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.	Civil Action No. 1:25-CV-12162-AK

DEFENDANTS' MEMORANDUM IN SUPPORT OF MOTION TO DISMISS COMPLAINT

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INTRODUCTION

Upon taking office, President Trump issued Executive Order 14187, entitled *Protecting Children From Chemical and Surgical Mutilation*. 90 Fed. Reg. 8771 (Jan. 28, 2025) (EO). Among other things, the child-protection order directs the Department of Justice (DOJ) to "prioritize investigations and take appropriate action" against individuals and entities that violate federal law while providing gender-related care to children. *Id.* at 8772-73. In response to the EO, DOJ issued internal Guidance on DOJ's enforcement priorities. Like that EO, the Guidance directs DOJ attorneys to prioritize investigations of suspected illegality occurring in relation to the provision of gender-related care to children. Neither the EO nor the Guidance, however, directs the investigation or prosecution of any particular entity. Nor does the EO or the Guidance assert that providing gender-related care is inherently illegal under federal law, or that state laws protecting such care are invalid.

Seventeen States (including the District of Columbia) filed suit to collaterally attack all of DOJ's current and future enforcement efforts in this space. They seek an order vacating the Guidance and EO, and enjoining "any action taken to enforce or implement" those directives. Doc No. 1, ¶ 235. Plaintiffs also seek a declaratory judgment that the provision of gender-related care to children does not, "standing alone," violate federal law.

Plaintiffs' claims lack merit, and the complaint should be dismissed in its entirety for at least three reasons. *First*, Plaintiffs lack standing to challenge the Executive's enforcement priorities. And even if courts could consider such challenges, Plaintiffs' asserted injuries are insufficient under traditional standing principles. Plaintiffs also lack standing to seek a declaratory judgment because they fail to allege any imminent or concrete dispute over the narrow question that they identify.

Second, even if Article III contemplated suits challenging the Executive's enforcement discretion, Plaintiffs' Administrative Procedure Act (APA) claims targeting the Guidance would still fail for independent threshold reasons. To start, an internal guidance document that merely articulates an agency's enforcement priorities does not qualify as "agency action" under the APA, much less reviewable final agency action. And Plaintiffs cannot fix this problem by mischaracterizing the Guidance as containing "novel interpretations" of federal law—on its face, it does not. Finality aside, Plaintiffs' APA claims are unreviewable for the separate reason that an agency's determination of its enforcement priorities is committed to its discretion by law.

Last, Plaintiffs fail to plausibly allege a Tenth Amendment violation. The Constitution does not prohibit the federal government from enforcing laws validly enacted by Congress simply because its enforcement efforts implicate conduct traditionally regulated by the States. Plaintiffs' contrary theory turns the Supremacy Clause on its head.

BACKGROUND

A. The Regulatory Landscape.

In function and effect, this case challenges the federal government's ability to enforce three statutes with a nexus to healthcare: (1) the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq*. (FDCA); (2) the False Claims Act (FCA), 31 U.S.C. § 3729 *et seq.*; and (3) the Female Genital Mutilation Act, 18 U.S.C. § 116 (FGM Act).

The Federal Food, Drug, and Cosmetic Act. The FDCA requires that drugs be approved by the FDA for specific uses before being distributed in interstate commerce. *See* 21 U.S.C. § 355(a). Once FDA-approved, prescription drugs can be prescribed by doctors for both FDA-approved and -unapproved uses. *See id.* § 396. But off-label *marketing* is different. The FDCA prohibits "misbranding," or "[t]he introduction or delivery for introduction into interstate

commerce of any . . . drug . . . that is . . . misbranded." *Id.* § 331(a), (b). And the government has long construed this prohibition to include the marketing or promotion of a drug for an unapproved use. *See United States v. Caronia*, 703 F.3d 149, 154-55 (2d Cir. 2012). Plaintiffs concede that "marketing . . . off-label uses of medication . . . is prohibited." Doc No. 1, ¶ 190.

The False Claims Act. The FCA provides that any person who knowingly submits, or causes to submit, false claims to the government is liable for damages. *See* 31 U.S.C. § 3729. It is thus an FCA violation for a healthcare provider to submit claims for payment to Medicare or Medicaid that he knows or should know are false or fraudulent. This includes "claims for medically unnecessary treatment," *Omni Healthcare, Inc. v. MD Spine Sols. LLC*, 761 F. Supp. 3d 356, 364 (D. Mass. 2025), and claims made with "improper billing codes," Doc No. 1, ¶ 190. By federal regulation, the Assistant Attorney General of the Civil Division is responsible for conducting FCA and FDCA litigation on behalf of the United States. *See* 28 C.F.R. § 0.45(d), (j).

The Female Genital Mutilation Act. The FGM Act makes it a felony to perform, attempt to perform, or conspire to perform female genital mutilation on any person under the age of 18. *See* 18 U.S.C. § 116(a)(1). "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." *Id.* § 116(e). The Act does not criminalize a surgical operation that is "necessary to the health of the person on whom it is performed, and is performed by a person licensed in the place of its performance as a medical practitioner." *Id.* § 116(b)(1). A conviction under the Act carries a maximum sentence of 10 years per count. *Id.* § 116(a).

B. The Challenged EO and Guidance.

Executive Order 14187. In January 2025, President Trump issued the Protecting Children EO. 90 Fed. Reg. at 8771-73. This Order establishes that "it is the policy of the United States that

it will not fund, sponsor, promote, assist, or support the so-called 'transition' of a child from one sex to another, and it will rigorously enforce all laws that prohibit or limit these destructive and life-altering procedures." EO 14187 § 1.

The EO, among other things, directs DOJ to take certain steps. Relevant here, Section 8 directs the Attorney General to "review . . . enforcement of" the FGM Act, and to "prioritize enforcement of protections against female genital mutilation." *Id.* § 8. Section 8 further provides that the Attorney General shall "prioritize investigations and take appropriate action to end deception of consumers, fraud, and violations of the [FDCA] by any entity that may be misleading the public about long-term side effects of chemical and surgical mutilation." *Id.* And all actions implementing the EO must be "consistent with applicable law." *Id.* § 11(b).

DOJ Guidance. In response to the EO, Attorney General Bondi issued a guidance memo to DOJ employees regarding the enforcement of the FDCA, the FCA, and the FGM Act. *See* Bondi Memo, Doc No. 1-6. The Bondi Memo directs DOJ's Civil Division to:

- "undertake appropriate investigations of any violations of the [FDCA] by manufacturers and distributors engaged in misbranding by making false claims about the on- or off-label use of" certain drugs; and
- "pursue investigations under the [FCA] of false claims submitted to federal health care programs for any non-covered services related to" gender-related care. *Id.* at 4.

The Bondi Memo also directs U.S. Attorneys to:

- "investigate all suspected cases of FGM—under the banner of so-called 'gender-affirming care' or otherwise—and to prosecute all FGM offenses to the fullest extent possible." *Id.* at 3-4.

The Assistant Attorney General of the Civil Division later issued similar guidance to his staff in a memorandum with the subject line, "Civil Division Enforcement Priorities." *See* Shumate Memo, Doc. No. 1-7 at 1. The Shumate Memo describes the policy objectives and directives in the EO and Bondi Memo, and "directs Civil Division attorneys to prioritize investigations and enforcement actions advancing those priorities." *Id.*

More specifically, the Shumate Memo directs the Civil Division to:

- "prioritize investigations of" "possible violations of the [FDCA] and other laws by (1) pharmaceutical companies that manufacture drugs used in connection with so-called gender transition and (2) dealers such as online pharmacies suspected of illegally selling such drugs," *id.* at 2-3; and
- "aggressively pursue claims under the [FCA] against healthcare providers that bill the federal government for impermissible services," including providers who "knowingly submit[] claims to Medicaid with false diagnosis codes," *id.* at 3.

C. This Collateral Attack.

Plaintiff States filed this suit, alleging that the Bondi and Shumate Memos (collectively, "Guidance") violate the APA and that Section 8 of the EO violates the Tenth Amendment. Plaintiffs also request a declaratory judgment that the provision of "medically appropriate" gender-related care does not "on its own" violate any federal law. Doc No. 1, ¶ 138.

LEGAL STANDARD

A district court must dismiss claims under Rule 12(b)(1) when it lacks subject-matter jurisdiction, including where the plaintiffs have failed to establish their standing to sue. *See Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992). Plaintiffs bear the burden of establishing the court's jurisdiction. *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994).

To survive a motion to dismiss under Rule 12(b)(6), a complaint must contain "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell. Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* Nor must a court accept "a legal conclusion couched as a factual allegation." *Twombly*, 550 U.S. at 555. A court must disregard "pleadings that, because they are no more than conclusions, are not entitled to the assumption of truth" and determine whether the "well-pleaded factual allegations . . . plausibly give rise to an entitlement to relief." *Iqbal*, 556 U.S. at 679.

ARGUMENT

I. Plaintiffs Lack Article III Standing.

This Court lacks subject matter jurisdiction over all claims because Plaintiffs lack Article III standing. To show standing, a plaintiff must plausibly allege three elements: (1) "injury in fact," (2) "that is fairly traceable to the challenged conduct of the defendant," and (3) "likely to be redressed by a favorable decision." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016). Where "the plaintiff is not himself the object of the government action or inaction he challenges, standing . . . is ordinarily substantially more difficult to establish." *Lujan*, 504 U.S. at 562. The challenged Guidance neither regulates nor forbids any action on the part of any Plaintiffs, so this higher standard applies. *See Summer v. Earth Island Inst.*, 555 U.S. 488, 493 (2009).

Plaintiffs' alleged injuries do not confer standing. As the Supreme Court has squarely held, federal courts lack jurisdiction over suits challenging the Executive Branch's enforcement priorities. *See United States v. Texas*, 599 U.S. 670, 677-79 (2023). And even if Article III contemplated litigation over the Executive's policy priorities, Plaintiffs' asserted injuries are insufficient under traditional standing principles. Plaintiffs also lack standing to pursue declaratory relief because they have failed to allege a concrete or imminent dispute.

A. States lack standing to challenge an agency's enforcement priorities.

Suits that try to control the Executive Branch's exercise of enforcement discretion "run up against the Executive's Article II authority to enforce federal law." *Id.* at 678. Parties thus lack standing to bring such suits, and federal courts are not empowered to assert jurisdiction over such claims. Plaintiffs' suit, which is an overt attempt to control the federal government's discretionary decisions about how to prioritize the enforcement of federal law, is no exception.

The Supreme Court's decision in *Texas* squarely forecloses Plaintiffs' claims. In *Texas*, the Supreme Court rejected States' standing "to challenge[] . . . the Executive Branch's exercise of enforcement discretion over whether to arrest or prosecute." 599 U.S. at 677. The Court reaffirmed the longstanding principle that to confer Article III standing, an asserted injury must be "legally and judicially cognizable"—*i.e.*, "the 'dispute [must be] traditionally thought to be capable of resolution through the judicial process." *Id.* at 676 (quoting *Raines v. Byrd*, 521 U.S. 811, 819 (1997)). Because Article II assigns the President the "authority to decide 'how to prioritize and how aggressively to pursue legal actions,'" suits challenging the Executive's exercise of that discretion are generally not cognizable in federal court. *Id.* at 678 (quoting *TransUnion LLC v. Ramirez*, 594 U.S. 413, 429 (2021)). Moreover, "the Executive Branch must prioritize its enforcement efforts," and "courts generally lack meaningful standards for assessing the propriety of enforcement choices in this area." *Texas*, 599 U.S. at 679-80. The Court thus rejected "[t]he States' novel standing argument," which "would entail expansive judicial direction of" the Executive's Article II prerogatives and violate the separation of powers. *Id.* at 681.

This conclusion follows longstanding Supreme Court precedent that a plaintiff lacks standing to challenge the government's policies concerning enforcement actions against third parties. In *Linda R.S. v. Richard D.*, 410 U.S. 614 (1973), the Supreme Court established that "a

citizen lacks standing to contest the policies of the prosecuting authority when he himself is neither prosecuted nor threatened with prosecution." *Id.* at 619. As the Court there explained, "in American jurisprudence at least, a private citizen lacks a judicially cognizable interest in the prosecution or nonprosecution of another." *Id.*

Texas straightforwardly controls this case. Because a plaintiff lacks standing to challenge "the Executive Branch's traditional discretion over whether to take enforcement actions against violators of federal law," *Texas*, 599 U.S. at 684, it follows *a fortiori* that a plaintiff lacks standing to challenge the Executive's discretion over how to prioritize *investigations* of potential violations of federal law. The federal government enforces federal law. How it prioritizes that enforcement is a matter of federal concern. As the Fourth Circuit recently put it, where "the interest . . . is a traditionally federal one, the States have no judicially cognizable injury under *Texas*." *Maryland v. USDA*, 151 F.4th 197, 210 (4th Cir. 2025).

That Article III does not permit States to dictate the federal government's enforcement priorities through litigation is unsurprising. Indeed, during the last administration, nearly every plaintiff involved in this case elsewhere asserted its "strong interest in supporting the executive authority to set law enforcement priorities, in order to deploy limited government resources to promotes the fairness, effectiveness, and integrity of criminal and civil enforcement systems."[1] And those plaintiffs rightly recognized that the Executive's prosecutorial discretion "has deep roots in the constitutional separation of powers, as well as the President's constitutional authority to (among other things) 'take Care that the Laws be faithfully executed.'"[2] Those principles continue

[1] *See* Br. for States of N.Y., Cal., Conn., Del., Ill., Me., Md., Mass., Minn., Nev., N.J., N.M., Or., R.I., Vt., Wash., & D.C., as Amici Curiae in Supp. of Pet., at 1, No. 22-58, *United States v. Texas*, ECF No. 21 (Sep. 19, 2022).

[2] *Id.* at 12.

to apply regardless of who occupies the White House. States lack standing to challenge the President's prerogative "to prioritize investigations and enforcement actions advancing [administration] priorities." Doc No. 1, ¶ 126 (quoting Shumate Memo, Doc No. 1-7 at 2). Policy disagreements with the federal government's enforcement priorities must be resolved by Congress or through the electoral process, not litigation by States. *See Texas*, 599 U.S. 670.

B. Plaintiffs' assert no cognizable injury fairly traceable to the Guidance.

Even if suits challenging agency enforcement priorities were cognizable as a general matter, Plaintiffs' hypothesized injuries do not confer standing here.

Start with Plaintiffs' alleged injuries as providers of gender-related care. They claim to fear imminent injury as "potential targets of the threatened federal enforcement." Doc No. 1, ¶ 180. To establish standing for purposes of pre-enforcement review, a plaintiff must show "a reasonably clear and specific threat of prosecution" or enforcement. *N.H. Hemp Council, Inc. v. Marshall*, 203 F.3d 1, 4 (1st Cir. 2000); *see MedImmune, Inc. v. Genetech, Inc.*, 549 U.S. 118, 129 (2007) (standing requires "genuine threat of enforcement"). "A plaintiff's subjective and irrational fear of prosecution is not enough to confer standing under Article III." *Mangual v. Rotger-Sabat*, 317 F.3d 45, 57 (1st Cir. 2003).

Plaintiffs have failed to plausibly allege a credible threat of enforcement against them. They claim they are "potential targets" because (1) they "provide medically necessary care to transgender adolescents," Doc No. 1, ¶ 179, and (2) "Defendants have asserted that the FGM statute, the FDCA, and the FCA make it unlawful for healthcare providers to provide medically necessary healthcare to treat gender dysphoria in adolescents," *id.* ¶ 239. But the latter statement is simply false. Contrary to Plaintiffs' contention, DOJ has not suggested, through the challenged Guidance or otherwise, that the provision of any medically necessary healthcare is, "standing

alone," a violation of any federal law. *Id.*, Prayer for Relief ¶ B. Nor has DOJ suggested that it will prosecute entities that provide gender-related care while following federal law. Just the opposite. The challenged Guidance details exactly what sorts of violations of federal law might eventually be subject to prosecution—and Plaintiffs do not claim or propose to engage in any of it.

Starting with the FDCA, DOJ directed investigations of "manufacturers and distributors engaged in misbranding by making false claims" about pharmaceuticals. Bondi Memo, Doc No. 1-6 at 4. But Plaintiffs do not even claim to manufacture or distribute pharmaceuticals, let alone to make false claims about them. As for the FCA, DOJ directed investigations "of false claims submitted to federal health care programs for any non-covered services related to" gender-related care, including inaccurate billing. *Id.* But Plaintiffs do not propose to engage in inaccurate billing or otherwise submit false claims while providing gender-related care. Nor can Plaintiffs show a realistic likelihood of prosecution under the FGM Act when they themselves expressly assert that "it is incredibly unlikely that any provider in the Plaintiff States has engaged in any conduct that conceivably could be captured by the FGM statute." Doc No. 1, ¶ 147.

Plaintiffs' "sovereign injury" theory fares worse. To be sure, a State possesses an interest in its "exercise of sovereign power over individuals and entities within the relevant jurisdiction," which "involves the power to create and enforce a legal code." *Alfred L. Snapp & Son., Inc. v. Puerto Rico*, 458 U.S. 592, 601 (1982). Thus, a State may have "standing based on a[n] [alleged] conflict between federal and state law." *Texas v. United States*, 787 F.3d 733, 749 (5th Cir. 2015); *see Diamond v. Charles*, 476 U.S. 54, 62 (1986) ("a State has standing to defend the constitutionality of its statute"). Though Plaintiffs vaguely claim that DOJ's narrow enforcement efforts somehow "functionally supersede[]" their authority to regulate medicine, Doc No. 1, ¶ 188,

they do not allege that any of the federal statutes at issue actually pre-empt or directly conflict with any state law or regulatory program. Plaintiffs have thus alleged no sovereign injury. *See United States v. Johnson*, 114 F.3d 476, 481 (4th Cir. 1997) ("Federal laws criminalizing conduct within traditional areas of state law . . . are of course commonplace under the dual-sovereign concept and involve no infringement per se of states' sovereignty[.]").

Plaintiffs' remaining theory of standing also fails. Their conclusory allegation that Defendants' enforcement efforts will drive up treatment costs at state-run hospitals, *see* Doc No. 1, ¶¶ 180-83, is based on a chain of speculation about third parties not before the court. And Article III standing's causation requirement "rules out attenuated links—that is, where the government action is so far removed from its distant (even if predictable) ripple effects [a] plaintiff[] cannot establish Article III standing." *FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 383 (2024). A theory of standing based on a federal policy's potential downstream effect on state-run hospitals is a quintessential example of this deficiency. Just as doctors cannot "challenge the government's loosening of general public safety requirements simply because more individuals might then show up at emergency rooms or in doctors' offices with follow-on injuries," *id.* at 391, States cannot sue the federal government over its enforcement efforts based on speculation that state entities may in the future choose to divert resources in response. Such an "unprecedented and limitless approach" is just as untenable as Plaintiffs' sovereign injury theory, as both would permit States to "challenge virtually every government action that they do not like." *Id.* at 391-92.

C. **Plaintiffs lack standing to seek a declaration resolving a hypothetical dispute.**

In Count V, Plaintiffs ask for a judgment declaring that the provision of "medically necessary" gender-related care to minors "and the accurate billing for such treatment" does not, "standing alone," violate the FCA, the FDCA, or the FGM Act. Doc No. 1, Prayer for Relief ¶ B.

But this relief would amount to no more than an advisory opinion. DOJ has never suggested that the provision of gender-related care to minors by itself violates federal law, and this Court lacks subject matter jurisdiction to resolve an artificial and abstract legal question that is irrelevant to Defendants' actual enforcement efforts in this space.

Under the Declaratory Judgment Act, a federal court "may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought," but only "[i]n a case of actual controversy." 28 U.S.C. § 2201(a). The "actual controversy" requirement is the same as the "case or controversy" requirement in Article III. *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 239-40 (1937). Thus, to receive declaratory relief, a plaintiff must "show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune*, 549 U.S. at 127. Parties may not request "an opinion advising what the law would be upon a hypothetical state of facts." *Id.* (quoting *Haworth*, 300 U.S. at 241).

Plaintiffs' request for declaratory relief is therefore improper. The question that Plaintiffs want addressed—whether the provision of gender-related care to minors is by itself a violation of federal law—is not the subject of any clear or concrete dispute. Again, DOJ has never suggested that merely providing medically necessary care violates federal law in the absence of independent misconduct. The Guidance is plain on its face. The only conduct plausibly implicated is misbranding (under the FDCA), "false claims" (under the FCA), and conduct meeting the statutory definition of FGM. The Guidance has thus not raised the question that Plaintiffs ask this Court to resolve, and this Court therefore lacks jurisdiction to decide it.

Relatedly, the Declaratory Judgment Act only permits courts to assess "legal liability on a set of already defined facts," meaning the anticipated dispute must "be adequately framed by [its]

factual dimensions." *In re Fin. Oversight & Mgmt. Bd. for P.R.*, 916 F.3d 98, 112 (1st Cir. 2019). So "[d]eclaratory claims based on abstractions are not justiciable under Article III." *Id.*; *see Pub. Serv. Comm'n of Utah* v. *Wycoff Co.*, 344 U.S. 237, 244-45 (1952) ("The disagreement must not be nebulous or contingent but must have taken on a fixed and final shape so that a court can see what legal issues it is deciding."). And that is exactly the sort of claim that Plaintiffs bring here. By requesting a declaration that the provision of gender-related care to minors does not "standing alone" violate federal law, Plaintiffs have intentionally sterilized their hypothetical dispute of all factual context. This Court lacks jurisdiction over an entirely abstract and artificial question divorced from DOJ's actual stated enforcement efforts.

II. Plaintiffs' APA Challenges to the Guidance Fail for Independent Threshold Reasons.

Even if Plaintiffs had standing to challenge the federal government's enforcement priorities, their APA claims challenging the Guidance would fail for independent threshold reasons. To start, the challenged Guidance does not constitute final agency action within the meaning of the APA. And, even apart from that, an agency's decisions about how to prioritize enforcement actions and investigatory efforts are committed to agency discretion by law.

A. Plaintiffs fail to allege final agency action.

The APA permits review only of "final agency action." 5 U.S.C. § 704. Thus, two "threshold questions" for every APA claim are "[w]hether there has been 'agency action'" and then "'final agency action' within the meaning" of section 704. *Fund for Animals, Inc. v. U.S. Bureau of Land Mgmt.*, 460 F.3d 13, 18 (D.C. Cir. 2006). "[I]f these requirements are not met," the APA claim "is not reviewable." *Id.* Plaintiffs flunk both requirements.

To state any APA claim, Plaintiffs first "must identify some 'agency action'" within the meaning of 5 U.S.C. § 551(13). *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 882 (1990). Plaintiffs assert that the Bondi and Shumate Memos by themselves qualify as agency actions. *See* Doc No.

1, ¶ 199. But they fail to specify, or even suggest, which category of "agency action" in 5 U.S.C. § 551(13) applies to a document that merely articulates an agency's policy priorities. Precedent and common sense indicate none fits. *See Arizona v. Biden*, 40 F.4th 375, 389 (6th Cir. 2022) (internal memorandum outlining "[immigration] enforcement priorities" is unreviewable).

Moreover, and more fundamentally, the Guidance does not rise to the level of *final* agency action. To be final, an action must both: (1) "mark the consummation of the agency's decisionmaking process [and] must not be of a merely tentative or interlocutory nature"; *and* (2) "be one 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). Neither prong is satisfied here.

First, the Guidance is preliminary and does not mark the consummation of DOJ's decisionmaking process. If "an agency's issuance of a summons," *Harper v. Werfel*, 118 F.4th 100, 114 (1st Cir. 2024), or even issuance of an administrative complaint, *FTC v. Standard Oil Co. of Cal.*, 449 U.S. 232, 241-42 (1980), is not a "final action," then an agency's initial guidance to prioritize certain investigations—which is "even more preliminary"—"cannot [itself] be 'final agency action[].'" *Cohen v. Rice*, 992 F.2d 376, 382 (1st Cir. 1993).

It is well-established that "[t]he decision to investigate is normally seen as a *preliminary* step" that is "non-final by definition." *Harper*, 118 F.4th at 116 (quoting *Univ. of Med. & Dentistry of N.J. v. Corrigan*, 347 F.3d 57, 69 (3d Cir. 2003)) (collecting cases). Indeed, "[a]n investigation" is a form of agency action that "is quintessentially non-final." *Ass'n of Am. Med. Colls. v. United States*, 217 F.3d 770, 781 (9th Cir. 2000). This makes sense. The choice to investigate merely "lead[s] toward the possibility of a 'final action' in the form of an enforcement or other action" down the road—a "path [that] is highly uncertain." *Corrigan*, 347 F.3d at 69; *see Nat'l Treasury Emps. Union v. Vought*, 149 F.4th 762, 778 (D.C. Cir. 2025) ("If an action affects the challenger's

rights only 'on the contingency of future administrative action,' it is not final."). Thus, without more, an investigation "do[es] not constitute final agency action[.]" *Reliable Automatic Sprinkler Co. v. CPSC*, 324 F.3d 726, 731 (D.C. Cir. 2003).

This hornbook principle of administrative law dooms Plaintiffs' APA claims. The Guidance precedes even an investigation, and is thus not final *a fortiori*. As the Complaint acknowledges, the Guidance "instruct[s] DOJ staff to use investigations and enforcement actions to advance" certain agency priorities. Doc No. 1, ¶ 114; *see also id.* ¶¶ 117, 119, 121, 126. Under binding First Circuit and Supreme Court precedent, a "preliminary investigative step"—including, of course, a decision to investigate at all—does not "mark the consummation of the agency's decision-making process" and is thus not final. *Harper*, 118 F.4th at 116.

Second, the Guidance has no "direct and immediate consequences," nor determines any rights or obligations. *Trafalgar Cap. Assocs., Inc. v. Cuomo*, 159 F.3d 21, 35 (1st Cir. 1998) (quoting *Standard Oil*, 449 U.S. at 241). Doctors may continue to provide care consistent with federal law, just as before. And States may continue to regulate the provision of care, just as before. It is only hypothetical later actions by government officials—culminating in an adverse judgment or conviction, for example—that determine any entity's legal rights. *See Georator Corp. v. EEOC*, 592 F.2d 765, 768 (4th Cir. 1979) (agency's reasonable cause determination not final because "[i]t is merely preparatory to further proceedings. If and when the EEOC or the charging party files suit in district court, . . . the plaintiff will have the opportunity to refute the charges."); *Cf. Air Brake Sys., Inc. v. Mineta*, 357 F.3d 632, 641 (6th Cir. 2004) ("An agency's determination of 'rights or obligations' generally stems from an agency action that is directly binding on the party seeking review, such as an administrative adjudication . . . or legislative rulemaking, both of which did not happen here.").

Plaintiffs try to conjure final agency action where none exists by vaguely asserting that the Guidance contains "novel and atextual legal interpretation[s]" of "several" federal laws. Doc No. 1, ¶ 114. This is wrong and, in any event, insufficient to save Plaintiffs' APA claims. As a threshold matter, the Guidance does not, nor does it purport to, offer new interpretations of any of the three statutes at issue here.

Plaintiffs' bald assertion that the government has newly interpreted the FGM Act finds no support in the Guidance itself, which merely directs the agency to prosecute suspected FGM violations "to the fullest extent possible." Bondi Memo, Doc No. 1-6 at 3-4. As for FCA, the Guidance contains the completely unremarkable observation that "[f]alsely billing the government"—including during the provision of gender-related care—"is a violation of the [FCA] and is subject to treble damages and severe penalties." *Id.* at 4; *see, e.g.*, *Universal Health Servs., Inc. v. Escobar*, 579 U.S. 176, 189 (2016) (misrepresentations made in Medicaid reimbursement claims are actionable under FCA); Doc No. 1, ¶ 133 (acknowledging "the use of improper billing codes" is "prohibited"). Similarly, with respect to the FDCA, the Guidance merely notes that "the promotion of off-label uses of hormones"—including during the provision of gender-related care—"run[s] afoul of the FDA's prohibitions of misbranding and mislabeling." Bondi Memo, Doc No. 1-6 at 5. This construction of the FDCA is neither novel nor contested. *See, e.g.*, *United States v. Facteau*, 89 F.4th 1, 15 (1st Cir. 2023) (observing that "off-label marketing would amount to the commercial distribution of an 'adulterated' and 'misbranded' device" under the FDCA); *accord Caronia*, 703 F.3d at 154. And an internal agency document that merely restates settled interpretations of federal law cannot plausibly be viewed as creating any direct effects or altering any rights or obligations. *See Nat'l Pork Producers Council v. EPA*, 635 F.3d 738, 756 (5th Cir. 2011) ("[T]he guidance letters merely restate section 1342's prohibition against discharging

pollutants without an NPDES permit. Agency actions that have no effect on a party's rights or obligations are not reviewable final action.").

Even if the Guidance could be viewed as containing new interpretations of federal law, that would not transform it into final agency action. A guidance document that states an agency's view of what the law requires has no legal effect on regulated parties and is not reviewable. *See Am. Tort Reform Ass'n v. OSHA*, 738 F.3d 387, 394-95 (D.C. Cir. 2013) ("a 'guideline' that 'advises the public of the agency's construction of the statute it administers" is not final because such statements are not "finally determinative of the issues or rights to which they are addressed" (cleaned up)); *AT&T v. EEOC*, 270 F.3d 973, 976 (D.C. Cir. 2001) (manual that "state[d] the Commission's view that the policy followed by AT&T violates the Act" is not final because the Commission "is not bound to sue AT&T," and it "has not inflicted any injury upon AT&T merely by expressing its view of the law"); *Ctr. for Auto Safety v. Nat. Highway Traffic Safety Admin.*, 452 F.3d 798, 808 (D.C. Cir. 2006) (courts "lack authority to review claims under the APA 'where an agency merely expresses its view of what the law requires of a party'") (quoting *Indep. Equip. Dealers Ass'n v. EPA*, 372 F.3d 420, 427 (D.C. Cir. 2004) (Roberts, J.)).

A contrary conclusion "ignores that" the FCA, FDCA, and FGM Act, "not the [Guidance], is the source of any binding legal obligations to which [Plaintiffs] [are] subject." *Whitewater Draw Nat. Res. Conservation Dist. v. Mayorkas*, 5 F.4th 997, 1009 (9th Cir. 2021). The Guidance "does not augment or diminish" Plaintiffs' obligations under federal law, and "Plaintiffs point to no provision in the [Guidance] for which [their] noncompliance might result in a consequence beyond those contained in" the statutes cited in the Guidance. *Id.* Such guidance is not final agency action reviewable under the APA.

B. Agency enforcement priorities are committed to agency discretion by law.

Under the APA, a plaintiff may not obtain judicial review of agency action "committed to agency discretion by law." 5 U.S.C. § 701(a)(2). Enforcement decisions are "generally committed to an agency's absolute discretion." *Heckler v. Chaney*, 470 U.S. 821, 831 (1985); *see also Trump v. United States*, 603 U.S. 593, 620 (2024) ("the Executive Branch has exclusive authority and absolute discretion to decide which crimes to investigate and prosecute"). Such decisions "often involve . . . a complicated balancing of a number of factors which are peculiarly within [the agency's] expertise." *Chaney*, 470 U.S. at 831. For example, an agency must assess not only the existence and severity of a violation but also "whether agency resources are best spent on this violation or another, whether the agency is likely to succeed if it acts, whether the particular enforcement action requested best fits the agency's overall policies, and, indeed, whether the agency has enough resources to undertake the action." *Id.* And particularly where limited resources mean that an "agency generally cannot act against each technical violation of the statute it is charged with enforcing," it is DOJ—not the courts or the States—that are best positioned "to deal with the many variables involved in the proper ordering of its priorities." *Id.* at 831-32.

As noted already, the challenged Guidance amounts to a decision by DOJ to prioritize investigations of certain categories of offenses that may occur in relation to the provision of gender-related care. And while "Congress may limit an agency's exercise of enforcement power if it wishes, either by setting substantive priorities, or by otherwise circumscribing an agency's power to discriminate among issues or cases it will pursue," Congress has not done so here. *Id.* at 833. Thus, the Guidance is unreviewable on the additional ground that "enforcement priorities are 'committed to agency discretion by law.'" *Arizona*, 40 F.4th at 389 (quoting 5 U.S.C. § 701(a)(2)) (internal memorandum outlining "[immigration] enforcement priorities" is unreviewable).

III. Plaintiffs Fail to State a Tenth Amendment Claim.

Plaintiffs fail to state a claim under the Tenth Amendment. Plaintiffs argue that the EO and Guidance violate the Tenth Amendment by "intrud[ing] on [their] sovereign authority to enforce their own laws and/or effectuate their policy choices regarding the provision of [gender-related] care." Doc No. 1, ¶ 234. But the federal government does not violate the Tenth Amendment when it enforces laws validly enacted by Congress: "If a power is delegated to Congress in the Constitution, the Tenth Amendment expressly disclaims any reservation of that power to the States." *New York v. United States*, 505 U.S. 144, 156 (1992).

Plaintiffs do not allege that Congress exceeded its enumerated powers in passing the FDCA, the FCA, or the FGM statute. *See* Doc No. 1, ¶ 220 ("Congress may legislate to regulate interstate activities, which may include the promulgation of criminal and regulatory laws."). Nor do Plaintiffs contend that those statutes or the challenged actions "command states to administer federal regulatory programs, conscript state officers directly, or otherwise treat state governments as federal handmaidens." *Herrara-Inirio v. INS*, 208 F.3d 299, 307 (1st Cir. 2000) (citing *New York*, 505 U.S. at 157). Rather, Plaintiffs' claim is that the federal government's decision to enforce these valid statutes against certain conduct "effectively usurp[s] a core state police power." Doc No. 1, ¶ 222. This counterintuitive and boundless theory of Tenth Amendment liability is foreclosed by governing precedent and incompatible with the Supremacy Clause.

Consider the First Circuit's decision in *Massachusetts v. U.S. Dept. of Health & Human Servs.*, 682 F.3d 1, 12 (1st Cir. 2012), in which Massachusetts challenged the Defense of Marriage Act (DOMA) on Tenth Amendment grounds. In rejecting the Tenth Amendment claim, the First Circuit acknowledged that DOMA "burden[s] the choice of states like Massachusetts to regulate the rules and incidents of marriage"—an area that "is a leading instance of the states' exercise of their broad police-power authority." *Id*. But the court explained that even where federal action

"intrudes extensively into a realm that has from the start of the nation been primarily confided to state regulation," the Tenth Amendment is only implicated "where Congress sought to commandeer state governments or otherwise directly dictate internal operations of state government." *Id.* Thus, because DOMA did "not share these two vices of commandeering or direct command," its "consequences do not violate the Tenth Amendment." *Id.*; *see also, e.g.*, *Connecticut v. Physicians Health Servs. of Ct., Inc.*, 287 F.3d 110, 122 (2d Cir. 2002) ("Federal statutes validly enacted under one of Congress's enumerated powers . . . cannot violate the Tenth Amendment unless they commandeer the states' executive officials.").

That logic straightforwardly applies here. In the absence of any alleged commandeering, Plaintiffs cannot state a viable Tenth Amendment claim by merely asserting that the government's enforcement of federal law "impermissibly intrude[s]" on state authority over the regulation of medicine. Doc No. 1, ¶226. Indeed, "[f]ederal laws criminalizing conduct within traditional areas of state law . . . are of course commonplace under the dual-sovereign concept"—"and involve no infringement *per se* of states' sovereignty in the administration of their criminal laws." *Johnson*, 114 F.3d at 481. Plaintiffs' Tenth Amendment claim should be dismissed out of hand.

* * *

At bottom, this suit is an outward attempt by States to preemptively immunize healthcare providers within their borders from federal law. This is a nonstarter under the Supremacy Clause. The Constitution empowers the federal government to investigate conduct that may violate federal law regardless of what state law permits. The parties' disagreement here sounds in policy, not in law.

CONCLUSION

For the reasons set forth above, the Court should dismiss the Complaint.

DATED: November 21, 2025 Respectfully submitted,

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CERTIFICATE OF SERVICE

On November 21, 2025, I electronically submitted the foregoing document with the clerk of court for the U.S. District Court, District of Massachusetts, using the electronic case filing system of the court. I hereby certify that I have served all parties electronically or by another manner authorized by Federal Rule of Civil Procedure 5(b)(2).

/s/ John Bailey
JOHN BAILEY