IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA
FORT MYERS DIVISION

THE FOUNDATION FOR GOVERNMENT ACCOUNTABILITY,

Plaintiff,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, XAVIER BECERRA *in his official capacity as Secretary of HHS*, U.S. DEPARTMENT OF LABOR, JULIE A. SU *in her official capacity as Acting Secretary of Labor*, U.S. DEPARTMENT OF THE TREASURY, *and* JANET YELLEN *in her official capacity as Secretary of the Treasury*,

Defendants.

No. 2:23-cv-207

PLAINTIFF'S COMBINED OPPOSITION TO DEFENDANTS' MOTION TO DISMISS (OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT) AND REPLY IN SUPPORT OF PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

The Agency Defendants' arguments confirm that they cannot win on the merits. They try to argue that the Prescription Drug and Safe Harbor Policies are general statements of policy, not legislative rules. But they completely ignore the "key inquiry" in distinguishing these two categories—"the extent to which the challenged policy leaves the agency free to exercise its discretion to follow or not to follow that general policy in an individual case." *Nat'l Min. Ass'n v. Sec'y of Lab.*, 589 F.3d 1368, 1371 (11th Cir. 2009). They have to, since even a cursory look at the Policies confirms that the Agencies have categorically disclaimed enforcement of the TiC Rule's requirements. *See* Pl.'s Ex. C (Doc. 33-3) at 1-2; Pl.'s Ex. D (Doc. 33-4) at 2. The Policies are legislative rules.

Since they can't win on the merits, the Agencies try a series of procedural arguments. They start by arguing that FGA lacks standing. But FGA's injury here is a classic case for informational standing: FGA seeks "information subject to [a] public-disclosure or sunshine la[w] that entitle[s] all members of the public to certain information." *TransUnion LLC v. Ramirez*, 141 S.Ct. 2190, 2214 (2021). And it is suffering "downstream consequences" from the nondisclosure because it cannot use the information in its research and advocacy efforts. *Id.* Despite this, the Agencies insist that FGA still lacks standing under the Supreme Court's decision in *United States v. Texas*, 143 S.

Ct. 1964 (2023). That decision found a lack of standing when a plaintiff sought an order that would restrain the Executive's prosecutorial discretion by requiring it to initiate prosecutions. *See id.* at 1968. An order for FGA would do the opposite; it would restore the Agencies' prosecutorial discretion by vacating procedurally-improper policies that prevent them from making case-by-case enforcement decisions.

The Agencies' attempt to insulate the Policies from review as actions committed to agency discretion fails for a similar reason. To begin, there is no dispute that the APA's procedural requirements give this Court "law to apply" to the Agencies' adoption of the Policies. *See Animal Legal Def. Fund v. USDA*, 789 F.3d 1206, 1214-15 (11th Cir. 2015). And while agencies retain discretion to decide whether to initiate a prosecution, *Heckler v. Cheney*, 470 U.S. 821, 830-31 (1985), these challenged Policies are an impediment to that discretion, not an exercise of it.

Finally, the Policies are final agency action. To be final action, it is enough that the Policies are substantive rules. Moreover, legal consequences flow from the Policies. The Agencies have foresworn any enforcement of the TiC Rule's requirements, and plans and issuers are no longer required to comply as a result. Nor can the Agency insulate this action as a temporary action merely because it could be displaced by a new policy in the future.

This Court should grant FGA's motion for summary judgment.

RESPONSE TO DEFENDANTS' STATEMENT OF MATERIAL FACTS

1. This paragraph is a legal conclusion to which no response is required.

2. This paragraph is a legal conclusion to which no response is required.

3. Disputed. FGA's stated purposes for this litigation are identified in its court filings and not limited to a desire for Defendants to follow the law. *See* Compl. (Doc. 1); FGA MSJ (Doc. 33). The quoted exhibit speaks for itself.

4. Disputed. FGA's stated purposes for this litigation are identified in its court filings and not limited to advocating for consumer interests. *See* Compl. (Doc. 1); FGA MSJ (Doc. 33). The quoted exhibit speaks for itself.

5. This paragraph is a legal conclusion to which no response is required. The quoted exhibit speaks for itself.

ARGUMENT

I. FGA has informational standing.

The Agencies first challenge FGA's standing. Specifically, they claim that FGA's lacks standing under the Supreme Court's recent decision in *United States v. Texas*, 143 S. Ct. 1964 (2023), and that FGA has failed to show standing even under a more-traditional approach. The Agencies are wrong on each point.

A. FGA has shown standing based on an informational injury.

The Agencies devote much of their argument to standing, but they only briefly address the informational injury at issue in this case. *See* Opp. (Doc. 39) at 16-18. This brief discussion fails to undermine FGA's showing that it has been injured by the non-disclosure of information covered by the TiC Rule.

1. FGA has suffered a cognizable informational injury.

A failure to disclose "information subject to public-disclosure or sunshine laws that entitle all members of the public to certain information" confers standing if the nondisclosure causes "downstream consequences" for the plaintiff. *TransUnion*, 141 S.Ct. at 2214; *see also, e.g.*, *FEC v. Akins*, 524 U.S. 11, 21 (1998) (refusal to disclose information that "must be publicly disclosed pursuant to a statute" and that would "help" voters "evaluate candidates for public office" is an injury in fact); *Pub. Citizen v. DOJ*, 491 U.S. 440, 449 (1989) (an agency's refusal to disclose "information under [FOIA]" or similar sunshine laws inflicts an injury-in-fact on members of the public who seek to "monitor its workings and participate more effectively in … [its] process[es]"); *see also Casillas v. Madison Ave. Assocs., Inc.*, 926 F.3d 329, 337-38 (7th Cir. 2019) (Barrett, J.) ("*denial of information subject to public disclosure*" is a cognizable injury). Both the Supreme Court and the Eleventh Circuit recently reaffirmed this principle. In *Trichell v. Midland Credit Mgmt., Inc.*, the Eleventh Circuit explained that a plaintiff has suffered an injury in fact when it seeks

information "made … subject to public disclosure" by a statute and can point to "consequential harms" from the denial of that information. 964 F.3d 990, 1004 (11th Cir. 2020). The Supreme Court relied on *Trichell* to reach the same conclusion in *TransUnion*. 141 S.Ct. at 2214. This case falls squarely in this well-established line of precedents.

First, there is a "public-disclosure or sunshine la[w] that entitle[s] all members of the public to certain information." *Id.* Section 1311 of the ACA promises the public "transparency in coverage" from health insurance plans. 42 U.S.C. §§18031(e)(3), 300gg-15a. It requires insurance exchanges and group plans to "*make available to the publi[c]* accurate and timely disclosure of" certain "information." *Id.* §18031(e)(3) (emphasis added). This includes "information as determined appropriate by the Secretary" of Health and Human Services. *Id.* Here, the Secretary of HHS determined in the TiC Rule that "appropriate" information includes the information sought by FGA—prescription-drug price information and other healthcare cost information in dollar amounts. 45 C.F.R. §§147.212(b), 147.210(a)(2)(xi), (xiv).

Second, FGA is suffering downstream consequences from the withholding of this information. Because the Agencies' Policies remove the obligation to report prescription-drug prices and waive the requirement to report some in-network items and services in dollar amounts, health plans and issuers are not reporting this information and FGA cannot access it. *See, e.g.*,

Pl.'s Ex. E (Doc. 33-5) (Ingram Decl.) at 5 ¶12; *see also* FGA MSJ (Doc. 33) at 19-20. This has deprived FGA of the ability to use that information to advance its mission in a variety of ways, including using the information to formulate policy recommendations and to persuade policymakers to adopt FGA's preferred policies. Pl.'s Ex. E (Ingram Decl.) at 2-5 ¶¶4-12.

The downstream consequences that FGA is suffering are exactly the kind that courts have held are enough for informational standing. *Public Citizen*, for example, found informational standing where an organization sought information to "participate more effectively in the judicial selection process." 491 U.S. at 449. And *Akins* involved a group of voters who claimed that information "would help them (and others to whom they would communicate it) to evaluate candidates for public office." 524 U.S. at 21. These downstream consequences were enough, and so is the frustration of FGA's research and advocacy by the Prescription Drug and Safe Harbor Policies.

The Agencies' response to this open-and-shut informational injury is to claim that no statute requires disclosure of the information FGA seeks. *See* Opp. (Doc. 39) at 17-18. That argument can be easily discarded. The ACA requires "information … determined appropriate by the Secretary" of HHS to be "ma[d]e available to the public." 42 U.S.C. §§18031(e)(3); 300gg-15a. The Secretary determined through the TiC Rule that the information FGA seeks should be made available to the public. 45 C.F.R. §§147.212(b),

147.210(a)(2)(xi), (xiv). So that information is subject to the ACA's public-disclosure mandate.

Finally, the Agencies point to FGA press statements to suggest that FGA brought this suit not to obtain the information exempted from the TiC Rule by the Prescription Drug and Safe Harbor Policies, but to ensure that the Agencies comply with the law and that consumers can access this information. *See* Opp. (Doc. 39) at 6-7 ¶¶3-4, 8 ¶10, 12-13, 18. But "[n]one of the statements in [FGA's] press releas[e] contradict the testimony in" FGA's declaration testimony. *Marcovecchio v. Wright Med. Grp., Inc.*, 2019 WL 1406606, at *4 (D. Utah). FGA's hope that the Agencies will follow the law and consumers will be able to access information that the public has a right to is entirely consistent with their own desire to access and use that information. *See* Pl.'s Ex. E (Ingram Decl.) at 2-5 ¶¶4-12.

2. FGA has shown causation and redressability.

The Agencies alternatively assert FGA has failed to show causation and redressability. Opp. (Doc. 39) at 13-16. They march through an assortment of arguments, but none of them undermine FGA's standing.

a. FGA has met the standards for causation and redressability. "Causation, or traceability, examines whether it is … probable that the challenged acts of the defendant, not of some absent third party, … cause[d] the particularized injury of the plaintiff." *Orangeburg, S.C. v. FERC*, 862 F.3d

1071, 1080 (D.C. Cir. 2017) (cleaned up). This standard does not require that the defendant's action was the sole or direct cause of the injury. "Instead, even harms that flow indirectly from the action in question can be said to be fairly traceable to that action for standing purposes." *MacPhee v. MiMedx Grp., Inc.*, 73 F.4th 1220, 1239 (11th Cir. 2023) (cleaned up). It is enough that the "defendant's conduct is one among multiple causes" of the injury. *Orangeburg*, 862 F.3d at 1080 (quoting Wright & Miller, 13A Fed. Prac. & Proc. Juris. §3531.5 (3d ed.)). And the standard for causation is "something less than the concept of proximate cause, as, for standing purposes, a plaintiff is not required to prove causation beyond a reasonable doubt or by clear and convincing evidence." *MacPhee*, 73 F.4th at 1239 (cleaned up).

Dispositive here, "'causation … is met when a plaintiff demonstrates that the challenged agency action authorizes the conduct that … caused the plaintiff's injuries, if that conduct would … be illegal otherwise.'" *Orangeburg*, 862 F.3d at 1080 (quoting *Animal Legal Def. Fund, Inc. v. Glickman*, 154 F.3d 426, 440 (D.C. Cir. 1998)); *see Simon v. E. Ky. Welfare Rts. Org.*, 426 U.S. 26, 45 n.25 (1976) (harmful competition is "directly traceable to" government action if it "would have been illegal without that [government] action" (citing *Ass'n of Data Processing Serv. Orgs., Inc. v. Camp*, 397 U.S. 150, 152 (1970))). That is precisely what happened here. The Agencies' Prescription Drug and Safe Harbor Policies authorized plans and issuers to stop reporting

information that the TiC Rule otherwise required to be disclosed. As a result, FGA has been unable to obtain that information. Pl.'s Ex. E. (Ingram Decl.) at 5 ¶12.

Turning to redressability, it is enough for FGA to show that it "might gain" some of the information that it seeks. *Public Citizen*, 491 U.S. at 451. For this reason, *Public Citizen* found that an advocacy group had standing even when it admitted that much of the information that it sought might be covered by exceptions to disclosure. *Id*. at 450-51. The group did not concede that "*all*" the information fell within an exemption, and some of the information "could well fall outside" any exemption. *Id*. at 450. Here, the Agencies do not even argue that FGA won't be able to obtain at least some of the information currently covered by the Policies if the Policies are vacated.

b. The Agencies try to side-step this straightforward causation and redressability case by arguing that FGA has not shown that plans and issuers are failing to publicly disclose the information covered by the Prescription Drug and Safe Harbor Policies. *See* Opp. (Doc. 39) at 13-14. This argument ignores the evidence. FGA submitted sworn testimony by its Vice President of Policy and Research, Jonathan Ingram, who explained that because of the Agencies' policies letting plans and issuers disregard the TiC Rule and refuse to make certain required disclosures "FGA has been unable to obtain that information." Pl.'s Ex. E (Ingram Decl.) at 5 ¶12. FGA also pointed to two plan or issuer

websites showing that they are not providing required information because of the Policies. *See* United Healthcare, *Transparency in Coverage Rule*, perma.cc/7P4M-4GJC; Premera Blue Cross, *Transparency in Coverage Rule*, perma.cc/W2FK-E76U. It is not clear what more evidence the Agencies think would be sufficient. And notably, they do not point to a single example of compliance with the TiC Rule's requirements despite the Policies.

The Agencies offer no response to the testimony offered by FGA, but they quibble with the plan or issuer websites showing that they are not complying. *See* Opp. (Doc. 39) at 14. The Agencies point to boilerplate statements from these websites about commitment to legal compliance. *See* United Healthcare, *Transparency in Coverage Rule*, perma.cc/7P4M-4GJC ("Compliance … is a fundamental commitment of UnitedHealth," and it "indend[s] to comply with the requirements of the new rules"); Premera Blue Cross, *Transparency in Coverage Rule*, perma.cc/W2FK-E76U ("Implementation efforts are underway … to ensure we are in compliance with all aspects of the rule."). These statements, however, don't undermine the direct statements on these websites that the companies are not providing required information and will not pending further guidance or rulemaking. *See id.* If anything, this expression of commitment to following legal requirements while refusing to provide required information shows that these companies understand that the Agencies have effectively amended the TiC Rule.

Finally, the Agencies argue that there is no causation because, at least in theory, state governments could decide to ignore the Agencies' Policies and start enforcing some of TiC Rule's requirements. *See* Opp. (Doc. 39) at 15. But even if state governments might be able to enforce some the TiC Rule's requirements instead of heeding the Agencies' request "to take a similar enforcement approach," it does not follow that the Agencies are not the cause of FGA's injury. Pl.'s Ex. C at 2; Pl.'s Ex. D at 3; *see* Pl.'s Ex. E (Ingram Decl.) at 5 ¶12. As explained, it is enough that the Agencies "conduct is one among multiple causes." *See, e.g.*, *Orangeburg*, 862 F.3d at 1080.

c. The Agencies next argue that FGA lacks standing because even if this Court vacates the Policies, the Agencies will probably still refuse to enforce the TiC Rule. *See* Opp. (Doc. 39) at 14-16. But this argument misunderstands the requirements for standing in this kind of challenge. *Akins* explained that a plaintiff seeking disclosure of information has standing "even though the agency … might later, in the exercise of its lawful discretion, reach the same result for a different reason." 524 U.S. at 25. The agency cannot insulate its legally-flawed decision by arguing that it could have validly exercised its discretion to get to the same result. *See id.* ("[T]hose adversely affected by a discretionary agency decision generally have standing to complain that the agency based its decision upon an improper legal ground.").

The Agencies relatedly claim that it is unlikely that plans or issuers would comply because they are already required to comply with the TiC Rule but are failing to do so. *See* Opp. (Doc. 39) at 15. But this attempt to turn the Agencies' procedural failures into a defense of the Policies puts form over substance. Courts look to the real-world effect, not formalities, when assessing agency action. *CropLife Am. v. EPA*, 329 F.3d 876, 883 (D.C. Cir. 2003). And here, the Agencies effectively amended the TiC Rule through categorical statements disclaiming all enforcement of the Rule's requirements. Unsurprisingly, regulated parties have complied with the *actual* policy implemented by the Agencies, not the terms of the TiC Rule as enacted. But once the procedurally-improper Policies are vacated, this Court must assume that regulated parties will comply with the Rule. *See, e.g.*, *Utah v. Evans*, 536 U.S. 452, 460 (2002); *Banks v. Sec'y of Ind. Fam. & Soc. Servs. Admin.*, 997 F.2d 231, 241 (7th Cir. 1993); *Graham v. FEMA*, 149 F.3d 997, 1003-04 (9th Cir. 1998).

d. Finally, the Agencies argue that FGA has failed to show that its advocacy efforts would be more successful with the withheld information. *See* Opp. (Doc. 39) at 16. This argument is rooted in a misunderstanding of the nature of the informational harm in this case. FGA is required only to show that it would use the information in its research and advocacy, not that those efforts would be successful. That is why *Akins* found that plaintiffs' injuries

were redressable because a favorable order might reveal the information they sought. 524 U.S. at 25-26. And *Public Citizen* found redressability because an advocacy group might get *some* of the information it sought. 491 U.S. at 450-51. Neither decision looked to whether efforts to use that information for advocacy would be successful. That makes sense. As then-Judge Barrett noted, public-disclosure provisions focus on "the public's interest in evaluating matters of concern to the political community." *Casillas*, 926 F.3d at 338. So it is FGA's use of this information for research and advocacy that matters. *See* Pl.'s Ex. E (Ingram Decl.) at 2-5 ¶¶4-12. The Agencies do not dispute that FGA would use the information for those purposes.

B. *United States v. Texas* does not apply to the Agencies' effective amendment of the TiC Rule.

Unable to refute FGA's informational standing, the Agencies turn to the Supreme Court's recent decision in *United States v. Texas*. *See* Opp. (Doc. 39) at 10-13. There, Texas and Louisiana challenged "Guidelines prioritiz[ing] the arrest and removal" of certain noncitizens. 143 S. Ct. at 1968. They argued that the Guidelines violated "two federal statutes that purportedly require the Department to arrest more criminal noncitizens pending their removal." *Id*. As the Court explained, the States "essentially want[ed] the Federal Judiciary to order the Executive Branch to alter its arrest policy so as to make more arrests." *Id*. The Court found that this challenge to "the Executive Branch's exercise of enforcement discretion over whether to arrest or prosecute" was not

redressable by a federal court. *Id*. at 1970. This decision was a "narrow" one, addressing "only the … question of whether the Federal Judiciary may in effect order the Executive Branch to take enforcement actions against violators of federal law." *Id*. at 1975. The Court emphasized that the case was "extraordinarily unusual" and "categorically different" from all other cases involving "routin[e]" judicial review of "statutory requirements or prohibitions on the Executive." *Id*. at 1974-76. Its decision should "in no way be read to suggest or imply that the Executive possesses some freestanding or general constitutional authority to disregard statutes requiring or prohibiting executive action." *Id*. at 1974. Instead, it extends only to cases "that purport to *require* the Executive Branch to make arrests or bring prosecutions." *Id*.

Texas has no application to this case. *Texas* found that there was no standing where a suit sought to control "the Executive Branch's exercise of enforcement discretion." *Id*. at 1970. In a "narrow" decision, the Court rejected a request to compel the government to abandon its enforcement priorities set forth in Guidance and arrest more individuals to comply with statutory mandates. *Id*. at 1975-76. The judiciary could not "order the Executive Branch to take enforcement actions against violators of federal law." *Id*. at 1975.

Here, a decision in favor of FGA would restore the Agencies' enforcement discretion, not dictate how it must be used. This case does not involve guidance setting priorities for the exercise of enforcement discretion. The Prescription

Drug and Safe Harbor Policies bar any enforcement of requirements of the TiC Rule. Pl.'s Ex. C, at 1-2 (categorically "defer[ring] enforcement of" the "requirement" to "publish machine-readable files relating to prescription drug pricing"); Pl.'s Ex. D at 2 (announcing a categorical "safe harbor" from the requirement to report certain costs in dollar amounts). Only after these policies have been vacated can the Agencies exercise their discretion to decide "how to prioritize and how aggressively to pursue legal actions against defendants who violate the law." *Texas*, 143 S. Ct. at 1971 (quoting *TransUnion*, 141 S.Ct. at 2207). In this way, this case is like *Akins*, where the Court held that plaintiffs had standing to challenge a legally-flawed decision that prevented an agency from compelling a third-party to provide information "even though the agency … might later, in the exercise of its lawful discretion, reach the same result for a different reason." 524 U.S. at 25.

Any remaining doubt about whether this case falls outside the scope of *Texas* is answered by the decision's explicit limitations. The Court agreed that its "standing analysis might differ when Congress elevates *de facto* injuries to the status of legally cognizable injuries redressable by a federal court." 143 S. Ct. at 1973. And it confirmed that cases seeking information under public-disclosure laws fell in this category by citing *Akins*. *See id*.

II. The Agencies' policies are not immune from APA review.

Moving on from standing, the Agencies argue that there is no subject matter jurisdiction because its challenged policies are immune from APA review. *See* Opp. (Doc. 39) at 19-22. That too is wrong. "The APA establishes a basic presumption of judicial review for one suffering legal wrong because of agency action," and the Agencies bear the burden of rebutting that presumption. *DHS v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1905 (2020) (cleaned up). The Agencies only attempt to evade this presumption is an inapplicable exception for decisions committed to agency discretion. *See* Opp. (Doc. 39) at 19-22.

The exception to review for "agency action … committed to agency discretion by law," 5 U.S.C. §701(a)(2), applies "quite narrowly." *Regents*, 140 S.Ct. at 1905. It is limited to "those rare administrative decisions traditionally left to agency discretion." *Id.* (cleaned up) The Eleventh Circuit summarizes the "agency discretion" exception as "preclud[ing] APA review whenever the statute under which the agency acts 'is drawn so that a court would have no meaningful standard against which to judge the agency's exercise of discretion'—that is, where a court would have 'no law to apply.'" *Animal Legal Def. Fund*, 789 F.3d at 1214-15 (quoting *Heckler*, 470 U.S. at 830-31).

A straightforward analysis confirms that there is law to apply here—the APA's procedural requirements. As FGA explained, the APA requires that

legislative rules must go through the notice-and-comment procedure. FGA MSJ (Doc. 33) at 17 (citing 5 U.S.C. §§553, 706(2)(D)). Since the Policies are legislative rules, they are invalid unless they passed through those procedures. *See id.* at 19-21.

Still, the Agencies insist that this case falls within this narrow exception because it involves "an agency's decision not to prosecute or enforce." *Heckler*, 470 U.S. at 831. This argument, however, ignores the nature of the Prescription Drug and Safe Harbor Policies. These policies categorically changed the TiC Rule. The Prescription Drug Policy effectively revoked the requirement to report prescription-drug price information by foreclosing enforcement. *See* FGA MSJ (Doc. 33) at 18-20. Similarly, the Safe Harbor Policy categorically provides that regulated parties will be treated as if they are in compliance if they provide information other than the dollar amounts required by the TiC Rule. *See id.* at 20-21. FGA challenged these policy changes.

The exception for an agency's decision not to prosecute or enforce does not apply to categorical policy changes—even if an agency labels its new policy a "nonenforcement policy." *See OSG Bulk Ships, Inc. v. United States*, 132 F.3d 808, 812 (D.C. Cir. 1998) ("[N]onenforcement decisions are generally unreviewable … [but] a general enforcement policy is subject to review."). Instead, this exception reaches only decisions not to initiate or pursue a

particular enforcement action. The Agencies own authorities confirm this conclusion, as none of those decisions involved a categorical decision to halt all enforcement of a rule without going through the APA's required procedures. Most of the Agencies' cases involved a request for an agency to initiate a specific enforcement proceeding. *See, e.g.*, *Heckler*, 470 U.S. at 824 (discussing request by death-row inmates for "the FDA to take various investigatory and enforcement actions to prevent" alleged violations); *Fla. Defs. of Env't v. USFS*, 2021 WL 4944806, at *5, 7 (11th Cir.) (challenging a "decision not to take enforcement action against the state for its unauthorized use of national forest land"). They also cite one case that involved a decision not to initiate a rulemaking to designate critical habitat for the Florida panther was committed to agency discretion. *Conservancy of Sw. Fla. v. USFWS*, 677 F.3d 1073, 1073 (11th Cir. 2012). That decision involved a similarly narrow and case-specific assessment by the agency. *See id.* More importantly, it reached its conclusion because of the absence of "any standard" to review the agency decision. *Id.* at 1082.

The Agencies also ignore binding precedent holding that an agency's affirmative action that permits conduct that would otherwise be prohibited is reviewable. In *Animal Legal Defense Fund v. U.S. Department of Agriculture*, the government argued that the decision whether to renew an aquarium's license was committed to agency discretion. 789 F.3d at 1214. The Eleventh

Circuit rejected this argument, explaining that the plaintiff did not "seek an injunction requiring USDA to initiate enforcement proceedings against Seaquarium," but instead sought an "order setting aside USDA's affirmative decision to renew Seaquarium's license." *Id.* at 1214-15. The same is true here. FGA is not seeking an injunction to require the Agencies to institute any enforcement proceeding. It is instead seeking a decision setting aside the Agencies' Prescription Drug and Safe Harbor Policies that effectively remove requirements of the TiC Rule.

Finally, the Agencies argue that the ACA gives them discretion to enact the Prescription Drug and Safe Harbor Policies because it requires disclosure of "information as determined appropriate by the Secretary." 42 U.S.C. §18031(e)(3); *see* Opp (Doc. 39) at 21-22. But that's an argument for a different case. FGA has not brought a claim about the substantive scope of the Secretary's authority to decide what information must be disclosed. This case is about whether—having determined in the TiC Rule what information must be disclosed to the public—the Agencies can discard those requirements without following the APA's procedures. The Agencies do not suggest that any statute gives them discretion to disregard the APA's procedural requirements.

III. The Agencies' challenged policies are final agency action.

The Agencies' final non-merits argument is that its challenged policies are not final agency action because they are tentative and without legal effect. *See* Opp. (Doc. 39) at 22-24. This argument is contradicted by undisputed facts.

To begin, a "substantive rule" is "by definition" a "final agency action." *Texas v. EEOC*, 933 F.3d 433, 441 (5th Cir. 2019) (cleaned up); *see Cohen v. United States*, 578 F.3d 1, 6 (D.C. Cir. 2009), *vacated in part on other grounds*, 599 F.3d 652 (D.C. Cir. 2010). As FGA demonstrated in its motion for summary judgment, the Prescription Drug and Safe Harbor Policies are substantive rules. *See* FGA MSJ (Doc. 33) at 17-21.

This conclusion is confirmed by the two-part test for final agency action. That test looks to whether an action "mark[s] the consummation of the agency's decisionmaking process" and whether "the action [is] one by which rights or obligations have been determined, or from which legal consequences will flow." *Canal A Media Holdings, LLC v. USCIS*, 964 F.3d 1250, 1255 (11th Cir. 2020) (cleaned up). Courts take a "pragmatic" and "flexible" approach to this inquiry. *EEOC*, 933 F.3d at 441.

Applying this test, both policies are final agency action. The announcement of a decision to suspend a regulatory requirement or to create a safe harbor from a rule's enforcement is the consummation of the decision to amend a regulation. *See Clean Air Council v. Pruitt*, 862 F.3d 1, 6-7 (D.C. Cir.

2017); *Scenic Am. v. DOT*, 836 F.3d 42, 56 (D.C. Cir. 2016). And legal consequences flow from that decision because there is no longer any danger of enforcement once the official announcement as been made. *See id.*; *see also EEOC*, 933 F.3d at 441 ("[A]n agency's guidance documents binding it and its staff to a legal position produce legal consequences or determine rights and obligations, thus meeting the second prong of *Bennett*.").

The Agencies respond that these policies are just "temporary" because they were implemented "pending further rulemaking." Pl.'s Ex. C at 1; *see* Opp. (Doc. 39) at 22-23. This argument is inapplicable for the Safe Harbor Policy, which the Agencies never said would be revoked after a future rulemaking. *See* Pl.'s Ex. D. And it doesn't fit the facts of the Prescription Drug Policy. That Policy was announced on August 20, 2021, and reiterated on April 19, 2022. Pl.'s Exs. C & D. But more than two years later there is not even a rumor of a future rulemaking, *see* Pl.'s Ex. E (Ingram Decl.) at 5 ¶12. The Agencies insist that "although they have not yet proposed … a new rule on this subject, doing so remains [their] intent." Opp. (Doc. 39) at 23. But "'trust us' is a poor operating principle for government." *Chehazeh v. Att'y Gen. of U.S.*, 666 F.3d 118, 130 (3d Cir. 2012). And the most recent regulatory agenda says nothing about it—there is no pending Notice of Proposed Rulemaking, no pending Advanced Notice of Proposed Rulemaking, and not even a pending Request For Information. *See* OIRA, HHS Rule List – Spring 2023, https://bit.ly/3qBhn0e.

Thus, at bottom, the Agencies ask this Court to treat the Policies as non-final because they might be changed through rulemaking at some unknown point in the future.

Treating policies as non-final because they might be changed by some future rulemaking would render the APA's finality requirement nonsensical. Agencies are always free to change their policies consistent with the requirements of the APA and their substantive authority. So the Agencies theory would mean that the vast majority of government policies are never really final.

The Agencies' only other argument is that parties are still bound by the requirements of the TiC Rule because the Policies include boilerplate language saying that they are "intended only to provide clarity to the public regarding existing requirements under the law," they "do not have the force and effect of law," and they "are not meant to bind the public in any way." Pl.'s Ex. C at 1. This argument is also inapplicable to the Safe Harbor Policy. *See* Pl.'s Ex. D. In any event, this type of boilerplate language does not control whether a document is final agency action. *See, e.g.*, *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1023 (D.C. Cir. 2000); *Philip Morris USA Inc. v. FDA*, 202 F. Supp. 3d 31, 46-47 (D.D.C. 2016). When assessing agency action, courts look to the actual effect of the agency's action. *See Azar v. Allina Health Servs.*, 139 S.Ct. 1804, 1812 (2019); *CropLife*, 329 F.3d at 883. An agency's characterization of

its action is "relevant" only to the extent that it clarifies the effect of its action. *Warshauer v. Solis*, 577 F.3d 1330, 1337 (11th Cir. 2009). But courts disregard this kind of boilerplate when it is inconsistent with the effect of an agency action. *See, e.g.*, *Chamber of Com. v. OSHA*, 636 F.2d 464, 468 (D.C. Cir. 1980) ("[B]ureaucratic boilerplate often obscures the true purpose."); *Hemp Indus. Ass'n v. DEA*, 333 F.3d 1082, 1087 (9th Cir. 2003) ("While the DEA has characterized its rule as an interpretive rule, the court need not accept the agency characterization at face value.").

The Agencies suggestion that the Policies have not had legal consequences fails for two reasons. First, as explained, the policies have permitted regulated parties to ignore the requirements of the TiC Rule with impunity. Second, even if the Agencies could show that private parties were still bound, the Agencies have given up their discretion to enforce the requirements of the TiC Rule by categorically disclaiming enforcement. And an action that limits an agency's ability to exercise enforcement discretion on a case-by-case basis has a "clear legal effect" on regulated parties. *Scenic Am.*, 836 F.3d at 56; *see also Nat'l Min. Ass'n*, 589 F.3d at 1371.

IV. The Prescription Drug and Safe Harbor Policies are legislative rules.

FGA has shown that the Prescription Drug and Safe Harbor Policies are legislative rules because they effectively amend the TiC Rule. They remove the obligation to report prescription drug prices at all and waive the requirement

to report some in-network items and services in dollar amounts, despite the Rule's compliance date of January 1, 2022. *See* MSJ (Doc. 33) at 17-21. The Prescription Drug Policy indefinitely "defer[s]" the TiC Rule's obligation to provide prescription-drug price information by January 1, 2022. *Compare* 45 C.F.R. §147.212 *with* Pl.'s Ex. C at 1. This endless delay is "tantamount to … revoking" it and is therefore a substantive change with "the status of law." *Clean Air Council*, 862 F.3d at 6. Similarly, the Safe Harbor Policy creates a new regulatory "safe harbor" from reporting covered in-network rates in dollar amounts in some situations. *Compare* 45 C.F.R. §147.212 *with* Pl.'s Ex. D. The creation of this safe harbor "withdraws some of the discretion" of the Agencies and has a "clear legal effect" on regulated parties. *Scenic Am.*, 836 F.3d at 56; *see United States v. Hawkes*, 578 U.S. 590, 598-99 (2016) (describing the consequences of "creating a … safe harbor").

Despite these real-world consequences, the Agencies argue that the Prescription Drug and Safe Harbor Policies are merely "general statements of policy." *See* Opp. at 26-28. But they cannot force the Policies into that category. Courts "focus[] on the effects of the agency action" when deciding whether it is a rule or a general statement of policy. *CropLife*, 329 F.3d at 883. An action that "establishes a binding norm" is a rule. *Nat'l Min. Ass'n*, 589 F.3d at 1371. "The key inquiry … is the extent to which the challenged policy leaves the agency free to exercise its discretion to follow or not to follow that general policy

in an individual case." *Id.* An action has "established a binding norm" and is a legislative rule unless "the agency remains free to consider the individual facts in the various cases that arise." *Id.*

The Agencies never mention the "key inquiry," let alone try to meet it. Opp. at 26-28. For good reason. The Policies refute any argument that the Agencies retain the kind of case-by-case discretion that a general statement of policy requires. *See* Pl.'s Ex. C at 1-2 (categorically "defer[ring] enforcement of" the "requirement" to "publish machine-readable files relating to prescription drug pricing"); Pl.'s Ex. D at 2 (announcing a categorical "safe harbor" from the requirement to report certain costs in dollar amounts).[1]

Since they have nothing to say about the key inquiry, the Agencies turn to three "[a]dditiona[l]" factors that "courts have looked at"—"(1) the agency's expressed intentions as reflected by its characterization of the statement, (2) whether the statement was published in the Federal Register or the Code of Federal Regulations, and (3) whether the action has binding effects on private parties." *Nat'l Min. Ass'n.*, 589 F.3d at 1371; *see* Opp. (Doc. 39) at 26-28. They

[1] In their Statement of Facts, the Agencies assert that the Policies "are not binding on the government." Opp. (Doc. 39) at 7 ¶5. But the only support they offer for this is the same boilerplate about how the Policies "do not have the force and effect of law and are not meant to bind *the public* in any way." *Id.* (emphasis added). Even on its face, that boilerplate disclaims a binding effect on the public, not the Agencies. And the Agencies never make any attempt to reconcile their assertion that they are not bound with the categorical language included in the Policies.

rely on a formulaic application of these additional considerations to argue that the Policies are only general statements. *See* Opp. (Doc. 39) at 26-28. Of course, this approach could not save a policy where there can be no dispute that the Agencies have not retained case-by-case discretion. *See Nat'l Min. Ass'n*, 589 F.3d at 1371. But in any event, the Agencies fail on their own terms.

The first and third factors confirm that the Prescription Drug and Safe Harbor Policies are legislative rules. To start, the Policies' language shows their intended effect, which was to make a binding amendment of the TiC Rule with legal effect for the Agencies and third-party plans and issuers. The Prescription Drug Policy declares that the Agencies "will defer" the prescription drug price disclosure requirement indefinitely. Pl.'s Ex. C at 1-2. The Safe Harbor Policy similarly declares that it is "providing an enforcement safe harbor" from reporting certain in-network pricing information in "dollar amounts. Pl.'s Ex. D at 2. This kind of categorical and mandatory language is indicative of a legislative rule. *See Cmty. Nutrition Inst. v. Young*, 818 F.2d 943, 946 (D.C. Cir. 1987) (explaining that "the choice between the words 'will' and 'may'" can be "decisive"); *Nat'l Min. Ass'n*, 589 F.3d at 1372 (looking to "advisory and permissive language" to support finding that action was a general statement of policy). Consistent with that language, these policies created the legal right for plans and issuers not to comply with provisions of the TiC Rule.

That leaves only one factor to weigh in favor of the Agencies—their failure to publish the policies in the Federal Register. But this factor is far from the "most important" since the key inquiry is whether the Policies have the "force of law." *Gen. Elec. Co. v. EPA*, 290 F.3d 377, 382 (D.C. Cir. 2002). The Agencies cannot save their invalidly promulgated Policies by failing to publish them.

The Agencies last-ditch effort is to assert that the Policies are not new rules because the TiC Rule "remains in full effect." Opp. (Doc. 39) at 28. But even if it were true that regulated parties should still comply with the TiC Rule, that would not save the Policies. As explained, the "key inquiry" looks to whether the Agency has limited its ability to exercise case-by-case discretion. *Nat'l Min. Ass'n*, 589 F.3d at 1371. Suggesting that third parties should comply even though the Agencies have renounced enforcement of the TiC Rule's requirements evades that inquiry.

The Agencies' argument also blinks reality. The Agencies announced categorically that they would not enforce the TiC Rule's requirements to report prescription drug-price information and to report certain information in dollar amounts. Unsurprisingly, plans and issuers understood that they were no longer required to report the information covered by these policies. *See, e.g.*, Pl.'s Ex. E (Ingram Decl.) at 5 ¶12. And they are refusing to provide this information because of the Agencies' policies. *See, e.g.*, United Healthcare,

Transparency in Coverage Rule, perma.cc/7P4M-4GJC; Premera Blue Cross, *Transparency in Coverage Rule*, perma.cc/W2FK-E76U. Any doubt about this is removed by the context in which the Prescription Drug Policy took effect. Industry groups sued the Agencies challenging the obligation to report prescription drug prices shortly before the TiC Rule was scheduled to go into effect. *See Chamber of Com. v. HHS*, 6:21-cv-309, Doc. 1 (E.D. Tex.). They dropped that suit after the Agencies responded by instituting Prescription Drug Policy, since they had obtained the relief that they wanted. *See id.*, Doc. 12.[2]

V. FGA is entitled to all the relief it requested.

The Agencies' do not appear to dispute that FGA is entitled to declaratory relief and vacatur of the Prescription Drug and Safe Harbor Policies if it prevails. *See* Opp. (Doc. 39) at 28-29.[3] But they assert that FGA

[2] The Agencies fault FGA for relying on the now-defunct *Paralyzed Veterans* doctrine, which required important changes in the interpretation of a substantive rule to go through notice-and-comment procedures. Opp. (Doc. 39) at 24-25. But FGA does not rely on the *Paralyzed Veterans* doctrine for an obvious reason—the Prescription Drug and Safe Harbors are not interpretations of the TiC Rule. Instead, these Policies have the effect of wholesale revocations and alternative mechanisms of compliance of some of the TiC Rule's requirements. As FGA noted in its complaint, the Supreme Court's decision overruling *Paralyzed Veterans* recognized that the APA "mandate[s] that agencies use the same procedures when they amend or repeal a rule as they used to issue the rule in the first instance." *Perez v. Mortgage Bankers Ass'n*, 575 U.S. 92, 101 (2015).

[3] The Agencies include a footnote stating that the APA does not authorize relief beyond the parties to the case. *See* Opp. (Doc. 39) at 28 n.9. They never explain

should not receive injunctive relief. *Id*. at 29. The Agencies' arguments collapse once this Court has concluded that FGA should prevail on the merits.

The Agencies first argue that FGA has not shown irreparable harm because it "simply restate[s] its theory of Article III injury," but FGA "has suffered no legally cognizable harm." *See* Opp. (Doc. 39) at 29. But as explained, FGA's has suffered an informational injury. *Supra* 4-13. And the Agencies do not even try to dispute that the harm to FGA is irreparable. *See* Opp. at 29.

The Agencies offer a similar circular argument on the public interest and balance of equities. *See* Opp. (Doc. 39) at 29. They do not dispute that there is no public interest in the perpetuation of unlawful agency action. *See id.*; FGA MSJ (Doc. 33) at 25. Their only response is that they *are* following the law—which is wrong. *Supra* 23-28.

The Agencies' last argument is that FGA's "remedial theory is inconsistent with its merits theory." *See* Opp. (Doc. 39) at 29-30. Specifically, the Agencies claim that FGA wants the Court to enjoin the challenged policies *on the merits* to prevent the Agencies from ever amending the TiC Rule through

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how this statement should apply in this case. In any event, they confirm that the Eleventh Circuit has recognized that "vacatur … is the ordinary APA remedy." *Id.* (quoting *Black Warrior Riverkeeper, Inc. v. U.S. Army Corps of Eng'rs*, 781 F.3d 1271, 1290 (11th Cir. 2015)). "Vacatur … 'make[s] void' the thing vacated." *United States v. Jackson*, 995 F.3d 522, 525 (6th Cir. 2021) (quoting Black's Law Dictionary, *Vacate* (11th ed. 2019)).

notice and comment. Not so. FGA has asked the Court for "[a]n order permanently enjoining the Agencies from implementing the Non-Enforcement Policies" in violation of the APA's procedural requirements as detailed in FGA's complaint and claim for relief. Compl. (Doc. 1) at 23-25. FGA has not asked for injunctive relief that would stop the Agencies from following the proper procedures.

CONCLUSION

The Court should thus grant FGA's motion for summary judgment and deny the Agencies' motion for either dismissal or summary judgment.

Dated: September 1, 2023

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I certify that on September 1, 2023, I filed this document on the CM/ECF filing system, which will notify all registered counsel.

/s/ *Michael A. Sasso*