effective, equitable, and accessible cancer care and prevention so all people can live better lives. Through the leadership and expertise of clinical professionals at NCCN Member Institutions, NCCN develops resources that present valuable information to the numerous stakeholders in the health care delivery system. NCCN has a strong interest in this case because oncology care professionals and people impacted by cancer depend on lawful, evidence-based off-label prescribing as part of routine and optimal cancer care.

The **National Multiple Sclerosis Society** exists because there are people living with MS. Our vision is a world free of MS. Our mission is: We will cure MS while empowering people affected by MS to live their best lives.

**NCODA** (Network of Collaborative Oncology Development & Advancement) is a nonprofit medical professional association founded in 2015. Its membership includes more than 16,000 oncology and hematology professionals—including pharmacists, physicians, advanced practice providers, nurses, financial advocates, pharmacy technicians, administrators, and other members of the multidisciplinary cancer care team—who practice within medically integrated oncology settings across

the United States and internationally. NCODA's mission is to improve the quality of cancer care by advancing the medically integrated oncology care model and equipping clinicians with the education, tools, and collaborative resources needed to optimize patient outcomes. NCODA has a strong interest in this case because its members routinely rely on lawful, evidence-based off-label prescribing—supported by nationally recognized clinical guidelines and peer-reviewed evidence—to provide medically appropriate, individualized treatment options for patients with cancer when such use represents the standard of care.

## CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Fed. R. App. P. 29(a)(5) and 32(a)(7)(B) because it contains 6,412 words, excluding the parts exempted by Fed. R. App. P. 32(f), and does not exceed one-half the maximum length authorized for a party's principal brief. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced 14-point typeface (Garamond) using Microsoft Word.

/s/ *Alice W. Yao*

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## CERTIFICATE OF SERVICE

I hereby certify that on July 21, 2026, I electronically filed the foregoing with the Clerk of the Court for the U.S. Court of Appeals for the First Circuit using the CM/ECF system, which will send notice of such filing to all counsel who have entered an appearance in this action.

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