

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF)	
MASSACHUSETTS, <i>et al.</i> ,)	
)	
Plaintiffs,)	
)	
v.)	Civil Action No. 1:25-CV-12162-AK
)	
DONALD J. TRUMP, <i>in his official capacity</i>)	
<i>as President of the United States, et al.,</i>)	
)	
Defendants.)	
)	

DEFENDANTS' REPLY IN SUPPORT OF MOTION TO DISMISS COMPLAINT

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INTRODUCTION

Plaintiffs' opposition confirms that this case should be dismissed at the threshold. Stripped of rhetoric, this suit asks the Court to supervise how the Executive Branch exercises its core enforcement discretion, to resolve abstract questions of statutory meaning untethered to any concrete application of federal law, and to constitutionalize disagreements about how concededly valid statutes should be interpreted. Neither Article III nor the APA permits such an exercise.

States lack Article III standing to veto the federal government's enforcement priorities through litigation. Even if the Executive's judgment on this score were reviewable, Plaintiffs would still lack standing because their asserted injuries are speculative, self-inflicted, or derivative of third-party choices. Their requests for declaratory relief fare worse, including because the Declaratory Judgment Act does not permit courts to issue advisory opinions on abstract legal questions untethered from any concrete controversy.

Even if this dispute were justiciable, Plaintiffs' APA claims would independently fail for at least two reasons. The challenged Guidance is not final agency action: it binds no one, alters no legal rights or obligations, and merely channels investigative and prosecutorial discretion. And under settled precedent, decisions about whether and how to prioritize enforcement are committed to agency discretion by law and thus beyond judicial review.

Last, Plaintiffs' Tenth Amendment claim should be dismissed out of hand. Plaintiffs do not dispute that Congress validly enacted the statutes at issue, so the government's enforcement of those laws cannot possibly violate the Tenth Amendment. Whether the government has properly construed the scope of a particular statute is a statutory question that must be tested in a concrete enforcement action; it presents no freestanding constitutional claim.

ARGUMENT

I. Plaintiffs Lack Article III Standing.

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

Plaintiffs lack standing to challenge the federal government's discretionary decisions about how to prioritize the enforcement of federal law. In *United States v. Texas*, the Supreme Court closed the courthouse doors to precisely these kinds of claims, holding that federal courts may not entertain suits that "challenge[] . . . the Executive Branch's exercise of enforcement discretion over whether to arrest or prosecute." 599 U.S. 670, 677 (2023). Such suits have no historical pedigree, "run up against the Executive's Article II authority to enforce federal law," and fail because courts "generally lack meaningful standards for assessing the propriety of enforcement choices in this area." *Id.* at 678-79. These principles apply squarely to Plaintiffs' suit. They may not attempt, through litigation in federal district court, to usurp "the Executive Branch's traditional discretion over whether to take enforcement actions against violators of federal law." *Id.* at 678.

Plaintiffs cannot show that these established principles are somehow "[i]napplicable." Doc No. 86 at 27. Their main retort—that the court should cabin *Texas* to suits challenging "the absence of enforcement"—fails for several reasons. Doc No. 86 at 27. Indeed, in a footnote, Plaintiffs implicitly recognize that *Texas* is not so limited. They concede the Supreme Court there "endorsed" the "rule" that "DOJ may optimize its limited resources by prioritizing certain offenses *for enforcement.*" Doc No. 86 at 28 & n.3 (emphasis added). That concession should end this litigation. The challenged Guidance merely directs DOJ attorneys to prioritize investigations of suspected illegality occurring in relation to the provision of gender-related care to children. As explained in Defendants' motion, and elaborated in more detail below, Plaintiffs are simply wrong that DOJ somehow "substantively expanded the scope of liability under existing statutes" through the Guidance. Doc No. 86 at 28 & n.3 (arguing *Texas* is distinguishable on that basis); *see* Doc

No. 82 at 23-24. The Guidance does not, nor does it purport to, reinterpret any of the three statutes at issue here, and thus *Texas* cannot be distinguished on that basis.

Nor does *Texas* suggest that the general “principle of enforcement discretion over arrests and prosecutions” only has purchase in the context of alleged underenforcement. 599 U.S. at 679. To be sure, *Texas* provided “[s]everal” reasons for its conclusion in the context of that case, including that the challenged policy concerned alleged underenforcement. *Id.* at 678. But “[t]he Court’s Article III *holding* . . . applies to challenges to the Executive Branch’s exercise of enforcement discretion over whether to arrest or prosecute”—precluding “judicial review of the Executive Branch’s arrest and prosecution policies.” *Id.* at 678-79 (emphasis added). That holding bars Plaintiffs’ suit.

B. Plaintiffs assert no imminent injury caused by the Guidance.

Even if Plaintiffs could challenge the federal government’s enforcement priorities through litigation, their asserted injuries would still be insufficient under settled standing principles. All of Plaintiffs’ asserted injuries face a fundamental redressability problem: an order vacating the Guidance would do “nothing to change the fact that federal officials possess the same underlying prosecutorial discretion” or otherwise “require federal officials to change how they exercise that discretion in the [Guidance’s] absence.” *Texas*, 599 U.S. at 690 (Gorsuch, J., concurring in the judgment). Nor would vacatur of the Guidance “void decisions made under it.” *Nat’l Insts. of Health v. Am. Pub. Health Ass’n*, No. 25A103, 145 S. Ct. 2658, 2661 (2025) (Barrett, J., concurring). So the enforcement-related harms asserted by Plaintiffs would remain even if the Guidance were vacated. Redressability aside, many of the harms Plaintiffs identify are self-inflicted and thus not fairly traceable to the Guidance in the first place. And Plaintiffs’ predictions

of future injury amount to little more than conjecture about hypothetical enforcement scenarios, which cannot satisfy Article III's requirements of a concrete and imminent injury.

Start with Plaintiffs' laundry list of self-inflicted harms. Plaintiffs' lead theory of injury is that state-run entities "were compelled to absorb patients whose care was terminated by other providers after" the issuance of the EO and Guidance, thereby increasing costs. Doc No. 86 at 24. But those alleged costs are not fairly traceable to the EO or Guidance. Nothing in those directives "compelled" Plaintiffs to take on more patients or expand the scope of care they provide. That choice rests with the Plaintiff States themselves or, to the extent state law "compelled" those expenditures, with the States' own legislatures.

It is long settled that "decisions by . . . state legislatures" to expend money from the public fisc are "self-inflicted," and "[n]o state can be heard to complain about [such] damage." *Pennsylvania v. New Jersey*, 426 U.S. 660, 664 (1976); *accord Colorado v. EPA*, 989 F.3d 874, 888 (10th Cir. 2021) (a state's "self-inflicted" injury "resulting from" its own "legislative decision" is "not legally cognizable"); *see also National Family Planning & Reproductive Health Ass'n v. Gonzales*, 468 F.3d 826, 831 (D.C. Cir. 2006) ("We have consistently held that self-inflicted harm doesn't satisfy the basic requirements for standing."). And more generally, the Supreme Court has recently made clear that a litigant's choice to "diver[t] its resources in response to a defendant's actions" does not establish standing. *FDA v. Alliance for Hippocratic Med.*, 602 U.S. 367, 395 (2024). A State's decision to provide gender-related care, and to reallocate resources to do so, reflects its own policy and budgeting choices—not an "injury" inflicted by DOJ's enforcement efforts.

Plaintiffs' related theory—that state-run hospitals have "divert[ed]" resources in response to "[t]hreatened DOJ investigations"—fails for similar reasons. Doc No. 86 at 24-25. Any such

diversion traces to risk-management choices made by state officials, not the EO or Guidance. A State’s preemptive allocation of resources, based on speculative enforcement concerns, does not constitute an injury fairly traceable to the federal government’s actions. *See Clapper v. Amnesty Int’l USA*, 568 U.S. 398, 416 (2013) (a litigant’s “contention that they have standing because they incurred certain costs as a reasonable reaction to a risk of harm is unavailing” when “the harm [they] seek to avoid is not certainly impending”); *accord Roe v. Healey*, 78 F.4th 11, 20 (1st Cir. 2023) (“A threatened harm that is too attenuated or too speculative does not provide standing to seek an injunction.”). A State cannot “manufacture standing” through its own independent decisions about how to allocate its personnel and funds “based on hypothetical future harm that is not certainly impending.” *Clapper*, 568 U.S. at 416. Otherwise, States could concoct “standing to challenge virtually every government action that they do not like—an approach to standing that” the Supreme Court “has consistently rejected as flatly inconsistent with Article III.” *Alliance for Hippocratic Med.*, 602 U.S. at 392.

Plaintiffs’ remaining conjecture about hypothetical enforcement actions is equally deficient. Plaintiffs contend that they may “potentially” incur costs responding to subpoenas or defending their state instrumentalities in litigation. Doc No. 86 at 25. Such “allegations of *possible* future injury are not sufficient.” *Clapper*, 568 U.S. at 409. Again, as Supreme Court has “repeatedly reiterated,” a “threatened injury must be *certainly impending* to constitute injury in fact.” *Id.* Plaintiffs’ speculation that state-run hospitals may face enforcement actions at some indefinite point in the future does not amount to a cognizable injury in fact under Article III.

Nor can Plaintiffs rely on alleged injuries to patients or “other providers in Plaintiff States.” Doc No. 86 at 25. States lack *parens patriae* standing to sue the federal government based on alleged harms to their citizens; after all, the federal government is also *parens patriae* to its

citizens. *See Haaland v. Brackeen*, 599 U.S. 255, 294-95 (2023); *Town of Milton v. FAA*, 87 F.4th 91, 96 n.1 (1st Cir. 2023). Plaintiffs attempt to skirt this rule by claiming the Guidance injures them “in their capacity as legal guardians of youth” in state custody who allegedly require gender-related care. Doc No. 86 at 26. But nothing in the Guidance or EO “impedes” Plaintiffs from providing that care, should they choose to do so. Plaintiffs may continue to provide gender-related care consistent with federal law, just as before.

Plaintiffs thus pivot to downstream costs to state budgets allegedly caused by reduced access to care. *See* Doc No. 86 at 19. But such harms are too “attenuated” to establish standing. *Texas*, 599 U.S. at 680 n.3; *see also All. for Hippocratic Med.*, 602 U.S. at 383. The Supreme Court long ago explained that a State may sue the federal government only if it has suffered a “direct injury” as a result of a federal action or policy. *Florida v. Mellon*, 273 U.S. 12, 18 (1927). “[R]emote and indirect” harms of the sort asserted here do not work. *Id.* This makes sense. Our federal system necessarily contemplates that the United States’ policies will have derivative effects on the State itself. *See id.*; *Texas*, 599 U.S. at 680 n.3. A State therefore has no judicially cognizable interest in avoiding the incidental effects of federal policies—particularly where, as here, those effects flow from the independent actions of private individuals.

Last, Plaintiffs’ “sovereign injury” goes nowhere because it is based on a false premise, as Plaintiffs’ own allegations and evidence make plain. The EO and Guidance do not “effectively proscribe” any treatments protected by state law. Doc No. 86 at 27. Indeed, Plaintiffs’ lead assertion of harm is that the challenged actions caused state-run hospitals to *expand* their provision of gender-related care, including by taking on more patients. Even if the EO and Guidance were not plain on their face, Plaintiffs’ own conduct is incompatible with the supposed sovereign harm they assert and underscores the absence of any intrusion on state regulatory authority.

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

Plaintiffs' request for a declaratory judgment must be denied because they have failed to "show that there is a substantial controversy . . . of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune, Inc. v. Genetech, Inc.*, 549 U.S. 118, 129 (2007). To start, they cannot demonstrate "a reasonably clear and specific threat of prosecution." *New Hampshire Health Council, Inc. v. Marshall*, 203 F.3d 1, 4 (1st Cir. 2000). Plaintiffs do not claim to engage in any conduct plausibly implicated by the Guidance: misbranding (under the FDCA), "false claims" (under the FCA), or conduct meeting the statutory definition of FGM.

Instead, Plaintiffs complain that the Guidance has nonetheless "cast a pall of liability" over the provision of gender-related care. Doc No. 86 at 23. But "[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). Nor can Plaintiffs show a realistic likelihood of prosecution against them by misleadingly asserting that DOJ has "already begun enforcement proceedings against" third parties. Doc No. 86 at 20 (citing Compl. ¶ 137). What Plaintiffs point to is the government's initiation of "investigations," including the service of "civil subpoenas." Doc No. 1 ¶ 137. That does not show a credible threat of prosecution to anyone, much less to Plaintiffs. The government, of course, is entitled to "investigate . . . even just because it wants assurance that" the law is not being violated. *United States v. Morton Salt Co.*, 338 U.S. 632, 364 (1950). DOJ's investigatory efforts therefore say nothing about whether entities complying with federal law will face prosecution.

Declaratory relief is independently unavailable because Plaintiffs ask this Court to rule on abstract legal questions unmoored from any concrete dispute or factual context. Tellingly, Plaintiffs entirely ignore binding precedent such as *In re Financial Oversight & Mgmt. Bd for*

Puerto Rico, which make clear that “[d]eclaratory claims based on abstractions are not justiciable.” 916 F.3d 98, 112 (1st Cir. 2019). A declaratory judgment claim premised on a threat of future enforcement must instead assess “legal liability on *a set of already defined facts*,” such that any future dispute is “adequately framed by [its] factual dimensions.” *Id.* (emphasis added).

Plaintiffs do the opposite. They ask the Court to do precisely what Article III forbids: “to give opinions upon . . . abstract propositions.” *Church of Scientology of Cal. v. United States*, 506 U.S. 9, 12 (1992) (quoting *Mills v. Green*, 159 U.S. 651, 653 (1895)). They seek advisory rulings on a series of “purely legal questions,” such as “whether the statutory definition of FGM includes—or excludes—gender-affirming care,” or “whether gender-affirming medical treatments remain ‘covered services’ under federal healthcare programs.” Doc No. 86 at 21-22. But those questions cannot even be answered in the abstract. Each turns on the precise nature of the particular “gender-affirming medical treatments” (whatever that means) and the surrounding facts and circumstances. Absent a concrete enforcement action or defined course of conduct, the Court would be forced to speculate about hypothetical scenarios and opine on the outer bounds of statutes untethered to any specific real-world application. It is difficult to imagine questions less suitable for resolution under Article III. *See also, e.g., Int'l Longshoremen's & Warehousemen's Union v. Boyd*, 347 U.S. 222, 224 (1954) (“Determination of the scope . . . of legislation in advance of its immediate adverse effect in the context of a concrete case involves too remote and abstract an inquiry for the proper exercise of the judicial function.”).

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

A. Plaintiffs fail to allege final agency action.

Even if this case presented a justiciable case or controversy under Article III, Plaintiffs’ APA claims would be unreviewable because the Guidance is not final agency action that could qualify for judicial review under the APA. The Guidance merely articulates enforcement priorities

to guide agency officials’ exercise of enforcement discretion and restates the core prohibitions of the relevant statutes; it does not alter any healthcare provider’s legal rights or obligations, compel agency personnel to make any particular enforcement decision, or otherwise create any “direct and appreciable legal consequences.” *Bennett v. Spear*, 520 U.S. 154, 178 (1997).

First, the Guidance is not final because it does not mark the consummation of DOJ’s decisionmaking process. The First Circuit has already “concluded that investigatory measures are not final agency action.” *Harper v. Werfel*, 118 F.4th 100, 116 (1st Cir. 2024) (collecting cases). That rule follows from the basic structure of administrative decisionmaking: investigation precedes enforcement, and neither commits the agency to a definitive legal position or outcome. As a matter of logic and law, then, an agency’s preliminary directives instructing staff how to allocate investigative resources—which are “even more preliminary” than any resulting investigation—simply “cannot themselves be ‘final agency action.’” *Cohen v. Rice*, 992 F.2d 376, 382 (1st Cir. 1993). As in *Harper*, it is “premature at this point to wade into the [agency’s] investigation of potential widespread” misconduct within its jurisdiction. 118. F4th at 117.

Plaintiffs’ attempt to distinguish this line of cases misunderstands both the Guidance and the governing law. This is not a case in which an agency has announced a binding, “across the board” rule that alters primary conduct or fixes legal consequences. Doc No. 86 at 32 (quoting *Lujan v Nat’l Wildlife Fed’n*, 497 U.S. 871, 890 n.2 (1990)). Plaintiffs miss the mark in arguing that the Guidance is reviewable because it is allegedly binding on DOJ employees. The finality inquiry focuses on whether the action in question has an “actual legal effect” on “regulated entities”—not on agency personnel. *National Mining Ass’n v. McCarthy*, 758 F.3d 243, 252 (D.C. Cir. 2014). In any event, the “conditional language” in the Guidance “preserves officials’ discretion.” *Arizona v. Biden*, 40 F.4th 375, 387 (6th Cir. 2022) (internal memorandum outlining

“[immigration] enforcement priorities” is unreviewable). The Bondi Memo, for example, directs DOJ “to undertake appropriate investigations” of suspected misconduct, Doc No. 1-7 at 5, consistent with the President’s directive to “prioritize investigations and take appropriate action to end deception of consumers, fraud, and violations of the [FDCA],” EO § 8(c), Doc No. 1-5. This is a “telltale sign[]” that the Guidance is not reviewable agency action but instead “a nonbinding policy statement.” *Arizona*, 40 F.4th at 387.

Moreover, and more fundamentally, even if Plaintiffs’ characterization of the Guidance were correct, DOJ’s articulation of how existing statutes apply to certain healthcare-related misconduct could not create any “new legal obligations beyond those the [statutes] already imposed.” *Rhea Lana, Inc. v. Department of Labor*, 824 F.3d 1023, 1028 (D.C. Cir. 2016). Any enforcement action under the FCA, FDCA, or FGM Act would ultimately result in the defendant’s rights being determined *de novo* by a court. *See Abramski v. United States*, 573 U.S. 169, 191 (2014) (“criminal laws are for courts, not for the Government, to construe”). This case is thus far removed from situations in which an agency issues a substantive regulation that binds agency staff to require compliance with non-statutory mandates imposed by regulation, such as permitting or licensing requirements. *Cf.* Doc No. 86 at 29-30 (citing *National Env’t Dev. Ass’n’s Clean Air Project v. EPA*, 752 F.3d 999 (D.C. Cir. 2014); *Barrick Goldstrike Mines Inc. v. Browner*, 215 F.3d 45 (D.C. Cir. 2000); *Appalachian Power Co. v. EPA*, 208 F.3d 1015 (D.C. Cir. 2000)). And it would be anomalous to hold here that while an investigation is not “final agency action,” the preliminary guidance that precedes such an investigation—which is not binding on either the parties or the courts—somehow is.

Nor do Defendants contend that agency guidance is never reviewable. Rather, the point is that an internal agency memo that merely restates settled interpretations of federal law and

prioritizes certain investigations cannot plausibly be viewed as creating any direct effects or altering any rights or obligations. *See National 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” and are thus not final). Seemingly recognizing this, Plaintiffs reprise their inaccurate refrain that Guidance “adopted . . . novel interpretations” of the FCA and FDCA. Doc No. 86 at 30. That assertion is incorrect. The Guidance does not—and could not—“extend[] FCA liability.” Doc No. 86 at 21. Both the Bondi and Shumate Memos simply direct “investigations under the [FCA] of false claims submitted to federal health care programs.” Doc No. 1-7 at 3 (quoting Doc No. 1-6 at 5). Plaintiffs cannot seriously contend that there has ever been a “norm[] or safe harbor[]” under the FCA permitting the submission of false claims to the federal government, including related to the provision of healthcare. Doc No. 86 at 30.

The same is true of the FDCA. The Guidance merely prioritizes enforcement of the statute’s longstanding “prohibitions on misbranding and mislabeling” of prescription drugs. Doc No. 1-6 at 5. Courts have long recognized that such conduct violates the FDCA. *See, e.g., United States v. Facteau*, 89 F.4th 1, 15 (1st Cir. 2023). Nothing in the Guidance suggests that providers will face liability for “prescrib[ing] FDA-approved drugs for off-label uses,” barring independent misconduct. Doc No. 86 at 30. Nor have Defendants in this litigation asserted that the act of writing a prescription for an off-label use would, in and of itself, “trigger[]” FDCA liability for the prescriber. Doc No. 86 at 22. Defendants do not contest that the FDCA generally permits the off-label prescribing of puberty blockers or hormones—so long as the prescriber does not otherwise violate the law, by, for example, conspiring with a manufacturer to misbrand a drug or doing any other act which causes the drug to become misbranded or adulterated. *See* 21 U.S.C. § 331(K)

(prohibiting the doing of any act which results in the drug becoming adulterated or misbranded while drug is held for sale after shipment in commerce).

At bottom, Plaintiffs' claim that the Guidance is reviewable because it has had a "direct effect" on their ability provide gender-related care is belied by their own allegations. Doc No. 86 at 30. Again, Plaintiffs expressly contend that, in response to the Guidance, their state-run hospitals have expanded their provision of gender-related care. Doc No. 86 at 17. Even accepting Plaintiffs' view of the Guidance at face value, and even if DOJ could through guidance documents expand the scope of liability of the statutes it enforces, Plaintiffs' own conduct undermines any assertion that the Guidance "is for all practical purposes binding" or otherwise "alters the legal regime." Doc No. 86 at 29, 30 (citations omitted).

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

Separately, Plaintiffs' APA claims are unreviewable because the decision to issue enforcement prioritization guidance is committed to agency discretion by law. The Supreme Court has explained that such enforcement decisions are "generally committed to an agency's absolute discretion." *Heckler v. Chaney*, 470 U.S. 821, 831 (1985). That principle applies with equal force to internal guidance that merely channels how the agency will exercise its prosecutorial and investigative discretion. The relevant statutes provide "no meaningful standard against which to judge" DOJ's choice of enforcement priorities, and courts thus lack competence to second-guess how the Department allocates limited resources or sequences investigations. *Id.* at 830. As the Sixth Circuit recognized in *Arizona*, enforcement memos of the sort challenged here are beyond APA review under *Chaney*. See 40 F.4th at 389.

Plaintiffs' principal response is again premised on their incorrect assertion that the Guidance newly interprets the "substantive requirements" of the FCA, FDCA, and FGM Act. Doc

No. 86 at 33. For this reason, Plaintiffs' reliance on *Casa de Maryland v. DHS*, 924 F.3d 684 (4th Cir. 2019), is misplaced. That case concerned the Attorney General's decision to rescind the Deferred Action for Childhood Arrivals (DACA) policy, which was "based on the agency's legal interpretation" of federal immigration law. 924 F.3d at 699. The Fourth Circuit reasoned that the decision was "too closely bound up with . . . evaluation of DACA's legality" to fall within *Chaney*'s "presumption of unreviewability." *Id.* at 700 (quotation omitted). Even if that decision were correct or binding here, it would not speak to the reviewability of an enforcement memo premised on settled constructions of the relevant statutes.

Nor are Plaintiffs right that any "broad or general enforcement policy" is reviewable under *Chaney*. Doc No. 86 at 33. That assertion cannot be reconciled with *Chaney* itself, in which the Supreme Court held unreviewable the FDA's categorical decision not to take enforcement action against a *class of actors* (drugs manufacturers, prison administrators, and others in the drug distribution chain). 470 U.S. at 824-25. That the decision was made by the agency head made no difference. *See id.* at 824. Nor could it be any other way. A broad exception for "general enforcement policies" would unduly impede the Executive Branch in enforcing federal law. The Attorney General, in particular, has every right to exercise enforcement discretion. "Whether the Secretary exercises her discretion over an individual case or provides guidance for how discretion should be applied in a class of cases, the decision is unreviewable as one 'committed to agency discretion by law.'" *Casa De Maryland*, 924 F.3d at 713 (Richardson, J., concurring in part and dissenting in part).

III. Plaintiffs Fail to State a Tenth Amendment Claim.

Plaintiffs do not dispute that the FCA, FDCA, and FGM Act were validly enacted under Congress' constitutional authority. That concession is dispositive. The Executive's enforcement of those statutes simply cannot give rise to a plausible Tenth Amendment claim. *See New York v.*

United States, 505 U.S. 144, 156 (1992). As the First Circuit has expressly held, this constitutional principle applies even where the challenged conduct is alleged to “intrude[] extensively into a realm . . . which is a leading instance of the states’ exercise of their broad police-power authority.” *Massachusetts v. U.S. Dep’t of Health & Human Servs.*, 682 F.3d 1, 12 (1st Cir. 2012). Plaintiffs’ Tenth Amendment theory—based solely on the Executive’s future enforcement of statutes whose constitutionality they concede—thus fails as a matter of law.

In opposition, Plaintiffs confirm that their Tenth Amendment claim is grounded not in any constitutional defect, but in disagreement with the Executive’s alleged interpretation of the FCA, FDCA, and FGM Act. Their argument is essentially that those statutes do not, as a matter of statutory interpretation, reach the misconduct the EO and Guidance identify as enforcement priorities. *See* Doc No. 86 at 35 (alleged “interpretation” of FGM Act reflected in EO and Guidance “contravene[s] the statute’s plain meaning”); *id.* at 36 (arguing the “[FCA] says nothing at all about second-guessing medical judgments, which the Medicaid statute leaves to the States”); *id.* (arguing the “FDCA vests the federal government with authority over only a discrete aspect of drug regulation . . . and expressly disclaims any intent to” regulate medicine). “In this way,” Plaintiffs contend, the EO and Guidance “intrude on States’ sovereign authority.” Doc No. 86 at 36.

Plaintiffs cannot recast their statutory objections into a freestanding constitutional claim. The Supreme Court rejected precisely that maneuver in *Dalton v. Specter*, holding that allegations that an official has acted in opposition to a statute are statutory claims—not “‘constitutional’ claims” that can be asserted through a direct cause of action. 511 U.S. 462, 473 (1994). Not “every action by the President, or by another executive official, in excess of his statutory authority is *ipso facto* in violation of the Constitution.” *Id.* at 472. The Court has instead “distinguished between

claims of constitutional violations and claims that an official has acted in excess of his statutory authority.” *Id.* (collecting cases). The Constitution is implicated, for example, if executive officers rely on it as an independent source of authority to act, as in *Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579 (1952), or if the officers rely on a statute that itself violates the Constitution. *See Dalton*, 511 U.S. at 473 & n.5. But claims alleging simply that an official has “exceeded his statutory authority are not ‘constitutional’ claims” that can be asserted through a direct cause of action. *Id.* at 473.

Thus, Plaintiffs’ claim that the EO and Guidance reflect legally erroneous interpretations of federal law presents, at most, a statutory dispute—not a constitutional one. Whether the government has misconstrued the reach of a particular statute is a statutory question to be tested in a concrete enforcement action. And although Plaintiffs cite cases in which federalism concerns informed statutory interpretation, *see* Doc No. 86 at 35-37, none suggests that an alleged statutory error can give rise to a freestanding Tenth Amendment claim.

CONCLUSION

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

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Respectfully submitted,

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CERTIFICATE OF SERVICE

On January 12, 2026, 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