Nos. 25-2092, 26-1093

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

IN RE: ADMINISTRATIVE SUBPOENA NO. 25-1431-019

THE CHILDREN'S HOSPITAL CORPORATION d/b/a Boston Children's Hospital,

Petitioner-Appellee,

v.

UNITED STATES DEPARTMENT OF JUSTICE,

Respondent-Appellant.

On Appeal from the United States District Court
for the District of Massachusetts

BRIEF OF *AMICI CURIAE* AMERICAN ACADEMY OF PEDIATRICS AND 17 OTHER NATIONAL MEDICAL AND MENTAL HEALTH ORGANIZATIONS IN SUPPORT OF PETITIONER-APPELLEE AND AFFIRMANCE

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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 curiae*, 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 subpoena-enforcement cases because the Department of Justice's (DOJ) subpoenas threaten to interfere with patient-physician relationships, impair health outcomes, and deter patient access to care. As experts in professional standards of care, *Amici* also wish to make the Court aware of fundamental errors underlying the subpoenas, including false assumptions about off-label prescribing and the scientific basis supporting gender-affirming medical care.

INTRODUCTION AND SUMMARY

In June 2025, the Department of Justice (DOJ) served numerous hospitals nationwide, including Boston Children's Hospital (Hospital), with administrative subpoenas seeking records relating to the provision of gender-affirming medical care (GAMC) to patients under age 18.[2] DOJ's subpoenas demand remarkably broad and intrusive information, including confidential medical records of every adolescent patient treated with GAMC by the recipient providers.

The district court properly granted the Hospital's motion to quash the administrative subpoena. As the Hospital persuasively explains in its response brief, the subpoena goes well beyond what federal law and precedent allow.

Amici submit this brief to make three 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

[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.

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, that generally depends on drug sponsors taking the initiative to seek them, and here—as in many instances—regulatory recognition lags behind accepted clinical practice.

Third, GAMC, including use of puberty blockers and hormone therapy, is evidence-based medicine supported by clinical guidelines. Major U.S. medical organizations recognize such care as medically necessary for certain carefully-evaluated adolescents. The government's assertion that such care is "radical gender experimentation" ignores consistent clinical evidence that supports GAMC and cannot justify its demand for unusually broad investigational latitude into patient records.

ARGUMENT

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

The district court properly quashed DOJ's subpoena demanding sensitive, personally identifying patient information.

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]

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

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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].

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

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 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]

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[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. Int. 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.

[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.*

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 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

[13] Levy et al., *Prevalence of and Factors Associated With Patient Nondisclosure of Medically Relevant Information to Clinicians*, JAMA Network Open 1, 7 (2018); *see also, e.g.*, ACOG, *Effective Patient-Physician Communication: Committee Statement*, 146 Obstet. & Gynecol. e115, e123 (Dec. 2025).

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

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

[16] *Id.*

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

Those policy commitments are founded upon decades of evidence showing that privacy concerns prevent many adolescents from seeking health

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[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].

[20] Ford et al., *Confidential Health Care for Adolescents: Position Paper of the Society for Adolescent Medicine*, 35(2) J. Adolescent 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").

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 barrier to adolescents seeking health care."[23] 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 contexts, the stakes are higher for adolescents. Adolescents

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[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. Adolescent Health 36, 37 (2018); Lehrer et al., *Forgone Health Care Among U.S. Adolescents: Associations Between Risk Characteristics and Confidentiality Concern*, 40(3) J. Adolescent 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).

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

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

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+ 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

[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.

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

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 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 or other harms associated with exposure of their children to

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[29] *See* Sankar et al., *Patient Perspectives of Medical Confidentiality*, 18(8) J. Gen. Int. 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. Adolescent Health 602, 602-09 (2025).

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

[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 [AAP Policy Statement on Gender-Affirming Care].

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

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.[36] Because DOJ's intrusive demands for patient records would directly undermine effective

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[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).

[35] *In re Subpoena No.25-1431-014*, 810 F. Supp. 3d 555, 565 (E.D. Pa. 2025).

[36] 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).

medical practice, including for transgender adolescents, the district court was correct to reject 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 transition and "'promot[ing] off-label uses of' certain drugs used in gender-related treatments of minors."[37] Of chief apparent concern is the Federal Food, Drug, and Cosmetic Act (FDCA), administered by the FDA. Regardless of the specific legal violations it claims to be investigating, through public statements both in and out of court, DOJ suggests "off-label" prescribing is unlawful or improper.[38] That is wrong.

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[37] Government's Resp. to Mot. to Quash at 5, *In re Administrative Subpoena*, No. 1:25-cv-91324-MJJ (D. Mass. July 23, 2025); *see also id.* at 13.

[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." Appellant's Br. 15, 37, 41. 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 Appellants Br. 46, *Parent AA v. U.S. DOJ*, No. 26-1104 (4th Cir. May 4, 2026).

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).

"[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, "physicians can—and do—lawfully prescribe prescription drugs for off-label uses,"[42] and that practice "is an accepted and necessary corollary of the

[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] *In re Celexa & Lexapro Mktg. & Sales Pracs. Litig.*, 915 F.3d 1, 12 (1st Cir. 2019).

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 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—

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

[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.

notwithstanding that FDA has only approved its use in persons 17 and older.[46] As another example, rescue inhalers containing albuterol were long "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

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

[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.").

"s[eeking] approval for that indication."[51] When FDA approval *has* been obtained for a particular use, that approval signifies the FDA has determined 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

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[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").

[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.

prescription resulting from about 18.5% of total pediatric visits.[56] Another outpatient study found that off-label prescribing accounts for some 60% of 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

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

[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. 238-245 (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).

acknowledged that off-label prescribing of a particular drug or device may "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, gonadotrophin-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

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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*, 2022(23) 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).

where its progress would exacerbate a patient's gender dysphoria.[66] The use of 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 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.

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

[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 Pharmacology and Therapeutics 565 (2020).

For the foregoing reasons, DOJ is fundamentally mistaken in suggesting that off-label prescribing is legally or medically suspect. Federal law does not prohibit off-label prescribing, which is standard practice across all fields of medicine and particularly prevalent in pediatrics. That GAMC includes off-label drug use does not support DOJ's intrusive requests here.

III. GENDER-AFFIRMING MEDICAL CARE IS EVIDENCE-BASED MEDICINE, NOT EXPERIMENTAL TREATMENT.

DOJ's asserted justification for its investigation—that GAMC is "radical gender experimentation"[69]—also reflects a fundamental misunderstanding about GAMC. This treatment is widely supported by experts when provided to carefully evaluated adolescents with gender dysphoria.

A. Understanding Gender Identity and Gender Dysphoria.

A person's "gender identity" is their deep internal sense of belonging to a particular gender.[70] Most people have a gender identity that aligns with their sex assigned at birth; transgender people do not.[71] In the United States, approximately 1.4 million individuals are transgender, of whom approximately

[69] DOJ Att'y Gen. Memo. at 4 (Apr. 22, 2025), https://perma.cc/HKC5-EFTL.

[70] AAP Policy Statement on Gender-Affirming Care, *supra* note 33, at 2 tbl. 1.

[71] *See* Am. Psychological Ass'n, *Guidelines for Psychological Practice With Transgender and Gender Nonconforming People*, 70(9) Am. Psychologist 832, 862 (2015).

10% are teenagers aged 13 to 17.[72] Individuals often start to understand their gender identity during childhood and adolescence.

Being transgender is a normal variation of human identity.[73] But many transgender people suffer from "gender dysphoria," a serious medical condition in which a patient experiences clinically significant distress due to marked incongruence between the patient's gender identity and sex assigned at birth. This distress can lead to significant "impairment in peer and/or family relationships, school performance, or other aspects of their life."[74] Gender dysphoria is a formal diagnosis under the American Psychiatric Association's Diagnostic and Statistical Manual (DSM-5-TR).[75]

Individuals with untreated or inadequately treated gender dysphoria are at increased risk for depression, anxiety, self-harm, and suicidality.[76] 65% of transgender and nonbinary young people reported recent symptoms of

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[72] Hughes et al., *Gender-Affirming Medications Among Transgender Adolescents in the US, 2018–2022*, 179(3) JAMA Pediatrics 342 (2025).

[73] Am. Psychological Ass'n, *APA Resolution on Gender Identity Change Efforts*, at 4 (Feb. 2021), https://perma.cc/78ST-3AVU.

[74] AAP Policy Statement on Gender-Affirming Care, *supra* note 33, at 3.

[75] *See* Am. Psychiatric Ass'n, *Diagnostic and Statistical Manual of Mental Disorders: DSM-5-TR*, 512-13 (2022). While gender dysphoria is included in the DSM-5-TR, it is not considered a psychotic disturbance.

[76] *See* Kameg et al., *Gender Dysphoria In Youth: An Overview For Primary Care Providers*, 30(9) J. Am. Ass'n Nurse Practitioners 493 (2018).

generalized anxiety disorder, and over 50% reported symptoms of depression.[77] 40% reported having seriously considered attempting suicide,[78] and more than 10% reported having attempted suicide in the preceding 12 months.[79] Transgender and nonbinary young people who wanted hormone treatment but could not access it were nearly twice as likely to attempt suicide than those who could.[80]

Leading members of the medical community, including *Amici*, recognize that gender dysphoria is best treated through a model of gender-affirming care, which supports an individual as they explore their gender identity.[81] In contrast, efforts to change individuals' gender identities to match their sex assigned at birth are known to be ineffective and harmful.[82]

For carefully evaluated adolescents with persistent gender dysphoria that intensifies with puberty onset, clinical guidelines indicate that prescription

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[77] *See* Nath et al., *The Trevor Project, 2025 U.S. National Survey on the Mental Health of LGBTQ+ Young People*, at 7, https://perma.cc/7CX3-583L.

[78] *See id.* at 3.

[79] *See* Johns et al., *Transgender Identity and Experiences of Violence Victimization, Substance Use, Suicide Risk, and Sexual Risk Behaviors Among High School Students–19 States and Large Urban School Districts, 2017*, 68 Morbidity & Mortality Wkly. Rep. 67, 70 (2019).

[80] Nath et al., *supra* note 77, at 2.

[81] AAP Policy Statement on Gender-Affirming Care, *supra* note 33, at 4.

[82] *See, e.g.*, Mallory et al., *Conversion Therapy and LGBT Youth: Update*, Williams Inst. (2019), https://perma.cc/HXY3-UX2J.

medications—GAMC—may be used to delay further progress of puberty and, if later determined appropriate, to align their physiology with their gender identity through hormone therapy.[83] These guidelines do not provide for prescribing such drugs for pre-pubertal children and indicate prescription medications only if comprehensive assessment and therapy determine that these treatments are appropriate.[84]

Empirical evidence indicates that treating carefully-evaluated adolescents who meet diagnostic criteria with such medications can alleviate clinically-significant distress and lead to significant improvements in mental health and overall wellbeing.[85] For these patients, GAMC is critical, medically necessary, evidence-based care.

B. Widely Accepted Guidelines for Treating Adolescents with Gender Dysphoria Provide for GAMC When Indicated.

Treatment recommendations for gender dysphoria are provided in evidence-based clinical guidelines: (i) the Endocrine Society's Clinical Practice Guidelines for Clinical Treatment of Gender-Dysphoria/Gender Incongruent

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[83] *See infra* Section III.B.

[84] *See* Boulware et al., *Biased Science: The Texas and Alabama Measures Criminalizing Medical Treatment for Transgender Children and Adolescents Rely on Inaccurate and Misleading Scientific Claims* (2022), https://perma.cc/C4X3-F2JR.

[85] *See* Martin et al., *Criminalization of Gender-Affirming Care—Interfering with Essential Treatment for Transgender Children and Adolescents*, 385(7) New Eng. J. Med. 579 (2021).

Persons, and (ii) the WPATH Standards of Care for the Health of Transgender and Gender-Diverse People.[86] These guidelines set forth extensive requirements addressing when GAMC may be appropriate for adolescents, including robust interdisciplinary diagnostic assessment; stringent guidelines regarding the qualifications of medical professionals; and strict patient criteria, including a prolonged pattern of gender dysphoria that worsens with puberty onset.[87]

If, after careful evaluation, healthcare providers determine that an adolescent with persistent gender dysphoria meets all criteria—including optimization of other mental-health conditions, sufficient maturity to understand the decision, and informed consent from patient and parent—GnRH analogues (puberty blockers) may be offered after puberty onset, for a finite period. These medications delay further pubertal development until adolescents are older and have had sufficient time to make informed decisions about further treatments.[88] Puberty blockers can make pursuing transition later easier by

[86] *See* Hembree et al., *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline*, 102(11) J. Clinical Endocrinology & Metabolism 3869 (Nov. 2017) [Endocrine Society Clinical Guideline]; WPATH Standards of Care, *supra* note 65, at S28.

[87] *See* Endocrine Society Clinical Guideline, *supra* note 86, at 3869, 3878, 3880-85; WPATH Standards of Care, *supra* note 65, at S48.

[88] Martin et al., *supra* note 85, at 2; Endocrine Society Clinical Guideline, *supra* note 86, at 3880.

preventing bodily changes that would otherwise occur, such as Adam's apple protrusion or breast growth.[89]

When used in this manner, the effects of puberty blockers are generally reversible, meaning that when a patient discontinues use, the patient typically resumes endogenous puberty.[90] Puberty blockers have been used by endocrinologists for more than 40 years to treat precocious puberty.[91] The risks of serious adverse effects from puberty blockers are exceedingly rare when provided under clinical supervision.[92]

Later in adolescence, and again only after careful evaluation and if all treatment criteria are met, hormone therapy may be used to initiate puberty consistent with the patient's gender identity.[93] Hormone therapy allows adolescents to develop secondary sex characteristics consistent with their gender identity. Although some changes caused by hormone therapy become

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[89] *See* AAP Policy Statement on Gender-Affirming Care, *supra* note 33, at 5.

[90] *See* Martin et al., *supra* note 85, at 2.

[91] *See* Comite et al., *supra* note 64.

[92] *See*, *e.g.*, Staphorsius et al., *Puberty Suppression and Executive Functioning: An fMRI-Study in Adolescents with Gender Dysphoria*, 56 Psychoneuroendocrinology 190 (2015) (no adverse impact on executive functioning); Pang et al., *Long-term Puberty Suppression for a Nonbinary Teenager*, 145 Pediatrics e20191606 (2020) (exceedingly low risk of delayed bone mineralization from hormone treatment).

[93] *See* Endocrine Society Clinical Guideline, *supra* note 86, at 3878-85; WPATH Standards of Care, *supra* note 65, at S48; Martin, *supra* note 85, at 2.

irreversible after those secondary sex characteristics are fully developed, others are partially reversible if the patient discontinues use.[94]

As in other areas of medicine, treatment recommendations involving GAMC require healthcare providers to obtain informed consent. Clinical practice guidelines for treating adolescent patients with GAMC include express, specific guidance on securing informed consent from both patients and their parents.[95]

The widely accepted view of the professional medical community is that, for some adolescents, GAMC is necessary and appropriate treatment for gender dysphoria. This care greatly reduces the negative physical and mental-health consequences that result when gender dysphoria is untreated.[96] The type and certainty of evidence supporting these treatments, and the manner in which that evidence has been evaluated, are consistent with best practices of the medical community in other clinical disciplines.[97]

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[94] *See* AAP Policy Statement on Gender-Affirming Care, *supra* note 33, at 5-6.

[95] *See* Endocrine Society Clinical Guideline, *supra* note 86, at 3878; WPATH Standards of Care, *supra* note 65, at S48.

[96] *See, e.g.*, Endocrine Soc'y, *Transgender Health: An Endocrine Society Position Statement* (2020), https://perma.cc/7L4P-VWME.

[97] *See* Gordon Guyatt et al., *Systematic Reviews Related to Gender-Affirming Care* (2025), https://perma.cc/5NFG-GZ64.

C. The Available Evidence Supports Providing GAMC for Adolescents with Gender Dysphoria When Indicated.

Many studies have examined the use of puberty blockers[98] and hormones[99] to treat adolescents with gender dysphoria. Although more research is appropriate and desirable, existing research supports the conclusion that, when

[98] A non-exhaustive list includes: Achille et al., *Longitudinal Impact of Gender-Affirming Endocrine Intervention on The Mental Health and Wellbeing of Transgender Youths: Preliminary Results*, 2020(8) Int'l J. Pediatric Endocrinology 1 (2020); Carmichael et al., *Short-Term Outcomes of Pubertal Suppression in a Selected Cohort of 12 to 15 Year Old Young People With Persistent Gender Dysphoria in the UK*, 16(2) PLOS One e0243894 (2021); Costa et al., *Psychological Support, Puberty Suppression, and Psychosocial Functioning in Adolescents with Gender Dysphoria*, 12(11) J. Sexual Med. 2206 (2015); de Vries et al., *Puberty Suppression in Adolescents with Gender Identity Disorder: A Prospective Follow-Up Study*, 8(8) J. Sexual Med. 2276-83 (2011); de Vries et al., *Young Adult Psychological Outcome After Puberty Suppression And Gender Reassignment*, 134(4) Pediatrics 696-704 (2014); Lavender et al., *Impact of Hormone Treatment on Psychosocial Functioning in Gender-Diverse Young People*, 10(5) LGBT Health 382 (2023); Turban et al., *Pubertal Suppression For Transgender Youth And Risk of Suicidal Ideation*, 145(2) Pediatrics e20191725 (2020).

[99] *See, e.g.*, Achille et al., *supra* note 98, at 1-5; Allen et al., *Changes in Suicidality Among Transgender Adolescents Following Hormone Therapy: An Extended Study*, 289 Pediatrics 114883 (2026); Allen et al., *Well-Being and Suicidality Among Transgender Youth After Gender-Affirming Hormones*, 7(3) Clinical Prac. in Pediatric Psychol. 302 (2019); Chen et al., *Psychosocial Functioning in Transgender Youth after 2 Years of Hormones*, 388(3) New Eng. J. Med. 240 (2023); Fisher et al., *Back to the Future: Is GnRH Treatment in Transgender and Gender Diverse Adolescents Only an Extended Evaluation Phase?*, 109(6) J. Clinical Endocrinology and Metabolism 1565 (2023); McGregor et al., *Association of Pubertal Blockade at Tanner 2/3 With Psychosocial Benefits in Transgender and Gender Diverse Youth at Hormone Readiness Assessment*, 74(4) J. Adolescent Health 801 (2024).

provided to patients for whom it is indicated under clinical guidelines, GAMC can be provided safely and ethically and can improve patient wellbeing.

Multiple studies have found positive mental-health outcomes for adolescents who receive GAMC, including statistically significant reductions in anxiety, depression, and suicidal ideation.[100] For example, a recent study following 432 transgender patients found that hormone therapy was associated with clinically meaningful reductions in suicidality over time, even across differences in sex-assigned-at-birth, age, and treatment duration. Those findings are consistent with but extend further than prior studies, "suggesting a stable and clinically meaningful association between [hormone therapy] and reduced suicidality."[101]

A 2023 study assessed adolescents, younger than 15 years but beyond puberty onset, who received puberty blockers followed by gender-affirming hormone treatment. The cohort was assessed before treatment, after one year of puberty blockers, and after one year of hormone treatment. The study found that dissatisfaction with primary sexual characteristics, gender dysphoria, and

[100] The data likewise indicate that adults who receive gender-affirming care experience positive mental-health outcomes. *See, e.g.*, Aldridge et al., *Long-Term Effect of Gender Affirming Hormone Treatment on Depression and Anxiety Symptoms in Transgender People: A Prospective Cohort Study*, 2021(9) Andrology 1808 (2021).

[101] *See* Allen et al. (2026), *supra* note 99, at 4.

social motivation improved significantly over time.[102] Self-harm and suicidality also showed a general decrease.[103]

Another 2023 study, following 315 participants age 12 to 20 who received gender-affirming hormone treatment, found that treatment was associated with decreased symptoms of depression and anxiety.[104] A six-year follow-up study of 55 individuals found that hormone therapy (followed by surgical interventions in adulthood) was associated with statistically-significant decreases in depression and anxiety.[105]

As clinicians, scientists, and researchers, *Amici* welcome more research, including for GAMC. But existing evidence is consistent with the conclusion that GAMC is appropriate and clinically effective for treating gender dysphoria in carefully evaluated patients. Thus, DOJ is incorrect to suggest its intrusive demands are justified because GAMC is supposedly experimental.

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[102] *See* Lavender et al., *supra* note 98, at 382.

[103] *Id*.

[104] *See* Chen et al., *supra* note 99, at 240.

[105] de Vries et al. (2014), *supra* note 98, at 700.

CONCLUSION

The judgment of the district court should be affirmed.

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 6,499 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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DATED: July 21, 2026

CERTIFICATE OF FILING AND SERVICE

I, Jeffrey E. Sandberg, hereby certify that on July 21, 2026, I caused the foregoing amicus brief to be filed with the Clerk of Court for the U.S. Court of Appeals for the First 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.

/s/ Jeffrey E. Sandberg
Jeffrey E. Sandberg
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DATED: July 21, 2026