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. 1:25-cv-12162 Oral Argument Requested

PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS

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PRELIMINARY STATEMENT

Plaintiff States challenge specific actions of the President and the U.S. Department of Justice (DOJ) that unlawfully wield the federal government's formidable prosecutorial authority in order to achieve their goal of ending medically necessary healthcare for transgender adolescents. Treatments for gender dysphoria, collectively known as gender-affirming care, are legal, evidence-based, and save lives. But in Executive Order 14187 (the EO), the Administration labeled these treatments a "horrifying tragedy" and "a stain on our Nation's history" that "must end." The EO ordered DOJ to target providers of adolescent gender-affirming care using the federal Female Genital Mutilation statute and the Food, Drug and Cosmetic Act. Shortly thereafter, the Attorney General and Assistant Attorney General issued directives to DOJ personnel (the DOJ Directives) to begin investigating and prosecuting providers of gender-affirming care based on completely novel interpretations of these statutes, as well as a third statute, the False Claims Act.

The EO and the DOJ Directives had an immediate, and intended, *in terrorem* effect on the medical community, patients, and their families. All institutions that offered gender-affirming care faced a lose-lose situation: suspend or curtail gender-affirming care and turn away patients in need, or continue to offer services as they had for years but risk substantial criminal and civil liability.

As to providers that stopped care, the President promptly claimed victory, boasting that self-inflicted suspension of gender-affirming care was the "intended effect." DOJ then set its sights on providers that continued treatment, wielding its baseless new legal interpretations and opening both a new enforcement branch and working group to carry out the DOJ Directives. DOJ has now served over twenty subpoenas on hospitals and providers of gender-affirming care, and the FBI has opened several criminal investigations. Plaintiff States challenged the EO and DOJ Directives as exceeding the Executive's constitutional and statutory authority, and as arbitrary and capricious.

Defendants now ask the court to dismiss the case on procedural grounds. This Court should deny the motion. First, the Court has jurisdiction. Defendants' novel assertions of expanded statutory authority give rise to substantial, immediate legal controversies under the Declaratory Judgment Act, regardless of the circumstances of any individual prosecution. Plaintiff States have standing because the DOJ Directives and EO directly injure state-run hospitals and state-employed providers; impede duties to provide healthcare to adolescents in state custody; and improperly displace state laws protecting access to gender-affirming care. And the Directives are not mere "enforcement prioritization" guidelines because they purport to change substantive law.

Second, the challenged actions are final agency actions reviewable under the Administrative Procedure Act. The actions establish on their face that the Administration has consummated its decision-making process as to the legality of gender-affirming care under the three statutes. And Defendants cannot realistically dispute that the DOJ Directives have immediate legal consequences. The Directives purport to dissolve long-established statutory protections for licensed medical care, and present providers a Hobson's choice of ceasing medically necessary care or risking significant penalties, including fines or incarceration. And although Defendants now claim that the DOJ Directives do not expand liability, Defendants cannot use the language of the DOJ Directives as both a sword—with which they have intentionally terrorized providers and claimed victory—and a shield against accountability for the consequences.

Last, Plaintiff States have plausibly alleged that the DOJ Directives and EO violate the Tenth Amendment. The States' historical role in regulating medicine lies at the heart of their sovereign authority. And, absent clear Congressional authority, an executive action may not alter the balance of power between the States and the federal government or displace States' traditional police powers. Yet the actions challenged here claim virtually limitless authority to criminalize

medical services that the Executive Branch disfavors. Because Plaintiffs adequately allege that this invades their rights under the Tenth Amendment, Defendants' motion to dismiss fails.

BACKGROUND

I. Factual Background

A. Gender Dysphoria Is a Recognized, Treatable Medical Diagnosis.

Gender dysphoria is a medical condition characterized by clinically significant distress or impairment in social, occupational, or other important areas of functioning due to a marked incongruence between the patient's gender identity (i.e., innate sense of one's gender) and sex at birth. Doc. No. 1 ¶ 38. Gender dysphoria is recognized by leading medical institutions, including the American Psychiatric Association in the current edition of the Diagnostic and Statistical Manual of Mental Disorders. *Id.* ¶ 38. If untreated or improperly treated, gender dysphoria can cause anxiety, depression, and self-harm. *Id.* ¶¶ 45–46. Gender dysphoria is also associated with increased risk of suicidality. *Id.* Leading medical associations agree that effective treatment of gender dysphoria confers significant physical and psychological benefits. *See id.* ¶ 51.

Transgender adolescents diagnosed with gender dysphoria may seek treatments from a medical provider who may offer evidence-based interventions known as "gender-affirming care." Doc. No. 1 ¶¶ 40–50. Treatment may begin with an assessment of the patient's needs, including for social support or psychotherapy. *Id.* ¶ 40. If additional treatment is necessary, providers may offer puberty-delaying medications, hormone therapies, or, rarely, surgery. *Id.* ¶¶ 42–44, 61. This medically necessary healthcare is supported by decades of clinical evidence. *See id.* ¶ 51.

Providers of gender-affirming care rely on established, evidence-based clinical guidelines. Doc. No. 1 ¶¶ 51–52. Some well-established gender-affirming care guidelines are published by the World Professional Association for Transgender Health and the Endocrine Society. *See id.* ¶ 61. Those guidelines include informed consent procedures so that both the patient and their parents or

guardians (if the patient is under the age of majority) understand risks and possible side effects before agreeing to a treatment. *Id.* ¶ 62. Under the guidelines, treatment is offered only after a thorough assessment by a licensed mental health provider and a licensed physician. *Id.* ¶ 41.

B. Plaintiffs Provide Medically Necessary Care for Transgender Adolescents Consistent with State and Federal Law.

Both state and federal law protect access to medically necessary, gender-affirming health care for adolescents. For example, States and the federal government have interpreted the Medicaid Act to protect access to medically necessary gender-affirming care. *Id.* ¶ 122 n.37. For decades, the federal government has authorized state Medicaid programs to reimburse the costs of gender-affirming care with both state *and federal* funds. *Id.* ¶ 122; *see also id.* ¶ 161. And, under both state and federal law, healthcare providers may lawfully prescribe medications for "off-label" uses, i.e., uses that the Food and Drug Administration (FDA) has not yet approved. *See id.* ¶¶ 150–51. Indeed, Medicaid *requires* coverage for medically accepted uses. *See* 42 U.S.C. § 1396r-8(d)(1)(B)(i).

Plaintiff States have further protected access to gender-affirming care through state laws, regulations, and state constitutional amendments. For example, many state laws prohibit healthcare providers or insurers from discriminating based on gender, Doc. No. 1 ¶¶ 64–78; require private or state insurance plans to cover gender-affirming care, *id.* ¶ 71; shield patients and providers from liability in jurisdictions that outlaw gender-affirming care, *id.* ¶ 79; and protect the ability of individuals who have reached the age of majority (typically, 18) to consent to their own medical care (including gender-affirming care), *id.* ¶ 107. Moreover, Plaintiff States have long regulated the practice of medicine within their borders, through licensing requirements, misconduct rules, informed consent protocols, and patient safety standards. *Id.* ¶¶ 83–100.

Many Plaintiff States also operate and fund public hospitals that provide gender-affirming care directly to patients, including adolescents. *Id.* ¶ 179; Ex. 1 (Plaintiff State Provider #1 Decl.) ¶¶ 1, 22–23; Ex. 2 (Plaintiff State Provider #4 Decl.) ¶¶ 3, 5–6; Ex. 3 (Plaintiff State Provider #5 Decl.) ¶¶ 3, 7, 16–18; Ex. 4 (Plaintiff State Provider #6 Decl.) ¶¶ 3, 7; *see also* Ex. 16 (Justicz Decl.).[1] Several Plaintiff States also monitor the provision of, or have a legal duty to provide, medically necessary care (including gender-affirming care) to adolescents in their care or custody, which may include adolescents in foster care, residing in shelters or other group residences, or remanded to juvenile justice facilities. *See id.* ¶ 184; Ex. 7 (Mueller Decl.) ¶¶ 10–11, 16, 22; Ex. 6 (Bagdasarian Decl.) ¶¶ 10–11, 15, 18; Ex. 8 (Maehr Decl.) ¶¶ 8–9; Ex. 9 (Aledort Decl.) ¶¶ 13–16, 18.

C. Defendants Target Providers of Gender-Affirming Care.

1. The Executive Order

Eight days after taking office, the President issued Executive Order 14187, "Protecting Children From Chemical and Surgical Mutilation." Doc. No. 1-5. In the EO, the President called gender-affirming care "maiming and sterilizing," a "horrifying tragedy," and "a stain on our Nation's history" that "must end." *Id.* § 1. The EO directed federal agencies to restrict "children," defined as anyone under age 19, *id.* § 2(a), from accessing puberty blockers, hormones, and surgeries *only* if the treatments are used to treat gender dysphoria. *Id.* § 2(c). The EO is silent on the legality of the same medicines and treatments for any other diagnoses.

Section 8(a) of the EO directs DOJ to review its enforcement of the federal statute criminalizing female genital mutilation (FGM), in connection with provision of gender-affirming

[1] Citations herein to "Ex. __" are to the Declaration of Andres Ivan Navedo.

care.[2] *Id.* § 8(a); *see* 18 U.S.C. § 116 (the "FGM statute"). The EO disregards that, under the FGM statute, a procedure qualifies as FGM only if it is performed for "non-medical reasons," and does not include a "surgical operation" that is "necessary to the health of the person on whom it is performed" and "performed by a person licensed in the place of its performance as a medical practitioner.*"* 18 U.S.C. §§ 116(b)(1), (e). Separately, Section 8(c) of the EO directs DOJ to "prioritize investigations" against "any entity" that may be misleading the public about long-term side effects of gender-affirming care under the federal Food, Drug and Cosmetic Act (FDCA). *See* Doc. No. 1-5 § 8(c); *see* 21 U.S.C. § 301 *et seq*.

The EO was intended to and did change established practices in the medical community. Many providers responded to the EO by immediately suspending or curtailing services. Doc. No. 1 ¶¶ 169, 171, 173–75; Ex. 13 (Wenger Decl.) ¶¶ 17–18; Ex. 16 (Justicz Decl.) ¶ 35. Offices of state attorneys general and governors were flooded with communications from providers and hospitals, expressing alarm and confusion over a directive that purported to outlaw medical care that was completely lawful the day before. Doc. No. 1 ¶¶ 164–65. Patients and parents searched frantically, and many continue to search, for new providers. Ex. 14 (CA Provider #1 Decl.) ¶ 67; Ex. 3 (Plaintiff State Provider #5) ¶ 39; Ex. 16 (Justicz Decl.) ¶¶ 35–40; Ex. 23 (Silva Decl.) ¶ 14; Ex. 24 (Plaintiff State Provider #3 Decl.) ¶¶ 34–35; Ex. 20 (Hone Decl.) ¶¶ 15–16; Ex. 29 (Moehlig Decl.) ¶¶ 32, 38; Ex. 5 (Sheldon Decl.) ¶ 47; Ex. 13 (Wenger Decl.) ¶ 46. According to the White House, this was the EO's "intended effect—preventing children from being maimed and sterilized by adults perpetuating a radical, false claim that they can somehow change a child's sex." Doc. No. 1 ¶ 165; Ex. 10 (White House Article, Feb. 3, 2025) (cited in Doc. No. 1 ¶ 165 n.69). In

[2] Under the statute, "female genital mutilation" is defined as "any procedure performed for non-medical reasons that involves partial or total removal of, or other injury to, the external female genitalia," including partial or total removal of the clitoris or labia, or narrowing of the vaginal opening. 18 U.S.C. § 116(e).

the wake of this terror and confusion, the White House boasted: "Hospitals around the country are taking action to downsize or eliminate their so-called 'gender-affirming care' programs."[3] Plaintiff States' residents immediately felt the medical consequences of the loss of services. Ex. 12 (Sewell Decl.) ¶ 37; Ex. 13 (Wenger Decl.) ¶ 41; Ex. 5 (Sheldon Decl.) ¶ 47; Ex. 18 (Del Monte Decl.) ¶ 32; ¶ 46; Ex. 6 (Bagdasarian Decl.) ¶ 31; Ex. 1 (Plaintiff State Provider #1 Decl.) ¶ 46; Ex. 6 (Bagdasarian Decl.) ¶ 31.

2. The DOJ Directives

On April 22, 2025, Attorney General Bondi issued a memorandum entitled "Preventing the Mutilation of American Children" (the "Bondi Directive"), which described the provision of medically necessary healthcare as "an unconscionable ideology" and pledged that DOJ "will bring these practices to an end." Doc. No. 1-6 at 6. The Bondi Directive instructed DOJ to enforce three federal statutes against providers and hospitals. *Id.* ¶¶ 115–21; Doc. No. 1-6 at 3–5. First, the Bondi Directive "put[] medical practitioners, hospitals, and clinics on notice" that performing FGM "under the guise of so-called 'gender-affirming care' or otherwise" is a felony, punishable by up to ten years in prison. *Id.* ¶ 115; Doc. No. 1-6 at 3–4 (vowing to prosecute individuals who "mutilate [children] under the guise of care"). The Directive ordered "all U.S. Attorneys to investigate all suspected cases" of FGM and to prosecute these cases "to the fullest extent possible." Doc. No. 1-6 at 3–4. Second, the Directive ordered DOJ to investigate medical providers under the FDCA for "mislead[ing] the public about long-term side effects" of gender-affirming care or promoting "off-label uses of hormones . . . under the guise of sponsored continuing medical education courses." Doc. No. 1-6 at 5 (citing 21 U.S.C. §§ 321, 331, 352). Third, under the False

[3] Ex. 10 (White House Article, Feb. 3, 2025) (cited at Doc. No. 1 ¶ 165 n.69); *see also* Ex. 11 (White House Article, Mar. 4, 2025) ("Health systems across the nation stopped or downsized their sex change programs for minors following President Trump's [EO].") (also cited at Doc No. 1 ¶ 165 n.69).

Claims Act, 31 U.S.C. § 3729 (FCA), the Directive ordered the Civil Division's Fraud Section to investigate physicians who submit "non-covered services related to radical gender experimentation" and identified gender dysphoria as "an illegitimate reason" to prescribe puberty blockers. Doc. No. 1 ¶¶ 121–22; Doc. No. 1-6 at 4. The Directive also invited *qui tam* whistleblowers to file actions against providers or forward tips to the DOJ, and reiterated that monetary incentives are available to individuals who bring private actions under the FCA[4] *Id.*

On June 11, 2025, Assistant Attorney General Shumate issued another memorandum directing the Civil Division to use "all available resources" to implement the EO and the Bondi Directive against doctors and hospitals, among other entities. Doc. No. 1-7 (Shumate Directive) at 2–3. The Shumate Directive vowed to enforce the FDCA and the FCA against medical providers, explaining that the Civil Division would enforce the FCA "against health care providers that bill the federal government for impermissible services" related to gender affirming care. *Id.* The Directives continued to intimidate a medical community still reeling from the EO. More providers ceased services. Ex. 18 (Del Monte Decl.) ¶¶ 29–30; Ex. 13 (Wenger Decl.) ¶ 21; *see* Ex. 5 (Sheldon Decl.) ¶ 46; Ex. 12 (Sewell Decl.) ¶¶ 34, 40; Ex. 22 (DC Provider #1 Decl.) ¶¶ 8, 23–24; Ex. 32 (Halsey Decl.) ¶¶ 10–11; Ex. 13 (Wenger Decl.) ¶¶ 39–40, 42–43, 48–49, 58; Ex. 16 (Justicz Decl.) ¶¶ 37–39; Ex. 25 (Lusk Decl.) ¶ 30; Ex. 24 (Plaintiff State Provider #3 Decl.) ¶¶ 32, 34; Ex. 21 (Plaintiff State Provider #2 Decl.) ¶¶ 28–29; Ex. 20 (Hone Decl.) ¶¶ 13–14; Ex. 29 (Moehlig Decl.) ¶¶ 28–31; Ex. 6 (Bagdasarian Decl.) ¶¶ 27–28; Ex. 14 (CA Provider #1 Decl.) ¶¶ 59–62 (each describing collective impact of EO and DOJ Directives on provision of care).

[4] The Attorney General has also issued joint guidance with HHS explaining how FCA whistleblowers may protect themselves when reporting "mutilation of children carried out by medical professionals in the name of radical gender ideology." *See* Ex. 28 (April 14, 2025, HHS Guidance for Whistleblowers).

Defendants again claimed victory: "President Trump Promised to End Child Sexual Mutilation – and He Delivered." Doc. No. 1-3; *see also* Doc. No. 1 ¶¶ 166–67.

D. Defendants Implement the DOJ Directives.

Defendants promptly began carrying out the Directives. Beginning in July, Defendants served at least twenty subpoenas to hospitals and individual providers across the country that offer gender-affirming care. Doc. No. 1 ¶¶ 132–34.[5] The subpoenas demanded, among other things, complete personnel files of any employee, contractor, or affiliate who billed for gender-affirming care; medical records of every patient prescribed puberty blockers or hormones (including names, social security numbers, and parent/guardian information); and documents related to the clinical indications, diagnoses, or assessments supporting treatment. *See* Ex. 17 (BCH Subpoena) at 5–6.

At the time of filing this opposition, Plaintiffs are aware of nine judicial challenges to these subpoenas (although others may be under seal). All courts that have issued decisions, including this district, have ordered the subpoena quashed or set aside at least in part, and all have concluded that the subpoenas are part of a concerted effort to intimidate and threaten providers into ceasing the provision of legal medical care. *See In Re: Administrative Subpoena No. 25-1431-019*, No. 1:25-mc-91324-MJJ, 2025 WL 2607784, at *7 (D. Mass. Sept. 9, 2025) ("It is abundantly clear that the true purpose of issuing the subpoena is to interfere with . . . Massachusetts' right to protect [gender-affirming care] within its borders, to harass and intimidate [a hospital] to stop providing such care, and to dissuade patients from seeking such care.") (pending appeal); *In re Subpoena Duces Tecum No. 25-1431-016*, No. 2:25-mc-00041, 2025 WL 3562151, at *12 (W.D. Wash. Sep. 3, 2025) ("DOJ requested documents as part of an effort to end gender-related care for minors."); *QueerDoc, PLLC, v. U.S. Dep't of Justice*, No. 2:25-mc-00042, 2025 WL 3013568, at *4 (W.D.

[5] *See* Ex. 30 (DOJ Press Release, July 9, 2025).

Wash. Oct. 27, 2025) ("The question before the Court is whether DOJ may use its administrative subpoena power to achieve what the Administration cannot accomplish through legislation: the elimination of medical care that Washington and other states explicitly protect. The answer is no.") (pending appeal); *In re: Subpoena No. 25-1431-014*, No. 2:25-mc-00039, 2025 WL 3252648, at *2 (E.D. Pa. Nov. 21, 2025) ("The three document requests to the Hospital before us today seek the identity of transgender children and their treatment seeking the most confidential of medical information in an environment where the described policy of the United States is to end this prescribed medical care notwithstanding Pennsylvania's exclusive authority to allow it.").[6] In several of these cases, DOJ filed a declaration by the Acting Director of the Enforcement and Affirmative Litigation Branch outlining the Department's novel theories of how doctors, hospitals, and hospital administrators trigger FDCA liability by providing this medically necessary care. *See, e.g.*, Ex. 27 (Hsiao Decl.).[7] As the declaration explains, FDCA liability obtains for administering puberty blockers to patients in hospital or clinical settings, *id.* ¶ 23, and for prescribing drugs for an off-label or "unapproved" use. *Id.* ¶¶ 17–18, 22.

In addition to the subpoenas, the Federal Bureau of Investigation (FBI) solicited the public for names of individual providers and institutions that offer gender-affirming surgeries, while parroting the language of the Directives. Doc. No. 1 ¶ 124 ("[W]e will protect our children and

[6] One court also dismissed as moot a challenge that had been brought by patients after it quashed the same subpoena in a parallel challenge brought by the hospital. *In re Administrative Subpoena No. 25-1431-01*, No. 2:25-mc-00054 (E.D. Pa. Nov. 21, 2025), Doc. No. 20. At least four other challenges to these subpoenas are pending. *See In re: 2025 UPMC SUBPOENA*, No. 2:25-mc-01069 (W.D. Pa. Sept. 24, 2025); *Department of Justice Administrative Subpoena No. 25-1431-030*, No. 1:25-mc-00063, (D. Colo. Aug. 8, 2025); *In Re: 2025 Subpoena to Children's National Hospital*, No. 1:25-cv-03780, (D. Md. Nov. 17, 2025); *In Re: 2025 Children's Hospital of Los Angeles Subpoena*, No. 2:25-cv-11183 (C.D. Cal. Nov. 21, 2025).

[7] This court may take judicial notice of the contents of the Hsiao Declaration, *see Oxford Asset Mgmt., Ltd. v. Jaharis*, 297 F.3d 1182, 1188 (11th Cir. 2002), and DOJ's apparent position therein. DOJ's legal position is "not subject to reasonable dispute because it: (1) is generally known within the trial court's territorial jurisdiction; or (2) can be accurately and readily determined from sources whose accuracy cannot be reasonably questioned." *Lopes v. Riendeau*, 177 F. Supp. 3d 634, 666 (D. Mass. 2016).

hold accountable those who mutilate them under the guise of gender-affirming care."). The FBI has since initiated criminal investigations into providers at three hospitals pursuant to the FGM statute. *Id.* ¶ 137. DOJ has also ramped up its enforcement capabilities by creating a joint working group with the U.S. Department of Health and Human Services (HHS) explicitly tasked with enforcing the Shumate Directive. *Id.* ¶ 153.

Since this litigation was filed, DOJ has taken additional steps to effectuate the Directives. DOJ established a new "Enforcement & Affirmative Litigation Branch" focused in part on "protecting women and children from pharmaceutical companies, *health care providers*, and medical associations profiting off of false and misleading claims related to so-called gender transition."[8] Attorneys in the new branch have already appeared in and defended DOJ in nearly all of the aforementioned subpoena challenges. Indeed, despite telling this Court during the shutdown that DOJ had classified this lawsuit as a *non*-emergent matter, Doc. No. 72 ¶ 2, DOJ told other courts that the subpoena litigation *was* emergent, defended the subpoenas during the shutdown, and described the subpoenas as part of "a bona fide, high-priority, and substantial investigation," to which it has assigned "substantial government resources"—including "several veteran, career prosecutors," "a team of document analysts and other forensic specialists," and multiple FBI agents.[9] Ex. 27 (Hsiao Decl.).

II. Procedural Background

On August 1, 2025, Plaintiff States filed the instant complaint alleging that (i) the DOJ Directives violate the Administrative Procedure Act (APA); (ii) the EO, the DOJ Directives, and their implementation undermine the Plaintiff States' right to regulate the practice of medicine in

[8] See Ex. 19. (Sept. 25, 2025, DOJ Press Release) (emphasis added).

[9] Indeed, implementation of the Directives was such a high priority that at least five other subpoena challenges were actively litigated during the fall 2025 government shutdown.

violation of the Tenth Amendment; and (iii) the DOJ Directives raise legal disputes between the parties about the proper legal interpretation of the FGM statute, the FDCA, and the FCA that justify relief under the Declaratory Judgment Act. On November 21, 2025, the government moved to dismiss the complaint. Doc. No. 82. Plaintiffs now oppose.

STANDARD OF REVIEW

When a district court considers a Rule 12(b)(1) motion, it must credit the plaintiff's well-pled factual allegations and draw all reasonable inferences in the plaintiff's favor. *Valentin v. Hospital Bella Vista*, 254 F.3d 358, 363 (1st Cir. 2001). In assessing subject-matter jurisdiction, a court may also consider evidence submitted by the parties in support of the pleadings. *Merlonghi v. United States*, 620 F.3d 50, 54 (1st Cir. 2010).

Under Rule 12(b)(6), the court accepts the factual allegations in the complaint as true, construes reasonable inferences in the plaintiff's favor, and determines "whether the factual allegations in the plaintiff's complaint set forth a plausible claim upon which relief may be granted." *Foley v. Wells Fargo Bank, N.A.*, 772 F.3d 63, 68, 71 (1st Cir. 2014) (internal citation omitted). A claim is facially plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). As to APA claims, however, the plausibility standard does not apply because "[t]he focal point of APA review is the existing administrative record." *Atieh v. Riordan*, 727 F.3d 73, 76 (1st Cir. 2013). Instead, resolution of APA claims should await production of the administrative record. *See id.*

ARGUMENT

III. This Court Has Jurisdiction to Hear This Case.

A. Plaintiffs Request Declaratory Judgment in Response to Actual Controversies.

The DOJ Directives announced novel theories of liability under three federal laws which have since been used to ground investigations into healthcare institutions and providers of gender-affirming care. These actions have created a justiciable "reasonably clear and specific threat of prosecution." *See N.H. Hemp Council, Inc. v. Marshall*, 203 F.3d 1, 4 (1st Cir. 2000). This threat of prosecution is premised on "substantial controvers[ies], between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *See MedImmune v. Genentech, Inc.*, 549 U.S. 118, 127 (2007; *accord Mass. Delivery Ass'n v. Coakley*, 769 F.3d 11, 16 (1st Cir. 2014).

First, Plaintiffs have clearly alleged a controversy that is immediate and real as Defendants have done more than merely announce legal theories—they are actively applying them. *See Mass. Delivery Ass'n*, 769 F.3d at 17 (risk of enforcement against plaintiff association was immediate and real where association's members had already been charged in separate proceedings); *see also Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1021 (D.C. Cir. 2000) (policies reviewable where agency "bases enforcement actions on the policies"). Before the filing of the complaint, Defendants had already begun enforcement proceedings against providers and hospitals (including providers in Plaintiff States) that offer puberty blockers, hormones, and surgical procedures to adolescents as treatments for gender dysphoria, Doc. No. 1 ¶ 137, and served at least twenty subpoenas against hospitals and providers. *Id.* ¶ 132. That alone shows a sufficiently immediate and real dispute to support standing. Since then, Defendants have gone further by litigating to enforce those subpoenas and creating both a targeted working group and litigation branch dedicated to "filing lawsuits against *states*, municipalities and private entities" that violate the

Administration's gender-related policies.[10] Doc. No. 1 ¶¶ 132–34, 137; *supra* § I.D. These actions have had a real and rapid impact on doctors and hospitals by forcing them to curtail access to gender-affirming medical care, stopped providing the care entirely, or shouldered the considerable risk that providing the care will subject them to criminal or civil penalties. *See supra* § I.C.; *see also* Ex. 18 (Del Monte Decl.) ¶¶ 25–31; Ex. 12 (Sewell Decl.) ¶¶ 22–23; Ex. 5 (Sheldon Decl.) ¶¶ 28–29, 32; Ex. 4 (Plaintiff State Provider #6 Decl.) ¶ 35.

Second, Plaintiffs have also alleged "substantial controvers[ies] between parties having adverse legal interests." *See MedImmune*, 549 U.S. at 127. Each of Plaintiffs' claims about the three federal statutes at issue raise legal questions that can be resolved regardless of any particular prosecution in which these statutes might be applied. For example, the Bondi Directive explicitly puts "medical practitioners, hospitals, and clinics"—entities that are expressly excluded by the statute's terms—"on notice" that DOJ plans to prosecute "all suspected cases of FGM—under the banner of so-called 'gender-affirming care' or otherwise." Doc. No. 1-6 at 3–4; *see id.* at 5 (vowing to "build [FGM] cases against hospitals and practitioners"). But the statute defines FGM as "a procedure performed for non-medical reasons," and contains carveouts for medically necessary procedures performed by licensed professionals. 18 U.S.C. § 116(b), (e). Thus, the purely legal questions presented are (i) whether the statutory definition of FGM includes—or excludes—gender-affirming care, 18 U.S.C. § 116(b), (e), and (ii) whether the President and Attorney General may override States' determinations that treatments protected by state law and provided by state-licensed professionals are medically unnecessary under the FGM statute, *see infra* § V.

Likewise, the Bondi Directive extends FCA liability to healthcare claims for "any non-covered services related to radical gender experimentation," and makes the categorical claim that

[10] Ex. 19 (DOJ Press Release, Sept. 25, 2025) (emphasis added).

prescribing puberty blockers to a child for gender dysphoria is "an illegitimate reason" to bill federal healthcare programs. Doc. No. 1-6 at 4. Thus, among the legal questions presented for review are (i) whether gender-affirming medical treatments remain "covered services" under federal healthcare programs, as they have been for decades, and (ii) whether gender dysphoria is a categorically "illegitimate" reason to bill these programs in Plaintiff States.

Finally, the Bondi Directive vows to hold "medical providers" accountable under the FDCA, Doc No. 1-6 at 4; *see also* Doc No. 1-5 § 8(c) (applying FDCA to "any entity"), and Defendants explain that the FDCA is triggered when a provider administers or "promotes" off-label use of hormone treatments "during the provision of gender-related care." Doc No. 82 at 16; *see also* Ex. 27 (Hsiao Decl.) ¶ 23 (provider or hospital enters "chain of distribution" by purchasing, storing, or administering puberty blockers or testosterone). This flies in the face of previously settled law that the FDCA does not regulate the practice of medicine and allows "off-label-prescribing." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350–51 (2001); *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). Accordingly, the purely legal questions presented for review are (i) whether communications between a provider and a patient during an appointment can trigger FDCA liability, and (ii) whether purchasing, storing, prescribing, or administering FDA-approved drugs for gender dysphoria violates the FDCA.

Defendants' only rejoinder is to claim that "DOJ has never suggested that merely providing *medically necessary* care violates federal law." Doc. No. 82 at 12 (emphasis added). But that statement is a tautology (and a profoundly misleading one): the Directives establish that Defendants deem gender-affirming care to be medically *unnecessary*. The Bondi Directive, for example, describes gender-affirming care as "junk science," puts the words "treatment" and

"professionals" in scare quotes, and repeatedly refers to gender-affirming care as "so-called 'care.'" Doc. No. 1-6 at 1; *see also id.* at 6 (comparing threat posed by "our own medical community" to that of "drug cartels [and] terrorists"). Defendants' feeble attempt to recast the DOJ Directives as simply restating preexisting law rings hollow, especially when Defendants have boasted that the Directives have achieved their desired policy changes. *See N.H. Lottery Comm. v. Barr*, 386 F. Supp. 3d 132, 142 (D.N.H. 2019) (refusing to engage in an "unwarranted speculative leap" in interpreting agency action in light of the clear record), *aff'd in part, vacated in part sub nom. N.H. Lottery Comm'n v. Rosen*, 986 F.3d 38 (1st Cir. 2021).

Defendants also insist that the dispute is "hypothetical," Doc. No. 82 at 11–13, because *Plaintiffs* maintain that they do not engage in unlawful conduct such as deliberate misbilling of federal healthcare programs or commercial promotion of drugs for off-label uses. But this case is not about deliberate misbilling or other conduct that has long been prohibited by the statutes. Instead, the entire point is that the Directives have newly cast a pall of liability for engaging in activity Plaintiffs have engaged in lawfully for years. *See Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 157–58 (2014). In such cases, the ripeness of a Declaratory Judgment Act claim "rises or falls with the enforcing authority's willingness to disavow enforcement." *See Peace Ranch, LLC v. Bonta*, 93 F.4th 482, 490 (9th Cir. 2024). And here, critically, Defendants do not disavow that they intend to enforce these statutes against providers of this medically necessary healthcare, though Defendants could easily do so. Moreover, Defendants cannot reasonably argue that they have not enlarged liability for preexisting conduct under the statute, nor that they have not "suggested that the provision of gender-related care to minors by itself violates federal law," Doc. No. 82 at 12, when they have weaponized new theories of liability under these federal statutes precisely in order to "bring the practice of [gender-affirming care] to an end." Doc. No. 1-6 at 6;

see id. at 3 ("Under my watch, the Department will act decisively to protect our children and hold accountable those who mutilate them under the guise of care."); Doc. No. 1-7 at 2 (directing the Civil Division to use "all available resources" for this purpose). There is nothing hypothetical about Defendants' actions, which have put Plaintiffs "on the horns of a dilemma": discontinue vital, medically necessary services for a vulnerable population or risk criminal and civil liability. *See Stern v. U.S. Dist. Ct. for Dist. Of Mass.*, 214 F.3d 4, 11 (1st Cir. 2000). It is this kind of "dilemma that [is] the very purpose of the Declaratory Judgment Act to ameliorate." *Abbott Lab'ys v. Gardner*, 387 U.S. 136, 152 (1967).

B. DOJ's Enforcement of the EO Directly Injures Plaintiff States.

Plaintiff States have also clearly suffered an injury-in-fact for Article III standing purposes. Several of the Plaintiff States fund and operate public hospitals and clinics, and/or employ medical providers, that provide gender-affirming care to patients under 19. *See, e.g.*, Doc. No. 1 ¶ 179; *see supra* § I.B. After services were impacted, many of these state-run entities were compelled to absorb patients whose care was terminated by other providers after the EO and DOJ Directives. *See, e.g.*, Ex. 1 (Plaintiff State Provider #1 Decl.) ¶ 45; Ex. 2 (Plaintiff State Provider #4 Decl.) ¶ 25; Ex. 3 (Plaintiff State Provider #5 Decl.) ¶ 41; Ex. 4 (Plaintiff State Provider #6 Decl.) ¶ 36; Ex. 18 (Del Monte Decl.) ¶ 31. This has dramatically increased providers' workloads and caused lengthy patient wait times and increased administrative burdens. *Id.*; *see* Ex. 22 (DC Provider #1 Decl.) ¶ 24. These burdens will only compound as more providers terminate services in response to the EO and Directives.

Threatened DOJ investigations into these state-run entities and their employees—merely for engaging in the legal provision of care—have severely disrupted, and will continue to disrupt, the operation of state-run healthcare facilities by requiring providers and administrators to divert time away from treating patients, requiring modifications to the scope of malpractice insurance,

and creating staffing shortages. Ex. 1 (Plaintiff State Provider #1) ¶ 44; *see* Ex. 23 (Silva Decl.) ¶ 11; Ex. 20 (Hone Decl.) ¶ 11; Ex. 18 (Del Monte Decl.) ¶¶ 25–26; Ex. 5 (Sheldon Decl.) ¶ 35; Ex. 12 (Sewell Decl.) ¶ 43 (each describing similar disruptions caused by DOJ investigations into private healthcare facilities); *see also Fellowship of Christian Athletes v. San Jose Unified Sch. Dist. Bd. of Educ.*, 82 F.4th 664, 683 (9th Cir. 2023) (diverting an organization's resources constituted injury for Article III standing). Investigations will also force Plaintiff States to expend public resources retaining counsel, responding to subpoenas, gathering information, and potentially defending their state instrumentalities and employees in litigation.[11] "[S]pending time defending against [a] meritless suit" is "itself an injury," *Demarais v. Gurstel Chargo, P.A.*, 869 F.3d 685, 693 (8th Cir. 2017), as is the expenditure or loss of public funds by state agencies or instrumentalities. *See Biden v. Nebraska*, 600 U.S. 477, 490–92 (2023) (finding state standing where agency action caused independent state instrumentality to lose loan servicing fees); *Uzuegbunam v. Preczewski*, 592 U.S. 279, 292–93 (2021) (monetary harm in any quantity satisfies Article III standing). If the Directives are allowed to stand, both state-run healthcare providers and other providers in Plaintiff States will continue to face these imminent harms from burdensome and improper legal actions.

In addition to the harms posed by a baseless investigation, state-run entities must also expend significant time and resources analyzing the new federal policies and their implications, altering their policies and practices accordingly, and responding to a multitude of panicked inquiries from the patients and families terrified of losing access to care—all of which further

[11] Indeed, because the Bondi Directive affirmatively invites private parties to file qui tam actions under the FCA (*see* Doc. No. 1-6 at 3–4)—and because the FCA requires qui tam complaints to be sealed for at least sixty days, without service on the defendant, to allow the federal government the option to intervene, *see* 31 U.S.C. § 3730(b)(2)—providers in Plaintiff States may already be the subject of litigation. Further, the Attorney General has also issued joint guidance with HHS explaining how FCA whistleblowers may protect themselves. *See* Ex. 24 (HHS, *Guidance for Whistleblowers on the Chemical and Surgical Mutilation of Children*, Apr. 14, 2025) at 6.

burdens staff and diverts time and resources away from patient care. *See, e.g.*, Ex. 3 (Plaintiff State Provider #5 Decl.) ¶ 41; Ex. 1 (Plaintiff State Provider #1 Decl.) ¶¶ 48–49; Ex. 4 (Plaintiff State Provider #6 Decl.) ¶¶ 34, 37; Ex. 2 (Plaintiff State Provider #4 Decl.) ¶ 28; *see also* Ex. 18 (Del Monte Decl.) ¶¶ 25, 27.

Further, state-run entities who have terminated or limited the gender-affirming care available to patients under 19 also face potential liability under state antidiscrimination laws.[12] *See, e.g.*, Ex. 18 (Del Monte Decl.) ¶¶ 29–30; Ex. 5 (Sheldon Decl.) ¶ 46; Ex. 14 (CA Provider #1 Decl.) ¶ 62; Ex. 6 (Bagdasarian Decl.) ¶ 28; Ex. 21 (Plaintiff State Provider #2 Decl.) ¶ 35; *see also* Ex. 18 (Del Monte Decl.) ¶ 34.

The targeting of medical institutions in Plaintiff States also directly injures Plaintiff States in their capacity as legal custodians of youth in foster care, juvenile detention, or other forms of state custody. Federal and state laws impose a legal obligation on custodial entities to provide all necessary healthcare to youth in their custody. Doc. No. 1 at ¶ 80; *supra* § I.B. The challenged actions here have already constrained and threaten to further impede Plaintiffs' execution of those mandatory custodial duties toward youth who need gender-affirming care and threaten to further burden Plaintiffs with increased public health costs for these youth and others, as denying gender-affirming care causes substantial negative health consequences. *See* Doc. No. 1 ¶ 45, 181–83; Ex. 9 (Aledort Decl.) ¶¶ 41–46; Ex. 6 (Bagdasarian Decl.) ¶¶ 26–28, 31–33; Ex. 7 (Mueller Decl.) ¶¶ 21–22; Ex. 8 (Maehr Decl.) ¶¶ 12–13; *see also California v. HHS*, No. 1:25-cv-12118, 2025 WL 3459579, at *9 (D. Mass. Dec. 2, 2025) (downstream healthcare costs associated with reduced access to care constituted injury for purposes of state standing).

[12] Indeed, at least one hospital in a Plaintiff State currently faces a complaint alleging it violated state antidiscrimination law by unlawfully denying gender-affirming care to transgender patients under 19 years of age. *See* Ex. 13 (Wenger Decl.) ¶ 62.

Plaintiff States also have standing because the EO and Directives harm their sovereign interest in the "continued enforceability of [their] own statutes." *Maine v. Taylor*, 477 U.S. 131, 137 (1986); *see also Ohio v. EPA*, 603 U.S. 279, 291 (2024) (regulation "issued unlawfully . . . necessarily impairs [States'] sovereign interests in regulating their own industries and citizens"); *see also Bowen v. Pub. Agencies Opposed to Soc. Sec.*, 477 U.S. 41, 50 n.17 (1986) (state possessed "judicially cognizable interest in the preservation of its own sovereignty"). As alleged in the complaint, many Plaintiff States have laws that protect transgender residents and ensure access to medically necessary treatment. *See* Compl. ¶¶ 63–82. Among other things, these laws explicitly authorize providers to provide gender-affirming care; prohibit providers, health systems, and payors from discriminating against transgender patients; and define the age of majority for medical procedures. Because the EO and the DOJ Directives effectively proscribe the same treatments that state laws protect, and because "[a]ny time a State is enjoined by a court from effectuating statutes enacted by representatives of its people, it suffers a form of irreparable injury," *Maryland v. King*, 567 U.S. 1301, 1303 (2012) (Roberts, C.J., in chambers), Plaintiffs have pleaded a direct, concrete, and imminent injury that satisfies Article III standing.

C. *United States v. Texas* Is Inapplicable to the Instant Case.

Contrary to Defendants' representations, *United States v. Texas*, 599 U.S. 670 (2023), does not bar the claims here. As the Supreme Court emphasized, *Texas* was a "rare" suit challenging an *absence* of enforcement—specifically, a case in which the plaintiffs asked the Department of Homeland Security to make "more arrests" and initiate "more prosecutions" of noncitizens than federal guidelines required. *Id.* at 677, 680. In those circumstances, the Court observed, plaintiffs "lack[] a judicially cognizable interest in the prosecution . . . of another" because the decision *not* to prosecute does not implicate "coercive power over an individual's liberty or property" and thus

the interests that federal courts are "often [] called upon to protect." *Id.* at 677–78. Critically, the Court explained that "coercive power" "makes a difference" for standing. *Id.* at 678.

Here, it is precisely the exercise of DOJ's coercive power that Plaintiffs challenge. *Cf. id.* at 6780. The DOJ Directives do not, as Defendants say, merely prioritize scarce enforcement resources, a "traditionally federal" interest. Doc No. 82 at 8; *cf. Maryland v. USDA*, 151 F.4th 197, 209 (4th Cir. 2025) (see *infra* § IV.B). As discussed above, Plaintiffs challenge Defendants' unlawful weaponization of existing statutes to force both public and private providers in Plaintiff States to stop providing medical care under threat of criminal or civil liability. This case thus fits squarely within the interests that federal courts are "often called upon to protect."[13] *Id.* at 677.

IV. Plaintiffs Challenge Reviewable Agency Actions Under the APA.

A. The DOJ Directives Are Final Agency Actions.

The APA "creates a basic presumption of judicial review for one suffering legal wrong because of agency action." *Weyerhaeuser Co. v. U.S. Fish and Wildlife Serv.*, 586 U.S. 9, 22 (2018) (quotation marks omitted). The "bite in the phrase 'final action' . . . is not in the word 'action,' which is meant to cover comprehensively every manner in which an agency may exercise its power," but rather in the word "final." *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 478 (2001). An action is "final" if it is both the "consummation" of the agency's decisionmaking process—i.e., not merely tentative or interlocutory in nature—and an action "by which rights or obligations have been determined or from which legal consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997) (quotations omitted). Finality is a "pragmatic" inquiry, *U.S. Army Corps of Eng'rs v. Hawkes Co.*, 578 U.S. 590, 599 (2016), that asks whether an action is a "definitive

[13] Defendants note that many Plaintiff States submitted an amicus brief in support of the United States in *United States v. Texas*. *See* Doc. No. 82 at 15. That brief stated the settled rule (later endorsed by the Supreme Court) that DOJ may optimize its limited resources by prioritizing certain offenses for enforcement. Neither *Texas* nor the amicus brief concerns the circumstances here, where DOJ substantively expanded the scope of liability under existing statutes.

statement of the agency's position" with "a direct and immediate effect on the day-to-day business of the complaining parties." *Sig Sauer, Inc. v. Brandon*, 826 F.3d 598, 600 n.1 (1st Cir. 2016).

The DOJ Directives are final agency action. DOJ leadership adopted these novel interpretations—and directed enforcement based on these interpretations—to "end" medically necessary healthcare, as directed by the President. Doc. No. 1-6 at 6; *see* Doc. No. 1-5 § 1. The Directives "provide[] firm guidance to enforcement officials about how to handle" provision of gender-affirming medical care to adolescents, even in States where that care is legal. *See Nat'l Env't Dev. Ass'n's Clean Air Project v. EPA*, 752 F.3d 999, 1007 (D.C. Cir. 2014) ("*NEDACAP*"); *Barrick Goldstrike Mines Inc. v. Browner*, 215 F.3d 45, 48 (D.C. Cir. 2000) ("That the issuance of a guideline or guidance may constitute final agency action has been settled in this circuit for many years."). And the Directives "leave[] . . . no room" for DOJ officials to conclude that gender-affirming surgery may be medically necessary or that gender dysphoria is anything but an "illegitimate reason" to bill a federal healthcare program. *See Tennessee v. Dep't of Educ.*, 104 F.4th 577, 599 (6th Cir. 2024) (agency guidance interpreting Title IX's nondiscrimination provision in light of *Bostock v. Clayton Cnty.*, 590 U.S. 644 (2020), was final agency action). Each Directive thus qualifies as a "rule" under the APA. *See* 5 U.S.C. §§ 551(4) (defining "rule" as "whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy"), 551(13) ("agency action" includes whole or part of agency rule).

Nothing indicates that DOJ's policies are "tentative or interlocutory." *Bennett*, 520 U.S. at 178. "If an agency acts as if a document issued at headquarters is controlling in the field . . . then the agency's document is for all practical purposes binding." *See Appalachian Power Co.*, 208 F.3d at 1021 (citation modified); *see, e.g.*, *NEDACAP*, 752 F.3d at 1007 (holding that "finality and

legal consequences of [EPA] Directive were made plain when the EPA relied on the directive in a permit decision"). Here, Defendants have already begun implementing these policies by serving at least twenty subpoenas on hospitals the same day they issued the Shumate Directive. *Supra* § I.D.; *cf. New York v. Kennedy*, 155 F.4th 67, 76 (1st Cir. 2025) (final agency action was an announcement followed "just days later" by the Department's implementation). In subpoena enforcement litigation, litigated by members of the new Affirmative Litigation Branch, Defendants have repeatedly taken legal positions consistent with the Directives. *See* Ex. 27 (Hsaio Decl.) ¶ 3. And Defendants boast that their actions accomplished this stated mission. Doc. No. 1-3 at 1 ("For years, politicians have promised to end the barbaric, pseudoscientific practice—but President Trump is the only one who has actually delivered."). DOJ has clearly "rendered its last word on the matter." *Omnipoint Holdings, Inc. v. City of Cranston*, 586 F.3d 38, 46 (1st Cir. 2009); *see N.H. Lottery Comm'n*, 386 F. Supp. 3d at 145.

Further, the Directives have had a "direct effect on [a plaintiff's] day-to-day business," *Sig Sauer*, 826 F.3d at 600 n.1, because they both eliminate well-established "norm[s] or safe harbor[s]" in the statutes, *Texas v. EEOC*, 933 F.3d 433, 442 (5th Cir. 2019), and carry "serious criminal and civil penalties," *Abbott Lab'ys*, 387 U.S. at 153. For example, prior to the Directives, providers relied on the ability to counsel patients and to prescribe FDA-approved drugs for off-label uses without risking FDCA liability. Ex. 18 (Del Monte Decl.) ¶¶ 17–18. The Directives' apparent elimination of these statutory safe harbors "alters the legal regime," thereby satisfying *Bennett*'s direct effects requirement. *See Texas*, 933 F.3d at 442. The threat of "significant criminal and civil penalties" also independently satisfies this requirement. *See Hawkes*, 578 U.S. at 600; *see also Tennessee*, 104 F.4th at 600. FDCA violations carry a penalty of up to one year in prison and a $1,000 fine, per violation. 21 U.S.C. § 333(a)(1). FCA violations notoriously carry treble

damages. 31 U.S.C. § 3729(a)(1). And each violation of the FGM statute carries a penalty of up to ten years' imprisonment, plus fines. 18 U.S.C. § 116(a).

Thus, the Directives have directly affected providers by forcing them to choose between stopping or curtailing treatments (thereby possibly violating their ethical obligations) or proceeding at great legal and financial risk to themselves, their staff, and their existing patients. *See* Ex. 1 (Plaintiff State Provider #1 Decl.) ¶¶ 40–43, 50–54; Ex. 2 (Plaintiff State Provider #4 Decl.) ¶¶ 29–31; Ex. 3 (Plaintiff State Provider #5) ¶¶ 40, 42; *see* Ex. 18 (Del Monte Decl.) ¶¶ 11, 24, 28, 31, 33–34; Ex. 5 (Sheldon Decl.) ¶¶ 33, 40, 48; Ex. 21 (Plaintiff State Provider #2 Decl.) ¶¶ 25–27, 35–38; Ex. 14 (CA Provider #1 Decl.) ¶¶ 69–71; Ex. 20 (Hone Decl.) ¶¶ 8–10, 12; Ex. 16 (Justicz Decl.) ¶ 41–42; Ex. 25 (Lusk Decl.) ¶¶ 29, 36–38; Ex. 24 (Plaintiff State Provider #3 Decl.) ¶¶ 29–30, 38–39; Ex. 13 (Wenger Decl.) ¶¶ 32–38, 53, 64–65; Ex. 12 (Sewell Decl.) ¶¶ 45–46. *See Abbott Lab'ys*, 387 U.S. at 152 (action reviewable where it created immediate, costly dilemma for regulated parties); *see also Nat'l Automatic Laundry & Cleaning Council v. Shultz*, 443 F.2d 689, 696–97 (D.C. Cir. 1971) (same).

Defendants miss the mark in arguing that the Directives are not final because they provide no novel interpretations of federal law. Doc. No. 82 at 2, 16–17. That argument fails for the reasons already discussed. *Supra* § III.A.; *cf. Tennessee*, 104 F.4th at 600 (rejecting similar argument where agency did not "point to anything" establishing consistency with prior interpretations). Further, it is implausible, in light of Defendants' own triumphant statements that their actions have transformed access to legal healthcare, that the Directives "mean[] only that DOJ should continue to do what it has been doing all along." *See City & Cnty. of San Francisco v. Trump*, 897 F.3d 1225, 1239 (9th Cir. 2018). In reviewing the record, a court "is not required to exhibit a naiveté from which ordinary citizens are free." *New York v. Trump*, 133 F.4th 51, 69 (1st Cir. 2025).

Defendants also misplace their reliance on cases involving summonses and administrative complaints, for which judicial review ordinarily must await "an enforcement or other action down the road." Doc. No. 82 at 14. An agency's initiation of an investigation in a specific case is materially different than an agency's announcement of "some particular measure across the board," which can "of course be challenged under the APA." *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 890 n.2 (1990). "Once the agency publicly articulates an unequivocal position . . . and expects regulated entities to alter their primary conduct to conform to that position, the agency has voluntarily relinquished the benefit of postponed judicial review." *Ciba-Geigy Corp. v. EPA*, 801 F.2d 430, 436 (D.C. Cir. 1986). Here, the Directives and subsequent enforcement actions, *supra* § I.D., represent the agency's unequivocal position that, under the cited statutes, gender-affirming care must "end." *See QueerDoc*, 2025 WL 3013568, at *5 ("[T]he Government's own repeated declarations that it seeks to end the very practice [gender-affirming care] it claims to be merely investigating" is proof of improper purpose.). Plaintiff States and providers should not "have to operate under a dangling sword of indictment while DOJ purports to deliberate without end the purely legal question it ha[s] apparently already answered and concerning which it offers no reason to expect an answer favorable to the plaintiffs." *See N.H. Lottery Comm'n*, 986 F.3d at 53.

Finally, Defendants' cited cases do not stand for the broad proposition that agency guidance is unreviewable and are distinguishable in any event. *See* Doc. No. 82 at 17. In *American Tort Reform Association v. OSHA*, the agency itself agreed that the agency guidance regarding preemption had no force of law because "OSHA lacks legal authority to determine the preemptive effect of the OSH Act." 738 F.3d 387, 390 (D.C. Cir. 2013). Defendants in this case do not claim that the DOJ Directives lack legal force, and could not so claim, as the Directives have already spurred enforcement actions. In *AT&T Co. v. EEOC*, 270 F.3d 973 (D.C. Cir. 2001), the plaintiff

acknowledged that the challenged letter was "not final agency action" and that the agency's legal position did "not affect any other party." *Id.* at 975. Plaintiffs here do not make those concessions. And *Center for Auto Safety v. NHTSA*, 452 F.3d 798 (D.C. Cir. 2006) did not involve threats of enforcement by the agency. *Id.* at 807. Here, the EO and DOJ Directives openly vow to apply those interpretations in enforcement actions that DOJ has itself characterized as "high-priority." *See supra* § I.D. (citing Ex. 27 (Hsiao Decl.) ¶ 44).

B. The Directives Are Not "Committed to Agency Discretion."

The exception to reviewability for action "committed to agency discretion by law," 5 U.S.C. § 701(a)(2), is "very narrow." *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 410 (1971). The Supreme Court has "generally limited the exception to certain categories of administrative decisions that courts traditionally have regarded as 'committed to agency discretion,'" such as a decision not to institute enforcement proceedings in a particular case, or a decision to fire an employee in the interest of national security. *Dep't of Com. v. New York*, 588 U.S. 752, 772 (2019) (citation omitted).

Defendants, relying on *Heckler v. Chaney*, 470 U.S. 821 (1985) and *Arizona v. Biden*, 40 F.4th 375 (6th Cir. 2022), attempt to shoehorn the Directives into the category of administrative decisions that prioritize scarce enforcement resources. Doc. No. 82 at 18; *see Heckler*, 470 U.S. at 823; *Arizona*, 40 F.4th at 389. But the Directives clearly do not fit into that category: instead, they adopt "a broad or general enforcement policy" that subjects medical providers to risk of prosecution for providing medical care. *See Casa De Maryland v. DHS*, 924 F.3d 684, 699 (4th Cir. 2019) (affirmative enforcement guidance was reviewable) (collecting cases). Because the challenged actions here concern "substantive requirements of the law," they are "not the type of discretionary judgment concerning the allocation of enforcement resources that *Heckler* shields from judicial review." *Edison Elec. Inst. v. EPA*, 996 F.2d 326, 333 (D.C. Cir. 1993).

V. Plaintiffs Plausibly Allege That the Challenged Actions Usurp States' Authority to Regulate the Practice of Medicine in Violation of the Tenth Amendment.

Finally, Plaintiff States plausibly allege that (i) the EO and DOJ Directives, collectively, invade States' traditional power under the Tenth Amendment to regulate the practice of medicine (Count Four)[14]; and (ii) that, for the same reasons, the Directives run "contrary to constitutional right, power, privilege or immunity" in violation of the APA, 5 U.S.C. § 706(2)(B) (Count Three). *See* Doc. No. 1 ¶¶ 215–35.

It is bedrock law that the federal government acts pursuant to limited, enumerated powers, and that any powers not expressly granted to the federal government "are reserved to the States respectively, or to the people." U.S. Const. amend. X; *see New York v. United States*, 505 U.S. 144, 156 (1992). Equally well-settled is the principle that among the traditional police powers reserved to the States is the power to protect the health and safety of their residents, including through the regulation of medicine. *See Medina v. Planned Parenthood S. Atl.*, 606 U.S. 357, 364 (2025) ("States have traditionally exercised primary responsibility over matters of health and safety, including the regulation of the practice of medicine.") (quotation marks omitted); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996) (health and safety are "primarily, and historically, matters of local concern") (quotation marks and alterations omitted). The Executive may displace States' traditional authority in this area only if Congress provides "clear and manifest" authorization to do so. *Gregory v. Ashcroft*, 501 U.S. 452, 460–461 (1991) (quotation marks omitted).

[14] The Court can sustain Plaintiffs' Tenth Amendment claim (Count Four) independent of whether it finds the Challenged Actions to be final under the APA. *See Soundboard Ass'n v. Fed. Trade Comm'n*, 888 F.3d 1261, 1274 n.6 (D.C. Cir. 2018) (discussing differences between Congressionally established finality requirement under the APA and justiciability doctrines); *see, e.g.*, *Hamdi ex rel. Hamdi v. Napolitano*, 620 F.3d 615, 623 (6th Cir. 2010) (allowing constitutional claims to proceed in absence of viable APA claims).

Gonzales v. Oregon is instructive. 546 U.S. 243, 271 (2006). There, after Oregon voters legalized medical aid-in-dying, the U.S. Attorney General issued a rule interpreting the Controlled Substances Act to criminalize the use of scheduled drugs for that purpose. 546 U.S. at 254. The Attorney General argued that the Act's provision requiring physicians to dispense scheduled drugs only for a "legitimate medical purpose" empowered him to determine the legitimacy of specific uses. *Id.* at 257. The Supreme Court struck down the rule, finding the statute did not delegate this broad authority to the Attorney General. *Id.* at 270–72. The Court explained that the Attorney General's interpretation raised significant federalism problems by invading States' established role in regulating medicine—a role that the Act itself "presume[d] and rel[ied] upon." *Id.*

Here, the Plaintiffs have plausibly alleged circumstances analogous to those in *Gonzales*. For example, the President and Attorney General have sought to criminalize medical treatments that are specifically authorized under Plaintiffs' laws by falsely equating them with the entirely distinct, non-medical practice of female genital mutilation. *See* Doc. No. 1-6 at 3–4 (citing 18 U.S.C. § 116); Doc. No. 1-5 § 8(a) (referencing same). Not only does this interpretation contravene the statute's plain meaning, *see supra* § III.A., but Defendants also ignore that the statute expressly "presumes and relies upon" state law to draw lines between when a procedure is an appropriate surgery—medically necessary and "performed by a person licensed in the place of its performance as a medical practitioner," 18 U.S.C. §§ 116(b)(1), (e)—and when it is a crime. Thus, as in *Gonzales*, Defendants' sweeping assertion of authority threatens to "alter sensitive federal-state relationships," *Bond v. United States*, 572 U.S. 844, 863 (2014) (quotation marks omitted), by transforming the FGM statute from a prohibition on a specific nonmedical act into a general regime enabling the Attorney General to criminalize disfavored medical and surgical procedures.

Likewise, under the FCA, the Bondi Directive categorically declares gender dysphoria "an illegitimate reason" to bill a federal healthcare program for puberty blockers. *See* Doc. No. 1-6 at 4. But the FCA is a general fraud recovery statute that says nothing at all about second-guessing medical judgments, which the Medicaid statute leaves to the States. *Cf. Bowen v. Am. Hosp. Ass'n*, 476 U.S. 610 (1986) (plurality opinion) (vacating medical neglect reporting rule where Congress "failed to indicate, either in the statute or in the legislative history, that it envisioned federal superintendence of treatment decisions traditionally entrusted to state governance"). Similarly, the Bondi Directive, by directing U.S. Attorneys to prosecute medical providers for merely discussing with patients the risks and benefits of FDA-approved medications for off-label uses, *see* Doc. No. 82 at 16, usurps States' authority well in excess of Congress's clear direction in the FDCA. The FDCA vests the federal government with authority over only a discrete aspect of drug regulation—the labeling of drugs and devices in interstate commerce—and "expressly disclaims any intent to directly regulate the practice of medicine." *Buckman*, 531 U.S. at 350–51. In this way, Defendants' actions impermissibly intrude on States' sovereign authority to regulate medicine.

While Plaintiffs overtly alleged a Tenth Amendment claim under the federalism principles at issue in *Gonzales*, Doc. No. 1 ¶¶ 219–220, 225, Defendants do not address this claim at all, focusing instead on the fact that Plaintiffs have not alleged a commandeering claim. But the Supreme Court has made clear that Tenth Amendment claims are not limited to commandeering, *see, e.g.*, *Shelby Cnty., Ala. v. Holder*, 570 U.S. 529, 544 (2013) (statute offended equal sovereignty principle inherent in Tenth Amendment), and courts of appeals have entertained claims like those alleged here. *See, e.g., Judge Rotenberg Educ. Ctr. v. FDA*, 3 F.4th 390, 400 (D.C. Cir. 2021) (striking, on statutory and Tenth Amendment grounds, FDA rule banning medical device). Indeed, Plaintiffs' Tenth Amendment interests are especially pronounced in this case,

where Defendants' actions encroach broadly on Plaintiffs' sovereign authority by interfering with state laws that protect informed consent, prohibit discrimination against transgender patients, require insurance coverage for gender-affirming care, and—because the EO defines individuals under 19 as "children"—establish the age of majority. Accordingly, at this stage of the litigation, Plaintiffs have alleged a plausible claim that the DOJ Directives, as well as the EO, alter the federal-state framework by encroaching upon a traditional state power without clear Congressional authorization. *See United States v. Bass*, 404 U.S. 336, 349 (1971); *see, e.g.*, *Bond*, 572 U.S. at 860–64 (invalidating interpretation of statute that invaded States' authority to punish "purely local crimes"); *see also Solid Waste Agency of N. Cook Cnty. v. U.S. Army Corps of Eng'rs*, 531 U.S. 159, 174 (2001) (invalidating interpretation of statute that threatened "significant impingement of the States' traditional and primary power over land and water use").

CONCLUSION

The Court should deny Defendants' Motion to Dismiss. In the alternative, should the court grant dismissal of any of Plaintiffs' claims, Plaintiffs respectfully request that this court grant leave to amend. *See* Fed. R. Civ. P. 15(a); *Foman v. Davis*, 371 U.S. 178, 182 (1962); *Palmer v. Champion Mortg.*, 465 F.3d 24, 30 (1st Cir. 2006).

Dated: December 22, 2025

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CERTIFICATE OF SERVICE

I hereby certify that I have filed this Motion with the Court's ECF system and will be sent electronically to the registered participants as identified in the Notice of Electronic Filing (NEF).

December 22, 2025

/s/ Andres Ivan Navedo
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