No. 26-1886

IN THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

Carter Coe, by and through his parent and next friend Caroline Coe; Reed Roe, by and through his parent and next friend Riley Roe; Nicole Noe, by and through her parent and next friend Norman Noe; Karl Koe, on behalf of themselves and all similarly situated; and Jay Doe, on behalf of themselves and all similarly situated,

Plaintiffs-Appellees,

v.

Todd Blanche, Acting United States Attorney General, in his official capacity; United States Department of Justice,

Defendants-Appellants,

NYU Langone Health System; NYU Langone Hospitals; NYU Grossman School of Medicine, a division of New York University,

Defendants.

On Appeal from the United States District Court
for the Southern District of New York

BRIEF OF *AMICI CURIAE* AMERICAN ACADEMY OF PEDIATRICS AND 17 OTHER NATIONAL MEDICAL AND MENTAL HEALTH ORGANIZATIONS IN SUPPORT OF PLAINTIFFS-APPELLEES AND IN OPPOSITION TO GOVERNMENT'S MOTION FOR STAY

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, the American Academy of Pediatrics (AAP), the American Academy of Child and Adolescent Psychiatry, the American Academy of Family Physicians, the American Academy of Nursing, the American College of Obstetricians & Gynecologists (ACOG), the American College of Osteopathic Pediatricians, the American College of Physicians, the Academic Pediatric Association, the American Pediatric Society, the American Psychiatric Association, the Endocrine Society, GLMA: Health Professionals Advancing LGBTQ+ Equality, the National Association of Pediatric Nurse Practitioners, the Pediatric Endocrine Society, the Societies for Pediatric Urology, the Society for Adolescent Health and Medicine (SAHM), the Society of Pediatric Nurses, and the World Professional Association for Transgender Health 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 the American Academy of Pediatrics (AAP), American Academy of Child and Adolescent Psychiatry, American Academy of Family Physicians, American Academy of Nursing, American College of Obstetricians & Gynecologists (ACOG), American College of Osteopathic Pediatricians, American College of Physicians, Academic Pediatric Association, American Pediatric Society, American Psychiatric Association, Endocrine Society, GLMA: Health Professionals Advancing LGBTQ+ Equality, National Association of Pediatric Nurse Practitioners, Pediatric Endocrine Society, Societies for Pediatric Urology, Society for Adolescent Health and Medicine (SAHM), Society of Pediatric Nurses, and World Professional Association for Transgender Health.[1]

Amici are eighteen professional medical and mental-health organizations representing thousands of healthcare providers across the United States. *Amici* and their members seek to ensure that all adolescent patients—including those with gender dysphoria—receive optimal medical and mental-health care. *Amici*

[1] Pursuant to Fed. R. App. P. 29(a)(4)(E), undersigned counsel certifies that no party's counsel authored this brief in whole or in part; no party or party's counsel contributed money intended to fund this brief, and no persons other than *Amici*, their members, and their counsel contributed money to fund this brief. All parties have consented to the filing of this brief.

have a strong interest in this and other pending cases because the Department of Justice's (DOJ) demands for sensitive patient records threaten to interfere with patient-physician relationships, impair health outcomes, and deter patient access to necessary and evidence-based medical care. As *Amici* explain below, patient confidentiality and off-label prescribing are of fundamental importance not only for the treatment of gender dysphoria but also for the medical care of adolescents more generally.

INTRODUCTION AND SUMMARY

In June 2025, the Department of Justice (DOJ) served numerous hospitals nationwide, including NYU Langone Health (Hospital), with administrative subpoenas seeking records relating to the provision of gender-affirming medical care (GAMC) to patients under age 18.[2] *See* District Court June 24 Oral TRO Decision (June 24 Tr.) at 5, 10. DOJ demanded not only the kinds of records customarily requested in federal healthcare investigations but other remarkably broad and intrusive sets of information, including confidential medical records of every adolescent patient treated with GAMC. *Id.* at 4-6. The Hospital produced responsive non-patient records but refused to turn over patient records. Not satisfied, DOJ convened a grand jury in the Northern District of Texas, which issued a criminal subpoena compelling the Hospital to produce those confidential patient records. *Id.* at 11.

Plaintiffs in this suit are patients who received GAMC at the Hospital or who are the parents of patients who received such care. They brought suit in the Southern District of New York—where the Hospital is located—to enjoin DOJ

[2] In this brief, the term "gender-affirming medical care" or "GAMC" refers to the use of gonadotropin-releasing hormone (GnRH) analogues (puberty blockers) and/or hormone therapy to treat gender dysphoria. Because this brief focuses on adolescents, it does not discuss surgeries that are typically available to transgender adults.

from demanding their confidential patient records (whether via administrative subpoena, grand jury subpoena, or otherwise).

The district court properly granted plaintiffs' motion for preliminary injunction. As the court persuasively explained in its June 24 oral decision, the government's demands for patient records go well beyond what federal law and precedent allow. And as plaintiffs explain in opposing the motion to stay, the government has offered no sound basis for disturbing the district court's injunction, which simply maintains the status quo pending further litigation.

Amici submit this brief to make two additional points. *First*, for clinicians, maintaining the confidentiality of medical records is central to preserving the trust of patients and parents and to delivering effective medical care, particularly for transgender adolescents. Intrusive government requests for patient records threaten to interfere with physician-patient-parent relationships, impair health outcomes, and deter access to care.

Second, DOJ's declared interest in investigating off-label prescribing reflects fundamental misunderstandings about proper medical practice. In all fields of medicine, but especially pediatrics, off-label prescribing of FDA-approved medications is common and accepted, and indeed often the standard of care. Drug uses are "off-label" not because those uses are unsafe, experimental, or improper, but because the drugs were FDA-approved for other

indications, ages, dosages, or methods of administration. Although updated FDA approvals can be obtained, such approvals generally depend on drug sponsors taking the initiative to seek them, and regulatory recognition often lags behind accepted clinical practice. Here, as in many other contexts, the off-label prescribing of medicines to patients receiving gender-affirming medical care is evidence-based and supported by clinical guidelines.

ARGUMENT

I. PERMITTING INTRUSIVE DISCLOSURE OF SENSITIVE PATIENT MEDICAL RECORDS WITHOUT A COMPELLING RATIONALE WOULD HARM PATIENT CARE.

The district court properly enjoined DOJ from demanding the "identifying or sensitive health information" of patients seeking gender-affirming care at the Hospital. ECF 71, at 5.

Confidentiality of patient information receives numerous legal protections.[3] But it is also a foundation of ethical and effective medical practice, both for adult patients and for adolescents (for whom treatment generally requires assent by both patients and their parents or guardians).[4]

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[3] *See* Chung et al., *Confidentiality in the Care of Adolescents: Technical Report,* 153 Pediatrics e2024066327 (2024) [*AAP Confidentiality Technical Report*], at 2-3 (discussing federal and state confidentiality protections).

[4] *See generally* AAP Committee on Bioethics, Informed Consent in Decision-Making in Pediatric Practice, 138 Pediatrics e20161484 (2016; reaffirmed 2023) [*AAP Policy Statement on Pediatric Informed Consent*].

For thousands of years, physicians have committed themselves to safeguarding private medical information. In the Hippocratic Oath's common modern rendering, physicians declare that "I will respect the privacy of my patients, for their problems are not disclosed to me [so] that the world may know."[5] The AMA Code of Medical Ethics specifies that physicians have an "ethical obligation to preserve the confidentiality of information gathered in association with the care of the patient" and should not release patients' medical information without consent.[6]

Confidentiality is critical to multiple "moral traditions" within medical ethics.[7] "Ethical principles of autonomy, nonmaleficence, beneficence, and justice are all key elements of the ethical framework for confidentiality in adolescent health care."[8] Autonomy requires respect for the rights of patients

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[5] Pozgar, *Legal and Ethical Issues for Health Professionals* 283 (5th ed. 2019).

[6] Am. Med. Ass'n, *Ethics Opinion 3.2.1: Confidentiality*, Code of Medical Ethics, https://perma.cc/H8DZ-S7TH.

[7] Morreale et al., *Policy Compendium on Confidential Health Services for Adolescents* 33 (2d ed. 2005) [*Policy Compendium*]; *see also* Varkey, *Principles of Clinical Ethics and Their Application to Practice*, 30(1) Med. Principles 17, 20-21 (2021); Am. Coll. of Physicians, *Ethics Manual: Sixth Edition*, 156(1) Ann. Intern. Med. 73, 76 (2012) [*ACP Ethics Manual*]; Society for Adolescent Health and Medicine, *Confidential Health Care for Adolescent Minors and Young Adults: A Position Paper of the Society for Adolescent Health and Medicine*, 77(4) J. Adolesc. Health 791, 792 (2025) [*SAHM Position Statement on Confidentiality*].

[8] *Policy Compendium*, *supra* note 7, at 3.

and families to make informed decisions about their own care.[9] Justice urges physicians to care about the needs of the entire community, including those who may face barriers to treatment.[10] Nonmaleficence cautions physicians to "do no harm."[11] And beneficence imposes a "duty to promote good and act in the best interest of the patient and the health of society."[12]

As those principles suggest, confidentiality matters both for its own sake and for achieving good patient outcomes. "The clinician-patient relationship requires honest and open communication between both parties to maximize the therapeutic benefit and avoid potential harms."[13] Providers "rely on patients to disclose their symptoms, health behaviors, and thoughts and feelings so that clinicians can make appropriate diagnoses and treatment recommendations."[14] Full disclosure is needed not only for "protecting adolescent minors and young

[9] Varkey, *supra* note 7, at 163.

[10] *AAP Confidentiality Technical Report*, *supra* note 3, at 2.

[11] *ACP Ethics Manual*, *supra* note 7, at 74.

[12] *Id.*

[13] Levy et al., *Prevalence of and Factors Associated With Patient Nondisclosure of Medically Relevant Information to Clinicians*, 1 JAMA Network Open e185293 (2018); *see also, e.g.*, ACOG, *Effective Patient-Physician Communication: Committee Statement*, 146 Obstet. & Gynecol. e115, e123 (Dec. 2025).

[14] Levy et al., *supra* note 13, at 2.

adults from health risks and promoting optimal health" but also for avoiding affirmative harm, such as drug interactions.[15]

Protecting confidentiality directly serves those interests. By assuring confidentiality, physicians encourage patients and their parents or guardians "to disclose [the patients'] symptoms and life circumstances fully and completely, thereby increasing the likelihood that they will receive appropriate care and enhancing the clinician's capacity to help them."[16] And the credibility of such assurances affects patients' and parents' "decision[s] [whether] to seek care" at all.[17]

Those conclusions are memorialized in policy statements by *Amici* and other leading organizations.[18] AAP affirms that "[c]onfidentiality is an essential component of high-quality adolescent care" with "profound implications for health care access and utilization, outcomes, and safety."[19] The Society for Adolescent Health and Medicine "has long recognized the importance of

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[15] *SAHM Position Statement on Confidentiality*, *supra* note 7, at 791-92.

[16] *Id.*

[17] *AAP Confidentiality Technical Report*, *supra* note 3, at 1.

[18] *See generally Policy Compendium*, *supra* note 7.

[19] Chung et al., *Confidentiality in the Care of Adolescents: Policy Statement*, *American Academy of Pediatrics*, 153 Pediatrics e2024066326, at 2 (2024) [*AAP Policy Statement on Confidentiality*].

confidential health care for adolescents."[20] Many other organizations similarly recognize that patient confidentiality is fundamental to ethical practice, promotes the best possible care, and increases the likelihood that patients seek care and remain in care.[21]

Those policy commitments are founded upon decades of evidence showing that privacy concerns prevent many adolescents from seeking health care.[22] Both "large nationally representative surveys and smaller state or local studies" have "confirm[ed] that concerns about privacy can act as a significant

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[20] Ford et al., *Confidential Health Care for Adolescents: Position Paper of the Society for Adolescent Medicine*, 35(2) J. Adolesc. Health 160, 163 (2004); *see SAHM Position Statement on Confidentiality*, *supra* note 7, at 791.

[21] Policy Compendium, *supra* note 7, at 6, 33-43 (collecting "nearly 100 policy statements that affirm the critical role that confidentiality plays in ensuring timely access to essential health care services").

[22] *See, e.g.*, Agostino et al., *Considerations for Privacy and Confidentiality in Adolescent Health Care Service Delivery*, 28 Paediatrics & Child Health 172, 172 (2023); Ford et al., *Foregone Health Care Among Adolescents*, 282(23) JAMA 2227, 2227-28 (1999); Ford et al., *Influence of Physician Confidentiality Assurances on Adolescents' Willingness to Disclose Information and Seek Future Health Care: A Randomized Controlled Trial*, 278(12) JAMA 1029 (1997); Fuentes et al., *Adolescents' and Young Adults' Reports of Barriers to Confidential Health Care and Receipt of Contraceptive Services*, 62(1) J. Adolesc. Health 36, 37 (2018); Lehrer et al., *Forgone Health Care Among U.S. Adolescents: Associations Between Risk Characteristics and Confidentiality Concern*, 40(3) J. Adolesc. Health 218, 218-19 (2007); Pathak et al., *Confidential Care for Adolescents in the U.S. Health Care System*, 6(1) J. Patient-Centered Research and Reviews 46, 46 (2019); Thrall et al., *Confidentiality and Adolescents' Use of Providers for Health Information and for Pelvic Examinations*, 154(9) Arch. Pediatrics & Adolesc. Med. 885, 885 (2000); *SAHM Position Statement on Confidentiality*, *supra* note 7, at 792 (citing additional studies).

barrier to adolescents seeking health care."[23] And even when adolescents do seek care, those with confidentiality concerns "discuss fewer topics" with providers, especially involving mental health, sexual issues, and substance abuse.[24]

Though the rationales for confidentiality are similar in pediatrics as in other medical contexts, the stakes are higher for adolescents and other vulnerable groups. Adolescents disproportionately "engage in high-risk behaviors that cause significant morbidity and mortality."[25]

Unfortunately, the "very patients who are in greatest need of high-quality health care" are often those most likely to withhold information or avoid seeking care.[26] Adolescents more likely to forgo care based on confidentiality concerns include those with "elevated prevalence of high depressive symptoms, suicidal ideation, and suicide attempt."[27] Marginalized groups, including "LGBTQIA+

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[23] *Policy Compendium*, *supra* note 7, at 1.

[24] *AAP Confidentiality Technical Report*, *supra* note 3, at 4.

[25] AAP Committee on Adolescence, *Achieving Quality Health Services for Adolescents*, 138 Pediatrics e20161347 (2016), at 3; *see also, e.g.*, Rubin et al., *Delivery of Confidential Care to Adolescent Males*, 23(6) J. Am. Bd. Fam. Med. 728, 728 (2010).

[26] Levy et al., *supra* note 13, at 6.

[27] Lehrer, *supra* note 22, at 222-23.

youth," may also be "particularly concerned about ensuring confidentiality of their health information."[28]

Confidentiality also facilitates disclosures among patients and trusted family members. Adolescent patients generally appreciate the difference between their providers sharing sensitive information with those who generally need to know—such as other healthcare providers or parents—and disclosure to persons outside those relationships.[29] Ensuring the trust of parents and guardians in the physician's confidentiality arrangements is critical to adequate care for adolescent patients.[30] Clinicians thus work to "encourage and facilitate communication between young people and their parents" where such communication will best serve the patient's needs.[31] Success requires trust and honest dialogue among patients, families, and healthcare providers.

Family support is particularly essential for gender-affirming medical care. The law generally requires parental consent before starting medical

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[28] *AAP Policy Statement on Confidentiality*, *supra* note 19, at 3.

[29] *See* Sankar et al., *Patient Perspectives of Medical Confidentiality*, 18(8) J. Gen. Intern. Med. 659, 663 (2003); Estroff et al., *Confidentiality: Concealing "Things Shameful to be Spoken About"*, 14(9) AMA J. Ethics 733, 735 (2012).

[30] McKay et al., *Parents' Perspectives on Confidentiality in Clinical Preventive Services for Adolescents*, 77(4) J. Adolesc. Health 602, 602-09 (2025).

[31] *SAHM Position Statement on Confidentiality*, *supra* note 7, at 791.

interventions on adolescent patients.[32] Providers work to build strong partnerships with adolescents and their families to facilitate understanding of a patient's gender experience while allowing questions and concerns to be raised in a supportive environment.[33] Among parents' most common concerns are those about stigma, discrimination, or other harms associated with potential exposure of their children to public scrutiny.[34] Maintaining confidentiality is essential for addressing those concerns and maintaining the trust of patients and parents alike.

DOJ's demands directly threaten those interests. By pursuing this appeal, DOJ has indicated it is not satisfied with obtaining the information customarily requested in federal healthcare investigations (such as specific hospital billing records), but instead continues to demand the medical files of every minor seeking gender-affirming care. Such records commonly contain extraordinarily sensitive information, including intimate disclosures about "discomfort with specific body parts, sexual history, past trauma, interfamily dynamics, use of

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[32] *See AAP Policy Statement on Pediatric Informed Consent*, *supra* note 4.

[33] Rafferty, *AAP Policy Statement: Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents*, 142 Pediatrics e20182162 (2018), at 4.

[34] Riley, *The Needs of Gender-Variant Children and Their Parents: A Parent Survey*, 23(3) Int'l J. Sexual Health 181, 190-91 (2011).

self-harm or other negative coping mechanisms," and "experiences of harassment and bullying."[35]

Those concerns are directly echoed in the record here. Plaintiff Caroline Coe explained that her son's medical records include "an enormous amount of personal information," which her family disclosed only because they believed "[they] could trust that his medical information would be kept confidential." D. Ct. Dkt. No. (ECF) 10, ¶¶ 13, 17. Similarly, the records of plaintiff Riley Roe's child contain "years of medical care notes, test results, communications about gender affirming care options, routine medical records, and lists of all medications that [Riley's child] has taken." ECF 11, ¶ 14; *see also* ECF 12, ¶ 14 (similar as to plaintiff Norman Noe's child). Plaintiffs Karl Koe and Jay Doe themselves received GAMC at the Hospital and affirmed that they divulged their "deeply private details" only because they understood it was necessary for their care and that their information would be kept confidential. ECF 13, ¶ 12; *see* ECF 14, ¶¶ 14-15 (similar).

DOJ asserted that rules governing grand-jury secrecy should protect patients' interests in avoiding public disclosure. But as the district court

[35] *In re Subpoena No. 25-1431-014*, 810 F. Supp. 3d 555, 565 (E.D. Pa. 2025); *see also* June 24 Tr. at 4, 17, 21, 26 (repeatedly emphasizing the comprehensive and detailed nature of information demanded by government, which is "among the most personal and sensitive a medical provider can hold").

explained, June 24 Tr. at 21, 28-29, this assertion ignores patients' and parents' fears about the government itself possessing their private information, as well as their fears that public disclosure may occur notwithstanding grand-jury rules.[36] Those fears of government investigation and public disclosure not only create undue stress for current patients and their families, but also threaten to deter future adolescents from pursuing care at all—whether for gender-affirming medications or for "any [other] sort of care" that could assist them.[37] Because DOJ's intrusive demands for patient records would directly undermine effective medical practice, including for transgender adolescents, the district court was correct to enjoin DOJ's demands for the sensitive health records at issue.

II. OFF-LABEL PRESCRIBING IS COMMON AND EXPECTED IN MEDICAL CARE, ESPECIALLY PEDIATRIC CARE.

DOJ's ongoing investigation is also motivated by faulty assumptions about medical practice. Although its stated rationales have shifted over time, DOJ ostensibly seeks to investigate alleged "misbranding" of "puberty blockers, sex hormones, or any other drug used to facilitate a child's so-called 'gender

[36] *See, e.g.*, ECF 10, ¶ 18 (Coe Decl.) (expressing fear that government will "target doctors who provide gender-affirming care and patients seeking it"); ECF 11, ¶¶ 18-20 (Roe Decl.); ECF 12, ¶¶ 8-9 (Noe Decl.); ECF 13, ¶¶ 15-17 (Koe Decl.); ECF 14, ¶¶ 19-21 (Doe Decl.).

[37] Seelman et al., *Transgender Noninclusive Healthcare and Delaying Care Because of Fear: Connections to General Health and Mental Health Among Transgender Adults*, 2 Transgender Health 17, 26 (2017).

transition'" and "promot[ing] … off-label uses of hormones." ECF 1, at 67. Of chief apparent concern is the Federal Food, Drug, and Cosmetic Act (FDCA), administered by the Food and Drug Administration (FDA). Regardless of the specific legal violations it claims to be investigating, through public statements both in and out of court, DOJ has suggested that "off-label" prescribing is unlawful or improper.[38] That is wrong.

Federal law does *not* prohibit healthcare providers from prescribing off-label. Rather, the FDCA only limits manufacturers' ability to market approved drugs for unapproved (off-label) indications. And a provider who prescribes drugs off-label is not liable for "causing" the distribution of misbranded drugs. 21 U.S.C. § 331(a)-(c).

[38] In litigation with other hospitals, DOJ has equivocated on whether it considers hospitals to be witnesses, targets, or both. In April 2026, DOJ stated that Boston Children's Hospital "could be a witness to federal misconduct by other actors in the distribution chain, like pharmaceutical companies." Brief for Appellant at 15, 37, 41, *In re Admin. Subpoena No. 25-1431-019*, Nos. 25-2092, 26-1093 (1st Cir. Apr. 17, 2026). But in May 2026, DOJ argued that a hospital itself could also be a "party" directly liable under the FDCA's misbranding and distribution provisions, either by "causing" the distribution of misbranded drugs or "conspiring with pharmaceutical companies to misbrand" them. Corrected Brief for Appellants at 46, *Parent AA v. U.S. DOJ*, No. 26-1104 (4th Cir. May 4, 2026).

"[I]t is essential to understand that the FDA does not regulate the use of drugs as they pertain to the practice of medicine."[39] Medical practice is principally regulated by the states, not the federal government.[40] Once the FDA has approved a drug or device for at least one indication, a healthcare provider may prescribe it as the provider determines to be medically appropriate, including for off-label use.[41] As the Supreme Court and this Court have long recognized, "prescription drugs can be prescribed by doctors for both FDA-approved and -unapproved uses,"[42] and that practice "is an accepted and necessary corollary of the FDA's mission to regulate" without "interfering with the practice of medicine."[43]

A drug use could be "off-label" for many reasons. Most commonly, off-label use occurs when a drug is prescribed for an indication the FDA was not asked to review when it first approved the drug. For example, although aspirin

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[39] Neville et al., *AAP Policy Statement: Off-Label Use of Drugs in Children* (2014), https://perma.cc/P98P-K2FM [*AAP Policy Statement on Off-Label Use*].

[40] *See, e.g.*, *Gonzales v. Oregon*, 546 U.S. 243, 270 (2006).

[41] *See* Wittich et al., *Ten Common Questions (and Their Answers) About Off-Label Drug Use*, 87(10) Mayo Clinic Proc. 982 (2012); FDA, *Understanding Unapproved Use of Approved Drugs "Off-Label"* (2018), https://perma.cc/L46Q-3TXM; Beck, *Off-Label Use in the Twenty-First Century: Most Myths and Misconceptions Mitigated*, 54 UIC J. Marshall L. Rev. 1, 14-34 (2021); 37 Fed. Reg. 16,503 (Aug. 15, 1972).

[42] *United States v. Caronia*, 703 F.3d 149, 153 (2d Cir. 2012).

[43] *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001); *see also* 21 U.S.C. § 396.

has long been FDA-approved for reducing pain, fever, and swelling, the FDA has never approved it for coronary-disease prophylaxis in diabetic patients. Yet this "off-label" use is widely recommended as front-line treatment for diabetic patients facing increased risk of cardiovascular disease.[44]

A drug use may also be "off-label" if it is used "at a different dose or frequency than specified on the label"; administered through a different route than FDA approved; or prescribed to a "different patient population" than FDA was asked to evaluate.[45] For example, as front-line treatment for pediatric constipation, doctors routinely prescribe Miralax—an over-the-counter drug—notwithstanding that FDA has only approved its use in persons 17 and older.[46] As another example, rescue inhalers containing albuterol were long

[44] Wittich et al., *supra* note 41, at 983.

[45] *Ironworkers Local Union 68 v. AstraZeneca Pharms.* LP, 634 F.3d 1352, 1356 n.4 (11th Cir. 2011); *see also* 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); Durant et al., Am. Ass'n of Health-Sys. Pharmacists, *ASHP Guidelines on the Evaluation of Off-Label Medication Use in the Inpatient Setting*, 82 Am. J. Health-Syst. Pharm. e1013-e1019 (2025) [*ASHP Guidelines*]; Wittich et al., *supra* note 41, at 982-83.

[46] North Am. Soc'y for Pediatric Gastroenterology, Hepatology & Nutrition, *Polyethylene Glycol 3350 (PEG 3350) Frequently Asked Questions* (2015), https://perma.cc/ZBP6-6FR3.

"routine[ly]" prescribed for childhood asthma even before any FDA approvals existed for patients under 12.[47]

Whatever the reason for being "off-label," that term "does not imply an improper, illegal, [or] contraindicated" use.[48] Rather, the purpose of off-label drug use—as with on-label use—is to "benefit [an] individual patient" by diagnosing, preventing, or treating the patient's particular condition.[49]

The term "off-label" also does not necessarily indicate a lack of evidence to support that use.[50] "[I]n the vast majority of instances, it simply reflects the fact that the [drug's] sponsor" has not undertaken the burden and expense of "s[eeking] approval for that indication."[51] When FDA approval *has* been obtained for a particular use, that approval signifies the FDA has determined

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[47] Henry, *Off-Label Prescribing: Legal Implications*, 20(3) J. Legal Med. 365, 380 (1999).

[48] *AAP Policy Statement on Off-Label Use*, *supra* note 39.

[49] *Id.*; *ASHP Guidelines, supra* note 45.

[50] *See, e.g.*, Yackey et al., *Off-Label Prescribing in Children Remains High: A Call for Prioritized Research*, 144 Pediatrics e20191571 (2019) ("Although drugs are often used off label, there may be sufficient preliminary research about a medical condition and particular drugs to support their use.").

[51] Grossman, *Criminalizing Transgender Health Care*, 110 Iowa L. Rev. 281, 306 (2024); *accord, e.g.*, FDA, *Use of Approved Drugs for Unlabeled Indications*, 12 FDA Drug Bull. 4-5 (1982) [*1982 FDA Drug Bulletin*] (recognizing that off-label use will not become on-label unless an application for that new use is submitted to the FDA, which "without the initiative of the drug manufacturer … may never occur").

the drug to be safe and effective for that use. But the converse is not true: "[t]he absence of labeling for a specific age group or for a specific disorder does not necessarily mean that the drug's use is improper for that age or disorder."[52]

Off-label drug use is common across all fields of medicine. "[I]t is undisputed that the prescription of drugs for unapproved uses is commonplace in modern medical practice and ubiquitous in certain specialties."[53] These include oncology, neurology, psychiatry, and infectious disease.[54]

Off-label prescribing is particularly widespread in pediatrics.[55] A nationwide study of pediatric prescriptions from 2006-2015 found roughly 41.2 million off-label orders *per year* in outpatient visits alone, with an off-label prescription resulting from about 18.5% of total pediatric visits.[56] Another outpatient study found that off-label prescribing accounts for some 60% of

[52] *AAP Policy Statement on Off-Label Use*, *supra* note 39.

[53] *Washington Legal Found. v. Henney*, 202 F.3d 331, 333 (D.C. Cir. 2000).

[54] *ASHP Guidelines*, *supra* note 45; Henry, *supra* note 47, at 365.

[55] Allen (2018), *supra* note 45, at 776-82.

[56] Hoon et al., *Trends in Off-Label Drug Use in Ambulatory Settings: 2006-2015*, 144 Pediatrics e20190896 (2019).

prescriptions for pediatric patients.[57] Off-label prescribing is particularly important for pediatric patients with rare conditions.[58]

The special prevalence of off-label drug use in pediatrics has several causes. FDA drug approval generally requires robust data from clinical trials serving a specific patient population, and historically manufacturers have been disinclined to undertake separate trials with children because of the additional difficulty and expense.[59] Manufacturers have also long been aware that FDA approval of drugs for use in adults may lead in practice to off-label prescribing in children, reducing their incentives to seek separate FDA approval.[60]

Over time, a particular off-label use can become not only prevalent but central to professional standards of care.[61] The FDA has repeatedly acknowledged that off-label prescribing of a particular drug or device may

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[57] Bazzano et al., *Off-Label Prescribing to Children in the United States Outpatient Setting*, 9 Acad. Pediatrics 81-88 (2009).

[58] Fung et al., *Off-label medication use in rare pediatric diseases in the United States*, 10 Intractable & Rare Diseases Rsch. 238-45 (2021).

[59] *See, e.g.*, Henry, *supra* note 47, at 379; Wittich et al., *supra* note 41, at 982, 989.

[60] Fung et al., *supra* note 58, at 238.

[61] *See* Hoon, *supra* note 56 (recognizing that off-label prescribing "can represent best practice based on extensive clinical experience and supporting evidence of efficacy and safety"); Wittich et al., *supra* note 41, at 983 (similar).

"constitute [the] medically recognized standard of care."[62] As AAP explains, effective pediatric medicine will "more than likely require a practitioner to use drugs off label to provide the most appropriate treatment of a patient."[63]

That is true in the context of gender-affirming medical care. For example, gonadotropin-releasing hormone (GnRH) analogues (puberty blockers) are FDA-approved medications that suspend the progress of puberty and have been used in pediatric care for more than forty years.[64] GnRH analogues were originally approved to treat precocious puberty (puberty that begins too early). Their use for that purpose is widely regarded as safe and effective, and their pharmacologic effects and clinical management are well understood.[65] Through the same pharmacological mechanisms, these drugs can also suspend puberty where its progress would exacerbate a patient's gender dysphoria.[66] The use of

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[62] *See* FDA, *Draft Guidance for Industry: Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs & Medical Devices* 2 (Dec. 2011), https://perma.cc/6455-CP29; *1982 FDA Drug Bulletin*, *supra* note 51, at 4-5.

[63] *AAP Policy Statement on Off-Label Use*, *supra* note 39.

[64] *See, e.g.*, Comite et al., *Short-Term Treatment of Idiopathic Precocious Puberty with a Long-Acting Analogue of Luteinizing Hormone-Releasing Hormone: A Preliminary Report*, 305(26) New Eng. J. Med. 1546 (1981).

[65] *See* Coleman et al., *Standards of Care for the Health of Transgender and Gender Diverse People*, *Version 8*, 23 (Suppl. 1) Int'l J. Transgender Health, S1-S259 (2022) [*WPATH Standards of Care*]; Lopez et al., *Trends in the "Off-Label" Use of GnRH Agonists Among Pediatric Patients in the United States*, 57(12) Clinical Pediatrics 1432 (2018).

[66] *See WPATH Standards of Care, supra* note 65; Lopez et al., *supra* note 65.

GnRH analogues in transgender and gender-diverse youth is "off-label" not because those medications are new, unsafe, experimental, or ineffective,[67] but because the FDA did not specifically consider them for use in transgender adolescents.

Ideally, all drug uses that clinical evidence shows to be safe and effective would ultimately be reflected in approved FDA labeling. Congress has sought to create greater incentives for manufacturers to conduct clinical trials in pediatric populations, and other efforts have been undertaken to work toward FDA approval for many off-label medications.[68] But off-label prescribing is likely to remain important for clinicians, particularly where use is supported by significant clinical evidence. The net effect of DOJ's efforts would be to deny patient access to effective and potentially life-saving medications.

For the foregoing reasons, DOJ is fundamentally mistaken in suggesting that off-label prescribing is legally or medically suspect. Federal law does not

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[67] The safe use of GnRH analogues in young children with precocious puberty has been researched extensively, and recent studies have confirmed that GnRH agonists can be an effective treatment for certain transgender adolescents. *See, e.g.,* Tornese et al., *Use of Gonadotropin-Releasing Hormone Agonists in Transgender and Gender Diverse Youth: a Systematic Review*, 16 Frontiers in Endocrinology (2025).

[68] Allen (2018), *supra* note 45, at 776-77; Burckart et al., *The Revolution in Pediatric Drug Development and Drug Use: Therapeutic Orphans No More*, 25(7) J. Pediatric Pharmacol. & Therapeutics 565 (2020).

prohibit off-label prescribing, which is standard practice across all fields of medicine and particularly prevalent in pediatrics. DOJ's skepticism of off-label drug use is particularly unwarranted in the context of GAMC, which is evidence-based medicine described in widely accepted clinical guidelines and supported by *Amici* and other leading medical organizations when provided to carefully evaluated adolescents with gender dysphoria. That GAMC includes off-label drug use thus does not support DOJ's intrusive requests here.

CONCLUSION

For the foregoing reasons, *Amici* respectfully submit that the government's motion for stay pending appeal should be denied.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the type-volume limit of Federal Rule of Appellate Procedure 29(a)(5) because it contains 4,901 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f). This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Microsoft Word 2016 in Calisto MT 14-point font, a proportionally spaced typeface.

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CERTIFICATE OF FILING AND SERVICE

I, Jeffrey E. Sandberg, hereby certify that on August 3, 2026, I caused the foregoing amicus brief to be filed with the Clerk of Court for the U.S. Court of Appeals for the Second Circuit by using the CM/ECF system, which will cause a copy of the foregoing to be served on all counsel who have entered an appearance in this action.

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