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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

Z.A., a minor, by and through their parent, A.A.; Z.B., a minor, by and through their parent, B.B.; Z.C., a minor, by and through their parent, C.C.; Z.D., a minor, by and through their parent, D.D.; Z.E., a minor, by and through their parent, E.E.; and F.F.,

Plaintiffs,

v.

TODD BLANCHE, in his official capacity as Acting Attorney General of the United States; U.S. DEPARTMENT OF JUSTICE; and LUCILE SALTER PACKARD CHILDREN'S HOSPITAL AT STANFORD, a California nonprofit public benefit corporation,

Defendants.

Case No. 5:26-cv-04998

[PROPOSED] BRIEF OF *AMICUS CURIAE* AMERICAN ACADEMY OF PEDIATRICS IN SUPPORT OF PLAINTIFFS' MOTION FOR A TEMPORARY RESTRAINING ORDER

Judge: Hon. P. Casey Pitts
Ctrm: 8, 4th Floor
Date: June 24, 2026
Time: 2:00 p.m.

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INTEREST OF AMICUS CURIAE[1]

The American Academy of Pediatrics ("AAP") was founded in 1930 and is a national not-for-profit organization with a mission to attain optimal physical, mental, and social health and well-being for all infants, children, adolescents and young adults. AAP's membership includes over 67,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists. AAP has devoted substantial resources to providing up-to-date, evidence-based guidance for pediatricians and for public health officials regarding pediatric health.

SUMMARY OF ARGUMENT

The Department of Justice appears to be pursuing subpoenas against medical providers in support of a theory that there is something improper about those providers' off-label use of medications. But the off-label use of medications, including in pediatrics, is lawful, common, and clinically appropriate when supported by evidence and professional judgment. The clinical and commercial uses of drugs and medical devices continue to evolve after marketing approval is granted by the U.S. Food and Drug Administration. Clinicians produce clinical comparison studies regarding benefits and risks, find new uses, apply the drug or device to new patient populations, and modify dosing regimens from those approved by the FDA in "off-label use." The 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. Rather, it only means that the evidence required by law to allow inclusion in the label has not yet been approved by the FDA. Evidence, not label indication, remains the gold standard from which practitioners should draw when making therapeutic decisions for their patients.

Off-label drug use is common in gender-affirming care because many medications were not initially approved by the FDA for the specific purpose of treating gender dysphoria in adolescents. But gender-affirming care for adolescents is both evidence-based and medically necessary, as recognized by

[1] 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 person other than *amicus curiae*, its members, and its counsel contributed money to fund this brief. All parties have consented to the filing of this brief.

several major medical associations. The decision of whether and when to initiate gender-affirmative treatment is personal and involves careful consideration of risks, benefits, and other factors unique to each patient and family, in consultation with medical providers.

The subpoena that the Department of Justice has issued in this case also appears to be premised on the notion that gender-affirming care for adolescents could never be medically appropriate. But this care is evidence-based, and it may be medically necessary in appropriate circumstances. Gender-affirming care, including the use of medications for such care for adolescents, is considered part of the standard of care by major medical associations, including AAP, the American Medical Association, and the American College of Obstetricians & Gynecologists. Adolescents who identify as transgender have high rates of depression and are particularly at risk for suicide. Care for transgender youth can improve their mental health outcomes and avoid a range of serious harms. In appropriate circumstances, after a clinician's consultation with an adolescent and their family, medication may be a part of the regimen of care that most improves the adolescent's psychological functioning.

Broad subpoenas of medical records—particularly those inquiring into common medical practices such as off-label prescribing—threaten patient privacy, will chill access to care, and may lessen the quality of that care. Confidentiality is a core component of the relationship between a physician, a patient, and their family, as evidenced by best practice guidelines and professional ethical standards. First, confidential care promotes trust of the clinician and encourages adolescent engagement in care and forthright exchange of accurate information. Adolescents will discuss fewer topics overall, and fewer confidential topics, with their health care professionals if they cannot be assured that clinicians' discussion with them and their family members will be kept confidential. Some may seek care elsewhere, fragmenting their care experience, and others may not seek care at all.

ARGUMENT

A. The off-label use of medications is lawful, common, and clinically appropriate when supported by evidence and professional judgment.

"Off-label" use includes (but is not limited to) prescribing a drug or device for a different purpose than the one approved by the U.S. Food and Drug Administration, administering a drug in a dose or route of administration not formally tested during the FDA approval process, or use of a drug or device in a patient population not tested during the clinical trials phase. For vulnerable, special populations that are often excluded from clinical trials (i.e., pediatric, geriatric, pregnant, or psychiatric patients), those with rare conditions for which treatment options are nonexistent or limited, or those with progressive or terminal diseases, off-label use can be the standard of care or only treatment option.[2]

The FDA does not regulate the practice of medicine. And, despite the claims of the Department of Justice in this case and similar cases, the fact that a medication has been prescribed off-label does not imply an improper, contraindicated, illegal, or investigational use.[3] Quite the opposite: off-label prescriptions for drugs are a common feature of modern medical practice and are, at times, the standard of care.[4] One study reports that off-label use of medication accounts for up to 21% of outpatient prescribing, up to 23% of inpatient prescribing in adults, and up to 60% of prescribing in pediatric patients.[5] Examples abound, including in the pediatric context.

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[2] *See, e.g.*, Karin Durant et al., *ASHP Guidelines on the Evaluation of Off-Label Medication Use in the Inpatient Setting*, 82 American Journal of Health System Pharmacy e1013, e1013–15 (2025).

[3] Katrina Furey & Kirsten Wilkins, *Prescribing "Off-Label": What Should a Physician Disclose?*, 18 Am. Med. Ass'n J. Ethics 587, 588–89 (2016). "Investigational drugs," also called "experimental drugs," are still being tested in clinical trials. *Understanding Investigational Drugs*, U.S. Food & Drug Admin. (Apr. 2, 2019), https://perma.cc/YZ3J-Y5MP.

[4] *See* Kathleen A. Neville et al., *Off-Label Use of Drugs in Children*, 133 Pediatrics 563, 565 (2014).

[5] *See, e.g.*, Durant, *supra* note 2, at e1014; *see generally* Robert M. Ward et al., *The Need for Pediatric Drug Development*, 192 J. Pediatrics 13 (2018); Gilbert J. Burckart & Clara Kim, *The Revolution in Pediatric Drug Development and Drug Use: Therapeutic Orphans No More*, 25 J. Pediatric Pharmacology and Therapeutics 565, 565–71 (2020) (summarizing the history of developing clinical evidence regarding safe and efficacious drug dosing in children); H. Christine Allen et al., *Off-Label Medication use in Children, More Common than We Think: A Systematic Review of the Literature*, 111 J. Okla. State Med. Assoc. 776–783 (2018).

Gabapentin—which is approved to prevent and control partial seizures, relieve postherpetic neuralgia after shingles, and moderate-to-severe restless legs syndrome—is often used to manage multimodal pain relief, and various studies confirm that such use is safe and should be considered when medically necessary for pediatric patients.[6] Ondansetron, a common anti-nausea medication, has been approved for the treatment of chemotherapy-induced nausea in children over the age of four for more than 20 years.[7] But it is also often used off-label for viral gastroenteritis to help children who are nauseated, and a recent study shows that use of ondansetron improves outcomes when used that way during emergency care.[8] And in neonatal care, the steroid dexamethasone is used to treat babies with severe lung issues despite not being specifically FDA-approved for use in that age group.[9] Given the limited research conducted in the neonatal population, doctors treating premature infants must often rely on expert consensus data and experience to treat life-threatening conditions.

These are but a few examples of the longstanding and prevalent off-label use of common medications, including in pediatric populations. They reflect that the clinical and commercial lives of drugs and medical devices continue to evolve after marketing approval is granted by the FDA. Indeed, the rapid pace of medical discovery and well documented barriers to pediatric clinical trials mean labeling often does not reflect all possible uses of an agent.[10]

The 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. It means only that the evidence required to allow inclusion in the label has not yet been presented to the FDA for a determination that the drug is

[6] Joshua W. Branstetter et al., *Safety and Efficacy of Gabapentin for Pain in Pediatric Patients: A Systematic Review*, 14 Hospital Pediatrics e57, e57, e63 (2024).
[7] Alexandria Griddine & Jeffrey S. Bush, *Ondansetron*, StatPearls (2023).
[8] Stephen B. Freedman et al., *Multidose Ondansetron after Emergency Visits in Children with Gastroenteritis*, 393 New England J. Med. 255, 255 (2025) ("Ondansetron improves outcomes when administered in emergency departments to children with acute gastroenteritis-associated vomiting").
[9] Praveen Kumar et al., *Medication Use in the Neonatal Intensive Care Unit: Current Patterns and Off-Label Use of Parenteral Medications*, 152 J. Pediatrics 412, 412–15 (2008).
[10] Neville, *supra* note 4, at 564.

safe and effective for that particular use.[11] Nor does the lack of labeling signify that therapy is unsupported by clinical experience or data in children.[12] Indeed, labeling with pediatric information still exists in less than 50% of products. Against that background, practitioners use their informed, professional judgment to determine appropriate uses of medication for their pediatric patients, in consultation with those patients and their parents.

The full range of medical evidence, not label indication, remains the gold standard from which practitioners are ethically required to draw when making therapeutic decisions with their patients. Because randomized control trials are often not available for the pediatric population, practitioners must rely on other information, including expert opinions for the age group they are treating or extrapolated evidence from a different population.[13]

There are many resources available to help assess the quality of evidence-based medicine, including but not limited to articles in peer-reviewed journals, practice guidelines and policy statements, consensus statements, and handbooks and databases. Practicing physicians may report adverse events to the FDA through MedWatch, the agency's medical product safety reporting program,[14] which practitioners may also use to remain informed of evidence relevant to the decision whether to prescribe a particular medication.

For these reasons, the off-label use of drugs in pediatrics is neither improper nor illegal. To the contrary: in many instances, off-label prescribing in pediatrics is a longstanding medical necessity for the provision of high-quality care to young people.

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[11] *Id.*
[12] *Id.*
[13] Aaron N. Sachs et al., *Pediatric Information in Drug Product Labeling*, 307 JAMA 1914, 1914–915 (2012).
[14] Neville, *supra* note 4, at 565.

B. Gender-affirming care for adolescents is evidence-based and may be medically necessary in appropriate circumstances.

The use of medications for gender-affirming care, including the use of medications for such care for adolescents, is considered to be part of the standard of care by major medical associations, including AAP, the American Medical Association,[15] and the American College of Obstetricians & Gynecologists[16]—in part because of existing empirical evidence that gender-affirming care improves mental health outcomes and reduces suicide risk in transgender youth.[17]

Adolescents and adults who identify as transgender have high rates of depression, anxiety, eating disorders, self-harm, and suicide.[18] As but one example: in one retrospective cohort study of 180 trans youth and matched cisgender peers, 56 youth who identified as transgender reported previous suicidal ideation, and 31 reported a previous suicide attempt, compared with 20 and 11 among matched youth who identified as cisgender, respectively.[19] Data also shows that youth who identify as transgender or gender diverse ("TGD") experience disproportionately high rates of homelessness, physical violence (at home and in the community), substance abuse, and high-risk sexual behaviors.[20]

Research substantiates that prepubertal individuals who assert an identity of TGD know their gender as clearly and as consistently as their developmentally equivalent peers who identify as cisgender and benefit from the same level of social acceptance.[21] In a gender-affirmative care model (GACM),

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[15] Am. Med. Ass'n., *Clarification of Evidence-Based Gender-Affirming Care H-185.927* (2024), https://perma.cc/TXR5-JVGM.

[16] Am. Coll. Obstetricians & Gynecologists, Health Care and Support for Transgender and Gender Diverse Adolescents (2021), https://perma.cc/GG62-MAEA.

[17] *See, e.g.*, I. Becker-Hebly et al., *Psychosocial Health in Adolescents and Young Adults with Gender Dysphoria Before and After Gender-Affirming Medical Interventions: A Descriptive Study from the Hamburg Gender Identity Service*, 30 European Child & Adolescent Psychiatry, 1755, 1755–67 (2021).

[18] Jason Rafferty et al., *Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents*, 142 Pediatrics e20182162 (2023), at 3–4 (collecting data).

[19] Sari L. Reisner et al., *Mental Health of Transgender Youth in Care at an Adolescent Urban Community Health Center: A Matched Retrospective Cohort Study*, 46 Journal of Adolescent Health 274, 274–79 (2015).

[20] Rafferty, *supra* note 18, at 3 (collecting data).

[21] Kristina R. Olson et al., *Gender Cognition in Transgender Children*, 26 Psychological Science 467, 467–74 (2015).

pediatric providers offer developmentally appropriate care that is oriented toward understanding and appreciating the youth's gender experience. An evidence-based GACM emphasizes the following principles:

- Transgender identities and diverse gender expressions do not constitute a mental disorder;
- Variations in gender identity and expression are normal aspects of human diversity, and binary definitions of gender do not always reflect emerging gender identities;
- Gender identity evolves as an interplay of biology, development, socialization, and culture; and
- If a mental health issue exists, it most often stems from stigma and negative experiences rather than being intrinsic to the child.[22]

A range of medical interventions can be appropriate for youth who identify as TGD. Care decisions are deeply personal and are made by youth and their families in consultation with their physician. Such decisions involve careful consideration of risks, benefits, and other factors unique to each patient and family.

Gender-affirming care, including medical intervention, is not novel. Gonadotrophin-releasing hormones have been used to delay puberty since the 1980s for central precocious puberty and can be used in adolescents who experience gender dysphoria to prevent development of secondary sex characteristics.[23] Nor are all such treatments permanent: reversible treatments such as gonadotrophin-releasing hormones[24] provide time—usually until 16 years of age—for the individual and the family to explore gender identity, access psychosocial supports, develop coping skills, and further define

[22] Rafferty, *supra* note 18, at 4.
[23] M. Joan Mansfield et al., *Longterm Treatment of Central Precocious Puberty With a Long Acting Analogue of Luteinizing Hormone Releasing Hormone*, 309 New England J. Med. 1286, 1286–90 (1983).
[24] Rafferty, *supra* note 18, at 4.

appropriate treatment goals.[25] If pubertal suppression treatment is suspended, endogenous puberty typically resumes.[26]

Often, pubertal suppression creates an opportunity to reduce distress that may occur with the development of secondary sexual characteristics and allow for gender-affirming care, including mental health support for the adolescent and the family. Data shows that pubertal suppression in adolescents who identify as TGD generally leads to improved psychological functioning in adolescence and young adulthood.[27] It also reduces the need for later surgery because physical changes that are otherwise irreversible (protrusion of the Adam's apple, male pattern baldness, voice change, breast growth, etc.) are prevented.[28]

C. Broad and intrusive subpoenas threaten patient privacy and will chill access to necessary care and undermine public health.

Scientific and educational societies, including not just AAP[29] but also the Society for Adolescent Health and Medicine, the American College of Obstetricians and Gynecologists, and the American Medical Association, have long affirmed the importance of confidentiality in adolescent health care and have advocated for a health care environment that supports optimal care for these young people.[30] Best practice guidelines and health care professional ethical standards articulated by these organizations support the provision of confidential services.[31] They do so because confidentiality is a foundational

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[25] *Id.* at 5.
[26] Norman P. Spack et al., *Children and Adolescents With Gender Identity Disorder Referred to a Pediatric Medical Center*, 129 Pediatrics 418, 418–25 (2012).
[27] *Id.*; Madeleine S.C. Wallien et al., *Psychosexual Outcome of Gender-Dysphoric Children*, 47 J Am. Acad. Child & Adolescent Psychiatry, 1413, 1413–23 (2008).
[28] Rafferty, *supra* note 18, at 5.
[29] *See generally* Richard J. Chung et al., *Confidentiality in the Care of Adolescents: Policy Statement*, 153 Pediatrics e2024066326 (2004).
[30] Am. Coll. Obstetricians and Gynecologists, *Confidentiality in Adolescent Health Care*, 135 *Obstetrics & Gynecology*, e171 (2020); Madlyn C. Morreale, *Policy Compendium on Confidential Health Services for Adolescents*, Ctr. for Adolescent Health and the Law (2005); C. Ford et al., *Confidential Health Care for Adolescents: Position Paper for the Society for Adolescent Medicine*, 35 J. Adolescent Health 160, 160–67 (2004); Confidential Health Services for Adolescents H-60.965, Am. Med. Ass'n (2021), https://perma.cc/9V9H-S62X .
[31] *See generally id.*

element of high-quality, accessible, and equitable health care that impacts the full health care experience: the initial decision to seek care; the encounter between patient, family, and health care professionals; billing and payment for services; and the subsequent exchange (with the approval of adolescent patients and their parents) of confidential health information between health care professionals and patients and between health care professionals and other health care entities.

At its core, confidential care promotes trust of the clinician and encourages adolescents to exchange accurate information forthrightly and to engage, together with their parents as appropriate, in health care decision-making. When a minor adolescent seeks care, the pediatrician's primary duty is to the patient, and the pediatrician or pediatric health care professional should structure all parts of the encounter to maximize privacy, comfort, and confidentiality in a manner consistent with ensuring the patient's safety. When not assured that their, and their parents', discussions with their clinicians will be kept confidential, adolescents will discuss fewer topics overall, and fewer confidential topics, with their health care professionals.[32] Some may seek care elsewhere, fragmenting their care experience, and others may not seek care at all.[33]

In addition to the wealth of clinical data described above, ethical principles—including autonomy, beneficence, and justice—also support the need for confidentiality.[34] The principle of autonomy requires medical professionals to respect adolescents' developing capacity to participate in making health care decisions, when appropriate, and to recognize that this capacity will change over time.[35] The principle of beneficence highlights the obligation to always seek the best interests of the patient,[36] which is of particular importance here because—as detailed above—public health data show

[32] Amy Lewis Gilbert et al., *Clinical Conversations About Health: The Impact of Confidentiality in Preventive Adolescent Care*, 55 J. Adolescent Health. 672, 672–77 (2014).
[33] Richard J. Chung et al., *Confidentiality in the Care of Adolescents: Technical Report*, 153 Pediatrics e2024066327 (2024), at 4.
[34] *Id.* at 2.
[35] *Id.*
[36] *Id.*

that confidentiality provisions promote access to needed services and improve health outcomes.[37] Finally, the principle of justice requires consideration of disparities in access to care, and confidentiality expectations help to mitigate racial and other disparities in access to care by cultivating an environment where patients and their families can openly share information with physicians.[38] For example, one study found that rates of private consultations between adolescents and clinicians were lowest among Hispanics. [39] These disparities in access to care along racial and cultural lines, as well as the mitigating impact of confidentiality provisions, are particularly prominent when care involves sensitive topics, including reproductive and gender-affirming care.[40]

Indeed, the unique needs of gender-diverse individuals require special consideration. Forcing compliance with the government's broad, overreaching subpoena—and others like it—increases the risk that patients and their families will be exposed to stigma, harassment, and other injury.[41] Moreover, as detailed above, untreated gender dysphoria can result in severe physical and psychological harms, including depression, substance use, self-injurious behaviors, and even suicide. If the Court were to uphold the Department of Justice's subpoena, medical care and safety will suffer, and it will become more difficult for those needing gender-affirming care to access it.

The government has weaponized its investigative authority to advance the administration's stated policy goal of eliminating gender-affirming care using subpoenas designed to (1) harass and intimidate medical institutions and providers to stop offering such care, and (2) dissuade patients from seeking such

[37] *See* Gilbert, *supra* note 32.
[38] Chung, *supra* note 33, at 2.
[39] Jennifer Edman et al., *Who Gets Confidential care? Disparities in a National Sample of Adolescents*, 46 J. Adolescent Health 393, 393 (2010).
[40] Liza Fuentes et al., *Adolescents' and Young Adults' Reports of Barriers to Confidential Health Care and Receipt of Contraceptive Services*, 62 J. Adolescent Health 36, 36 (2017) (finding that, among sexually experienced girls and women, confidentiality concerns were associated with a reduced likelihood of having received a contraceptive service in the past year).
[41] *See* Rafferty, *supra* note 18, at 5 (describing the impact of stigma on non-gender conforming adolescents).

care. That runs contrary to public health policy and existing laws and regulations,[42] as well as professional medical and ethical standards. Most importantly, it will impede and degrade the quality of medically necessary care for one of our country's most vulnerable populations.

CONCLUSION

For the foregoing reasons, *amicus curiae* urges the Court to grant Plaintiffs' Motion for a Temporary Restraining Order.

June 16, 2026

Respectfully submitted,

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[42] These include, for example, the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, the Title X Family Planning Program; and the confidentiality regulations for substance use disorder programs; the Family Educational Rights and Privacy Act, the 21st Century Cures Act, and state laws that address granular issues including the legal status of minors seeking services, the interpretation of exactly which services fall under state minor consent laws, the age at which minors can consent to services, and circumstances requiring parental notification of specific health issues.