No. 25-7384

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

QUEERDOC, PLLC,

Plaintiff-Appellee,

v.

DOJ – UNITED STATES DEPARTMENT OF JUSTICE,

Defendant-Appellant.

On Appeal from the United States District Court
for the Western District of Washington

BRIEF OF *AMICI CURIAE* AMERICAN ACADEMY OF PEDIATRICS AND 16 OTHER NATIONAL MEDICAL AND MENTAL HEALTH ORGANIZATIONS IN SUPPORT OF PETITION FOR REHEARING EN BANC

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1 and Circuit Rule 26.1-1, the American Academy of Pediatrics (AAP), 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 17 professional medical and mental-health organizations representing thousands of healthcare providers across the United States: the American Academy of Pediatrics (AAP), 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. All parties have consented to this brief.[1]

Amici have a strong interest in this and other pending cases because the Department of Justice's 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.

[1] Undersigned counsel certifies that no party's counsel authored this brief in whole or 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.

INTRODUCTION AND SUMMARY

In June 2025, the Department of Justice (DOJ) served administrative subpoenas on healthcare providers across the country, including QueerDoc, seeking information about gender-affirming medical care provided to patients under age 18. In a departure from normal practices, DOJ's subpoena demanded not only the kinds of records customarily requested in healthcare investigations, but also the confidential medical records of every adolescent patient treated by the practice. The district court quashed the subpoena, finding that it was not issued to further a legitimate healthcare investigation but instead "to pressure providers to cease offering [lawful] gender-affirming care." *QueerDoc, PLLC v. U.S. Dep't of Just.*, 807 F.Supp.3d 1295, 1304 (W.D. Wash. 2025).

A divided panel of this Court then reversed. The majority did not dispute that DOJ's stated rationales were "pretextual." *QueerDoc, PLLC v. U.S. Dep't of Just.*, 187 F.4th 1112, 1129 (9th Cir. 2026). Instead, it declared that "[t]he President may direct DOJ to exercise its statutory authority in a manner that aligns with his broader policy goals." *Id.* at 1125. It accordingly held that DOJ may investigate QueerDoc based on little more than the President's declared hostility toward gender-affirming medical care.

As QueerDoc's rehearing petition explains, the panel majority misapplied this Court's precedent in numerous respects, warranting en banc review. *Amici*

submit this brief to make two additional points, each of which supports affirmance of the district court's factual findings that DOJ acted with an improper purpose.

First, confidentiality of medical records is central to effective medical care, particularly for transgender adolescents, because it preserves the trust of patients and parents on which treatment depends. Intrusive government requests for patient records threaten to interfere with physician-patient-parent relationships, impair health outcomes, and deter access to care. Indeed, as Judge Paez recognized, that appears to have been the point of DOJ's subpoena: "[w]hile the government's demand for intrusive identifying information bears little on its purported purpose of investigating federal health care offenses, it effectively serves the goal of intimidating patients and providers." *Id.* at 1160 (Paez, J., dissenting). The panel majority fundamentally erred in treating DOJ's demand for patient information as irrelevant to the improper-purpose inquiry.

Second, DOJ's stated justification for its investigation reflects serious misunderstandings about proper medical practice. In all medical fields, 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 they 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, they generally depend on drug sponsors seeking them, and regulatory recognition often lags behind accepted clinical practice. Here, as in many other contexts, off-label prescribing for gender-affirming medical care is evidence-based and supported by clinical guidelines. The panel majority erred in accepting, without scrutiny, DOJ's premise that off-label prescribing suggests legal or professional wrongdoing warranting a law-enforcement investigation.

ARGUMENT

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

The district court properly found that DOJ's subpoena, including its demands for "[a]ll medical records, diagnoses, and treatment documentation" of QueerDoc's patients, was issued for the improper purpose of "pressur[ing] providers to cease offering gender-affirming care." *QueerDoc*, 807 F.Supp.3d at 1304.

Confidentiality of patient information receives numerous legal protections.[2] But it is also a foundation of ethical and effective medical practice,

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

both for adult patients and for adolescents (for whom treatment generally requires assent by both patients and their parents or guardians).[3]

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."[4] 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.[5]

Confidentiality is critical to multiple "moral traditions" within medical ethics.[6] "Ethical principles of autonomy, nonmaleficence, beneficence, and

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[3] *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*].

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

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

[6] 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*

(*continued*…)

justice are all key elements of the ethical framework for confidentiality in adolescent health care."[7] Autonomy requires respect for the rights of patients and families to make informed decisions about their own care.[8] Justice urges physicians to care about the needs of the entire community, including those who may face barriers to treatment.[9] Nonmaleficence cautions physicians to "do no harm."[10] And beneficence imposes a "duty to promote good and act in the best interest of the patient and the health of society."[11]

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."[12] Providers "rely on patients to disclose their symptoms, health behaviors, and thoughts and feelings so that

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the Society for Adolescent Health and Medicine, 77(4) J. Adolesc. Health 791, 792 (2025) [*SAHM Position Statement on Confidentiality*].

[7] *Policy Compendium*, *supra* note 6, at 3.

[8] Varkey, *supra* note 6, at 19-20.

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

[10] *ACP Ethics Manual*, *supra* note 6, at 74.

[11] *Id.*

[12] 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).

clinicians can make appropriate diagnoses and treatment recommendations."[13] 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.[14]

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."[15] And the credibility of such assurances affects patients' and parents' "decision[s] [whether] to seek care" at all.[16]

Those conclusions are memorialized in policy statements by *Amici* and other leading organizations.[17] AAP affirms that "[c]onfidentiality is an essential component of high-quality adolescent care" with "profound implications for

[13] Levy et al., *supra* note 12, at 2.

[14] *SAHM Position Statement on Confidentiality*, *supra* note 6, at 791-92.

[15] *Id.*

[16] *AAP Confidentiality Technical Report*, *supra* note 2, at 1.

[17] *See generally Policy Compendium*, *supra* note 6.

health care access and utilization, outcomes, and safety."[18] The Society for Adolescent Health and Medicine "has long recognized the importance of confidential health care for adolescents."[19] 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.[20]

Those policy commitments are founded upon decades of evidence showing that privacy concerns prevent many adolescents from seeking health care.[21] Both "large nationally representative surveys and smaller state or local

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[18] 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*].

[19] 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 6, at 791.

[20] *Policy Compendium*, *supra* note 6, 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").

[21] *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*

(*continued*…)

studies" have "confirm[ed] that concerns about privacy can act as a significant barrier to adolescents seeking health care."[22] 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.[23]

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."[24]

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.[25] Adolescents more likely to forgo care based on confidentiality concerns include those with "elevated prevalence of high depressive symptoms, suicidal ideation, and suicide attempt."[26] Marginalized groups, including "LGBTQIA+

Concern, 40(3) J. Adolesc. Health 218, 218-19 (2007); *SAHM Position Statement on Confidentiality*, *supra* note 6, at 792 (citing additional studies).

[22] *Policy Compendium*, *supra* note 6, at 1.

[23] *AAP Confidentiality Technical Report*, *supra* note 2, at 4.

[24] AAP Committee on Adolescence, *Achieving Quality Health Services for Adolescents*, 138 Pediatrics e20161347, at 3 (2016).

[25] Levy et al., *supra* note 12, at 6.

[26] Lehrer et al., *supra* note 21, at 222-23.

youth," may also be "particularly concerned about ensuring confidentiality of their health information."[27]

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.[28] Ensuring the trust of parents and guardians in the physician's confidentiality arrangements is critical to adequate care for adolescent patients.[29] Clinicians thus work to "encourage and facilitate communication between young people and their parents" where such communication will best serve the patient's needs.[30] 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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[27] *AAP Policy Statement on Confidentiality*, *supra* note 18, at 3.

[28] *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).

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

[30] *SAHM Position Statement on Confidentiality*, *supra* note 6, at 791.

interventions on adolescent patients.[31] 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.[32] Among parents' most common concerns are those about stigma, discrimination, or other harms associated with potential exposure of their children to public scrutiny.[33] Maintaining confidentiality is essential for addressing those concerns and maintaining the trust of patients and parents alike.

DOJ's demands directly threaten those interests. In issuing this subpoena, DOJ did not merely request the kinds of information customarily at issue in federal healthcare investigations, but demanded the sensitive medical files of every minor seeking gender-affirming care. The ensuing patient 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

[31] *See AAP Policy Statement on Pediatric Informed Consent*, *supra* note 3.

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

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

[other] sort of care" that could assist them.[34] DOJ's intrusive demands for patient records directly undermine effective medical practice, and the panel majority erred in deeming those demands irrelevant to the improper-purpose inquiry.

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

DOJ's ongoing investigation has also reflected faulty assumptions about medical practice. Although its stated rationales have shifted over time, DOJ ostensibly issued this subpoena in order to investigate the alleged "misbranding" of "off-label . . . puberty blockers, sex hormones, or any other drug used to facilitate a child's so-called 'gender transition.'" *QueerDoc*, 807 F.Supp.3d at 1298. Of chief apparent concern is the Federal Food, Drug, and Cosmetic Act (FDCA), administered by the Food and Drug Administration (FDA). In and out of court, DOJ has at times suggested that "off-label" prescribing is medically improper or even unlawful. That is wrong.

As an initial matter, 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

[34] 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).

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."[35] Medical practice is principally regulated by the states, not the federal government.[36] 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.[37] As the Supreme Court and this Court have long recognized, "physicians are free to prescribe drugs for off-label uses,"[38] and that practice "is an accepted and necessary corollary of the FDA's mission to regulate" without "interfering with the practice of medicine."[39]

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

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[35] 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*].

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

[37] *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).

[38] *In re Gilead Scis. Sec. Litig.*, 536 F.3d 1049, 1051 (9th Cir. 2008).

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

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.[40]

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 the FDA approved; or prescribed to a "different patient population" than the FDA was asked to evaluate.[41] For example, as front-line treatment for pediatric constipation, doctors routinely prescribe Miralax—an over-the-counter drug—notwithstanding that the FDA has only approved its use in persons 17 and older.[42] As another example, rescue inhalers containing albuterol were long

[40] Wittich et al., *supra* note 37, at 983.

[41] *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 37, at 982-83.

[42] 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.[43]

Whatever the reason for being "off-label," that term "does not imply an improper, illegal, [or] contraindicated" use.[44] 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.[45]

The term "off-label" also does not necessarily indicate a lack of evidence to support that use.[46] "[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."[47] 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

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

[44] *AAP Policy Statement on Off-Label Use*, *supra* note 35.

[45] *Id.*; *ASHP Guidelines*, *supra* note 41.

[46] *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.").

[47] 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*].

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."[48]

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."[49] These include oncology, neurology, psychiatry, and infectious disease.[50]

Off-label prescribing is particularly widespread in pediatrics.[51] 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.[52] Another outpatient study found that off-label prescribing accounts for some 60% of prescriptions for pediatric patients.[53] Off-label prescribing is particularly important for pediatric patients with rare conditions.[54]

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[48] *AAP Policy Statement on Off-Label Use*, *supra* note 35.

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

[50] *ASHP Guidelines*, *supra* note 41; Henry, *supra* note 43, at 365.

[51] Allen et al., *supra* note 41, at 776-82.

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

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

[54] Fung et al., *Off-Label Medication Use in Rare Pediatric Diseases in the United States*, 10 Intractable & Rare Diseases Rsch. 238-45 (2021).

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.[55] 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.[56]

Over time, a particular off-label use can become not only prevalent but central to professional standards of care.[57] The FDA has repeatedly acknowledged that off-label prescribing of a particular drug or device may "constitute [the] medically recognized standard of care."[58] 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."[59]

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[55] *See*, *e.g.*, Henry, *supra* note 43, at 379; Wittich et al., *supra* note 37, at 982, 989.

[56] Fung et al., *supra* note 54, at 238.

[57] *See* Hoon et al., *supra* note 52 (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 37, at 983 (similar).

[58] *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 47, at 4-5.

[59] *AAP Policy Statement on Off-Label Use*, *supra* note 35.

That is true 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.[60] 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.[61] Through the same pharmacological mechanisms, these drugs can also suspend puberty where its progress would exacerbate a patient's gender dysphoria.[62] The use of GnRH analogues in transgender and gender-diverse youth is "off-label" not because those medications are new, unsafe, experimental, or ineffective,[63] but

[60] *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).

[61] *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).

[62] *See WPATH Standards of Care*, *supra* note 61; Lopez et al., *supra* note 61.

[63] 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 1, 10-12 (2025).

because the FDA did not specifically consider them for use in transgender adolescents. Gender-affirming medical care 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.

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 pediatric clinical trials, and other efforts have worked toward FDA approval for many off-label medications.[64] But off-label prescribing is likely to remain important for clinicians, particularly where use is supported by significant clinical evidence. The effect of DOJ's efforts would be to deny patient access to effective and potentially life-saving medications.

[64] Allen et al., *supra* note 41, 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).

CONCLUSION

For the foregoing reasons, *Amici* respectfully submit that the petition for rehearing en banc should be granted.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the type-volume limit of Circuit Rule 29-2(c)(2) because it contains 4,198 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 SERVICE

I, Jeffrey E. Sandberg, hereby certify that on October 8, 2026, I caused the foregoing amicus brief to be filed with the Clerk of Court for the U.S. Court of Appeals for the Ninth Circuit by using the ACMS 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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