IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS; *et al.* *Plaintiffs*, v. DONALD J. TRUMP, in his official capacity as President of the United States; *et al.* *Defendants*.	Case No. 25-cv-12162 Hon. Angel Kelley

BRIEF OF *AMICI CURIAE* AMERICAN ACADEMY OF PEDIATRICS AND 17 OTHER NATIONAL MEDICAL AND MENTAL HEALTH ORGANIZATIONS IN SUPPORT OF PLAINTIFF STATES' MOTION FOR SUMMARY JUDGMENT AND AGAINST DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

TABLE OF CONTENTS

TABLE OF AUTHORITIES iii

INTEREST OF *AMICI CURIAE* 1

INTRODUCTION 2

ARGUMENT 3

I. Off-Label Prescribing Is Common and Expected in Medical Care, Especially Pediatric Care. 3

II. Permitting Intrusive Disclosure of Sensitive Patient Medical Records Without a Compelling Rationale Would Harm Patient Care. 7

CONCLUSION 13

CERTIFICATE OF SERVICE 15

TABLE OF AUTHORITIES

Page(s)

Cases

Buckman Co. v. Plaintiffs' Legal Comm.,
531 U.S. 341 (2001) 4

U.S. ex rel. Carpenter v. Abbott Lab'ys, Inc.,
723 F. Supp. 2d 395 (D. Mass. 2010) 4

In re Celexa & Lexapro Mktg. & Sales Pracs. Litig.,
915 F.3d 1 (1st Cir. 2019) 4

Gonzales v. Oregon,
546 U.S. 243 (2006) 4

In re Subpoena No. 25-1431-014,
810 F. Supp. 3d 555 (E.D. Pa. 2025) 12

Washington Legal Found. v. Henney,
202 F.3d 331 (D.C. Cir. 2000) 5

In re Zofran (Ondansetron) Prods. Liab. Litig.,
541 F. Supp. 3d 164 (D. Mass. 2021), *aff'd*, 57 F.4th 327 (1st Cir. 2023) 3, 4

Statutes

21 U.S.C. § 396 5

37 Fed. Reg. 16,503 (Aug. 15, 1972) 4

False Claims Act 2

Food, Drug, and Cosmetic Act (FDCA) 2, 3, 4

Other Authorities

AAP Committee on Adolescence, *Achieving Quality Health Services for Adolescents*, 138 Pediatrics e20161347 (2016) 11

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] 7, 12

ACOG, *Effective Patient-Physician Communication: Committee Statement*, 146 Obstet. & Gynecol. e115 (Dec. 2025) 9

Agostino et al., *Considerations for Privacy and Confidentiality in Adolescent Health Care Service Delivery*, 28 Paediatrics & Child Health 172 (2023) 10

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) 5

Am. Coll. of Physicians, *Ethics Manual: Sixth Edition*, 156(1) Ann. Intern. Med. 73 (2012) [ACP Ethics Manual] 8, 9

Am. Med. Ass'n, *Ethics Opinion 3.2.1: Confidentiality*, Code of Medical Ethics, https://perma.cc/H8DZ-S7TH 8

Bazzano et al., *Off-Label Prescribing to Children in the United States Outpatient Setting*, 9 Acad. Pediatrics 81 (2009) 5

Beck & Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 Food & Drug L.J. 71, 76 (1998) 4

Beck, *Off-Label Use in the Twenty-First Century: Most Myths and Misconceptions Mitigated*, 54 UIC J. Marshall L. Rev. 1 (2021) 4

Chung et al., *Confidentiality in the Care of Adolescents: Policy Statement*, *American Academy of Pediatrics*, 153 Pediatrics e2024066326 (2024) [AAP Policy Statement on Confidentiality] 10, 11

Chung et al., *Confidentiality in the Care of Adolescents: Technical Report*, 153 Pediatrics e2024066327 (2024) [AAP Confidentiality Technical Report] 7, 8, 9, 10

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 (2022) [WPATH Standards of Care] 6

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) 6

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 (2025) [ASHP Guidelines] 5

Estroff et al., *Confidentiality: Concealing "Things Shameful to be Spoken About"*, 14(9) AMA J. Ethics 733 (2012) 11

FDA, *Understanding Unapproved Use of Approved Drugs "Off-Label"* (2018), https://perma.cc/L46Q-3TXM 4

Ford et al., *Confidential Health Care for Adolescents: Position Paper of the Society for Adolescent Medicine*, 35(2) J. Adolesc. Health 160 (2004) 10

Ford et al., *Foregone Health Care Among Adolescents*, 282(23) JAMA 2227 (1999) 10

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) 10

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 (2018) 10

Fung et al., *Off-label medication use in rare pediatric diseases in the United States*, 10 Intractable & Rare Diseases Rsch. 238 (2021) 5

Henry, *Off-Label Prescribing: Legal Implications*, 20(3) J. Legal Med. 365 (1999) 5

Hoon et al., *Trends in Off-Label Drug Use in Ambulatory Settings: 2006-2015*, 144 Pediatrics e20190896 (2019) 5

Lehrer et al., *Forgone Health Care Among U.S. Adolescents: Associations Between Risk Characteristics and Confidentiality Concern*, 40(3) J. Adolesc. Health 218 (2007) 10, 11

Levy et al., *Prevalence of and Factors Associated with Patient Nondisclosure of Medically Relevant Information to Clinicians*, 1 JAMA Network Open e185293 (2018) 9, 11

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) 6

McKay et al., *Parents' Perspectives on Confidentiality in Clinical Preventive Services for Adolescents*, 77(4) J. Adolesc. Health 602 (2025) 11

Morreale et al., *Policy Compendium on Confidential Health Services for Adolescents* 33 (2d ed. 2005) [Policy Compendium] 8, 9, 10

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] 4, 5, 6

Pathak et al., *Confidential Care for Adolescents in the U.S. Health Care System*, 6(1) J. Patient-Centered Research and Reviews 46 (2019) 10

Pozgar, *Legal and Ethical Issues for Health Professionals* 283 (5th ed. 2019) 8

Rafferty, *AAP Policy Statement: Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents*, 142 Pediatrics e20182162 (2018) 12

Riley, *The Needs of Gender-Variant Children and Their Parents: A Parent Survey*, 23(3) Int'l J. Sexual Health 181 (2011) 12

Rubin et al., *Delivery of Confidential Care to Adolescent Males*, 23(6) J. Am. Bd. Fam. Med. 728 (2010). 11

Sankar et al., *Patient Perspectives of Medical Confidentiality*, 18(8) J. Gen. Intern. Med. 659 (2003) 11

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 (2017).....13

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 (2025) [SAHM Position Statement on Confidentiality].....8, 9, 10, 12

Thrall et al., *Confidentiality and Adolescents' Use of Providers for Health Information and for Pelvic Examinations*, 154(9) Arch. Pediatrics & Adolesc. Med. 885 (2000).....10

Tornese et al., *Use of Gonadotropin-Releasing Hormone Agonists in Transgender and Gender Diverse Youth: a Systematic Review*, 16 Frontiers in Endocrinology (2025).....6

Varkey, *Principles of Clinical Ethics and Their Application to Practice*, 30(1) Med. Principles 17 (2021).....8

Wittich et al., *Ten Common Questions (and Their Answers) About Off-Label Drug Use*, 87(10) Mayo Clinic Proc. 982 (2012).....4

INTEREST OF *AMICI CURIAE*[1]

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.

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. As experts in professional standards of care, *Amici* have a strong interest in this case because the executive order and Department of Justice (DOJ) memoranda at issue threaten to interfere with physician-patient-parent relationships, impair health outcomes, and deter patient access to care.

In June 2025, DOJ served numerous hospitals nationwide with administrative subpoenas seeking records relating to the provision of gender-affirming medical care (GAMC) to patients under age 18. Those subpoenas demand remarkably broad and intrusive information, including confidential medical records of every adolescent patient treated with GAMC by the recipients.

---

[1] No party's counsel authored this brief in whole or in part. No entity or person—other than *amici curiae*, their members, and their counsel—made any monetary contribution intended to fund the preparation or submission of this brief.

Amici have submitted amicus briefs in challenges to DOJ's subpoenas in the First, Second, Fourth, and Ninth Circuits. *See In re Administrative Subpoena No. 25-1431-019*, Nos. 25-2092, 26-1093 (1st Cir.) (Boston Children's Hospital administrative subpoena case); *Coe v. Blanche*, No. 26-1886 (2d Cir.) (NYU Langone grand jury subpoena case); *In re 2025 Subpoena to Children's National Hospital*, No. 26-1104 (4th Cir.) (Children's National Hospital administrative subpoena case); *Z.A. v. Blanche*, No. 26-4388 (9th Cir.) (Stanford grand jury subpoena case).

INTRODUCTION

In August 2025, fifteen states, the Governor of Pennsylvania, and the District of Columbia (Plaintiff States) brought this suit against President Trump, then-Attorney General Bondi, and the DOJ, challenging Executive Order 14,187 and two DOJ memoranda—the Bondi Memo and the Shumate Memo (the Memos)—that announce new interpretations of the Food, Drug, and Cosmetic Act (FDCA), the False Claims Act, and federal female genital-mutilation statutes as applied to the provision of GAMC to patients under age 19.[2] Plaintiff States allege that these directives effectively outlaw GAMC for adolescents by reinterpreting long-standing federal statutes to criminalize or penalize medically necessary care, and that they have caused concrete harms including clinic closures, disruptions to patient care, and increased costs borne by state-run medical facilities.

This Court denied Defendants' motion to dismiss, holding that the memoranda constitute final agency actions announcing new interpretations of federal law—not mere enforcement priorities—and that Plaintiff States have standing based on both the threat of prosecution and direct

[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.

operational and financial injuries to their institutions. Defendants and Plaintiff States have now filed cross motions for summary judgment.

Amici submit this brief to make two points. *First*, while DOJ now concedes—as it must—that off-label prescribing of medications is lawful, the Memos themselves suggest that the practice is somehow improper. But in all fields of medicine—and especially pediatrics—off-label prescribing of FDA-approved medications is common and accepted, and indeed often necessary to provide the most appropriate treatment of a patient.

Second, the enforcement actions that DOJ has taken pursuant to the Memos have involved overbroad and intrusive requests for patient records, which suggest that the Memos' true motivation is not the evenhanded enforcement of federal law but rather, as the Court found, "to intimidate and harass." ECF 105 at 35. 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. Expansive requests for patient records like those that DOJ has already issued to hospitals across the country—and which might reasonably be expected to be issued to Plaintiff States' healthcare facilities under the Executive Order and Memos—threaten to interfere with physician-patient-parent relationships, impair health outcomes, and deter access to care.

ARGUMENT

I. Off-Label Prescribing Is Common and Expected in Medical Care, Especially Pediatric Care.

While the Memos appear to suggest that off-label prescribing is inherently suspect under federal law, Defendants in this case have now conceded that "the FDCA generally permits the off-label prescribing of puberty blockers or hormones," ECF 90 at 11, and that "the FDCA does not generally prohibit a physician from prescribing an approved drug for off-label use," ECF 124 at 9. DOJ's concession is unavoidable, as federal law does *not* prohibit healthcare providers from

prescribing off-label. *In re Zofran (Ondansetron) Prods. Liab. Litig.*, 541 F. Supp. 3d 164, 173 (D. Mass. 2021), *aff'd*, 57 F.4th 327 (1st Cir. 2023) ("[I]t is generally lawful for physicians to prescribe medications for purposes for which they have not been FDA-approved . . ."). Rather, the FDCA only limits *manufacturers'* ability to *market* approved drugs for unapproved (off-label) indications.[3] And a provider who prescribes drugs off-label is not liable for "causing" the distribution of misbranded drugs. *See U.S. ex rel. Carpenter v. Abbott Lab'ys, Inc.*, 723 F. Supp. 2d 395, 398 (D. Mass. 2010) ("a doctor is free to prescribe drugs for off-label uses").

"[I]t is essential to understand that the FDA does not regulate the use of drugs as they pertain to the practice of medicine."[4] Medical practice is principally regulated by the states, not the federal government.[5] 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.[6] As the Supreme Court and the First Circuit have long recognized, "physicians can—and do—lawfully prescribe prescription drugs for off-label uses,"[7] and that practice "is an accepted and necessary corollary of the FDA's mission to regulate" without "interfering with the practice of medicine."[8]

---

[3] Beck & Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 Food & Drug L.J. 71, 76 (1998).

[4] 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].

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

[6] *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).

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

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

Whatever the reason for being "off-label," that term "does not imply an improper, illegal, [or] contraindicated" use.[9] 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.[10]

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."[11] These include oncology, neurology, psychiatry, and infectious disease.[12]

Off-label prescribing is particularly widespread in pediatrics.[13] 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.[14] Another outpatient study found that off-label prescribing accounts for some 60% of prescriptions for pediatric patients.[15] Off-label prescribing is particularly important for pediatric patients with rare conditions.[16] As AAP explains, effective pediatric medicine will "more than

---

[9] AAP Policy Statement on Off-Label Use, *supra* note 4.

[10] *Id.*; 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 (2025) [ASHP Guidelines].

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

[12] ASHP Guidelines, *supra* note 10; Henry, *Off-Label Prescribing: Legal Implications*, 20(3) J. Legal Med. 365 (1999).

[13] 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).

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

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

[16] Fung et al., *Off-label medication use in rare pediatric diseases in the United States*, 10 Intractable & Rare Diseases Rsch. 238-245 (2021).

likely require a practitioner to use drugs off label to provide the most appropriate treatment of a patient."[17]

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.[18] 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.[19] Through the same pharmacological mechanisms, these drugs can also suspend puberty where its progress would exacerbate a patient's gender dysphoria.[20] The use of GnRH analogues in GAMC for transgender youth is "off-label" not because those medications are new, unsafe, experimental, or ineffective,[21] but because the FDA did not specifically consider them for use in transgender adolescents.

For the foregoing reasons, the suggestion in the Memos that off-label prescribing is inherently suspect under federal law is incorrect because federal law does not prohibit off-label

---

[17] AAP Policy Statement on Off-Label Use, *supra* note 4.

[18] *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).

[19] *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 (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).

[20] *See* WPATH Standards of Care, *supra* note 19; Lopez et al., *supra* note 19.

[21] 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).

prescribing, which is standard practice across all fields of medicine and particularly prevalent in pediatrics.

II. Permitting Intrusive Disclosure of Sensitive Patient Medical Records Without a Compelling Rationale Would Harm Patient Care.

The Executive Order and Memos also risk unwarranted interference with patient care and medical confidentiality. As this Court has already found in concluding that Plaintiff States have standing to challenge the Memos, state-run hospitals and clinics that provide gender-affirming care to adolescents have suffered direct operational and financial harms—including surges in patient inquiries, an influx of displaced patients from shuttered programs, and the increased costs of delayed care—as a predictable result of the federal directives. *See* ECF 105 at 23–25. Part of these harms is the threat to patient and provider privacy: as the Del Monte Declaration attests, providers fear that "patient confidentiality or their own personal privacy will be compromised" by federal subpoenas and that they will be forced to divert clinical time to "quelling the fears of young people and families who worry that their private information has or will be shared with the federal government."[22]

Confidentiality of patient information receives numerous legal protections.[23] 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).[24]

---

[22] ECF 87-18 (Del Monte Decl.) ¶ 25.

[23] *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).

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

For thousands of years, physicians have committed themselves to safeguarding private medical information. In the Hippocratic Oath's common modern rendering, physicians declare that "I will respect the privacy of my patients, for their problems are not disclosed to me [so] that the world may know."[25] 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.[26]

Confidentiality is critical to multiple "moral traditions" within medical ethics.[27] "Ethical principles of autonomy, nonmaleficence, beneficence, and justice are all key elements of the ethical framework for confidentiality in adolescent health care."[28] Autonomy requires respect for the rights of patients and families to make informed decisions about their own care.[29] Justice urges physicians to care about the needs of the entire community, including those who may face barriers to treatment.[30] Nonmaleficence cautions physicians to "do no harm."[31] And beneficence imposes a "duty to promote good and act in the best interest of the patient and the health of society."[32]

---

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

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

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

[28] Policy Compendium, *supr*a note 27, at 3.

[29] Varkey, *supr*a note 27, at 163.

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

[31] ACP Ethics Manual, *supra* note 27, at 74.

[32] *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."[33] Providers "rely on patients to disclose their symptoms, health behaviors, and thoughts and feelings so that clinicians can make appropriate diagnoses and treatment recommendations."[34] 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.[35]

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."[36] And the credibility of such assurances affects patients' and parents' "decision[s] [whether] to seek care" at all.[37]

Those conclusions are memorialized in policy statements by *Amici* and other leading organizations.[38] 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

---

[33] Levy et al., *Prevalence of and Factors Associated with Patient Nondisclosure of Medically Relevant Information to Clinicians*, 1 JAMA Network Open e185293, 7 (2018); *see also, e.g.*, ACOG, *Effective Patient-Physician Communication: Committee Statement*, 146 Obstet. & Gynecol. e115, e123 (Dec. 2025).

[34] Levy, *supra* note 33, at 2.

[35] SAHM Position Statement on Confidentiality, *supra* note 27, at 791-92.

[36] *Id*.

[37] AAP Confidentiality Technical Report, *supra* note 23, at 1.

[38] *See generally* Policy Compendium, *supra* note 27.

safety."[39] The Society for Adolescent Health and Medicine "has long recognized the importance of confidential health care for adolescents."[40] Many other organizations similarly recognize that patient confidentiality is fundamental to ethical practice and promotes the best possible care.[41]

Those policy commitments are founded upon decades of evidence showing that privacy concerns prevent many adolescents from seeking health care.[42] 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."[43] Even when adolescents do seek care, those with confidentiality concerns "discuss fewer topics" with providers, especially involving mental health, sexual issues, and substance abuse.[44]

---

[39] 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].

[40] 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 27, at 791.

[41] Policy Compendium, *supra* note 27, 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").

[42] *See, e.g.*, Agostino et al., *Considerations for Privacy and Confidentiality in Adolescent Health Care Service Delivery*, 28 Paediatrics & Child Health 172, 172 (2023); Ford et al., *Foregone Health Care Among Adolescents*, 282(23) JAMA 2227, 2227-28 (1999); Ford et al., *Influence of Physician Confidentiality Assurances on Adolescents' Willingness to Disclose Information and Seek Future Health Care: A Randomized Controlled Trial*, 278(12) JAMA 1029 (1997); Fuentes et al., *Adolescents' and Young Adults' Reports of Barriers to Confidential Health Care and Receipt of Contraceptive Services*, 62(1) J. Adolesc. Health 36, 37 (2018); Lehrer et al., *Forgone Health Care Among U.S. Adolescents: Associations Between Risk Characteristics and Confidentiality Concern*, 40(3) J. Adolesc. Health 218, 218-19 (2007); Pathak et al., *Confidential Care for Adolescents in the U.S. Health Care System*, 6(1) J. Patient-Centered Research and Reviews 46, 46 (2019); Thrall et al., *Confidentiality and Adolescents' Use of Providers for Health Information and for Pelvic Examinations*, 154(9) Arch. Pediatrics & Adolesc. Med. 885, 885 (2000); SAHM Position Statement on Confidentiality, *supra* note 27, at 792 (citing additional studies).

[43] Policy Compendium, *supra* note 27, at 1.

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

Though the rationales for confidentiality are similar in pediatrics as in other contexts, the stakes are higher for adolescents. Adolescents disproportionately "engage in high-risk behaviors that cause significant morbidity and mortality."[45] 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.[46] Adolescents more likely to forgo care based on confidentiality concerns include those with "elevated prevalence of high depressive symptoms, suicidal ideation, and suicide attempt."[47] Marginalized groups, including "LGBTQIA+ youth," may also be "particularly concerned about ensuring confidentiality of their health information."[48]

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.[49] Ensuring the trust of parents and guardians in the physician's confidentiality arrangements is critical to adequate care for adolescent patients.[50] Clinicians thus work to "encourage and facilitate communication between young

---

[45] 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).

[46] Levy et al., *supra* note 33, at 6.

[47] Lehrer, *supra* note 42, at 222-23.

[48] AAP Policy Statement on Confidentiality, *supra* note 39, at 3.

[49] *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).

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

people and their parents" where such communication will best serve the patient's needs.[51] 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.[52] 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.[53] Among parents' most common concerns are those about stigma or other harms associated with exposure of their children to public scrutiny.[54] Maintaining confidentiality is essential for addressing those concerns and maintaining the trust of patients and parents alike.

The kinds of enforcement actions envisioned by the Bondi and Shumate Memos—and the enforcement actions that DOJ has already undertaken—threaten the confidentiality that is critical to pediatric patients and their families, impairing physician-patient-parent relationships, health outcomes, and access to care. The subpoenas that DOJ has already issued to multiple hospitals seek records for all patients receiving GAMC. 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."[55] DOJ's intrusive demands for

---

[51] SAHM Position Statement on Confidentiality, *supra* note 27, at 791.

[52] *See* AAP Policy Statement on Pediatric Informed Consent, *supra* note 24.

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

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

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

patient records directly undermine effective medical practice. 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.[56]

CONCLUSION

Plaintiff States' motion for summary judgment should be granted, and Defendants' motion for summary judgment should be denied.

[56] 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).

Dated: September 21, 2026

Respectfully submitted,

/s/ Paul Killebrew
D. Jean Veta (*pro hac vice* pending)
William R. Isasi (*pro hac vice* pending)
Jeffrey E. Sandberg (*pro hac vice* pending)
Paul Killebrew (*pro hac vice* pending)
Max M. Larson (*pro hac vice* pending)
Carter McCants (*pro hac vice* pending)
COVINGTON & BURLING LLP
One CityCenter
850 Tenth Street, N.W.
Washington, DC 20001
Phone: (202) 662-6000
jveta@cov.com
wisasi@cov.com
jsandberg@cov.com
pkillebrew@cov.com
mlarson@cov.com
cmccants@cov.com

/s/ Joy A. Chen
Joy A. Chen (BBO No. 714192)
COVINGTON & BURLING LLP
1 International Pl., Ste. 1020
Boston, MA 02110
(617) 603-8831
jchen@cov.com

Counsel for Amici Curiae

CERTIFICATE OF SERVICE

I certify that this brief and all supporting papers filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants.

/s/ Paul Killebrew
Paul Killebrew

DATED: September 21, 2026 *Counsel for Amici Curiae*