UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

Plaintiff,

v.

XAVIER BECERRA, et al.,

Defendants.

Civil Action No. 1:21-cv-1395 (CJN)

MEMORANDUM OPINION

A trade association known as Pharmaceutical Research and Manufacturers of America, or PhRMA for short, challenges a final rule promulgated by the Department of Health and Human Services relating to drug rebates under Medicaid. *See generally* Compl., ECF No. 1. The Government argues that PhRMA lacks Article III standing for two reasons. *Id.* First, as the Government sees it, PhRMA has failed to satisfy a fundamental prerequisite to establish associational standing: identifying in its Complaint at least one member of the association that has standing to sue. *Id.* Second, the Government contends that PhRMA fails to demonstrate that any member will suffer Article III injury from the final rule. *Id.* The Court denies the Government's motion for the reasons that follow.

I. Background

Medicaid, "a cooperative federal-state program" established in 1965, "provides federal funding for state medical services to the poor." *Frew ex rel. Frew v. Hawkins*, 540 U.S. 431, 433 (2004). A state need not participate in the Medicaid program. *Id.* Yet when a state does, it must

offer Medicaid plans that meet certain federal statutory and regulatory requirements to receive federal funds. *See Cookeville Reg'l Med. Ctr. v. Leavitt*, 531 F.3d 844, 845 (D.C. Cir. 2008).

In 1990, Congress passed legislation that permitted participating states to begin offering outpatient prescription drug coverage as part of their Medicaid plans. *See* 42 U.S.C. § 1396d(a)(12); *Pharm. Rsch. & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 652 (2003). To manage the costs of covering prescription drugs, Congress conditioned receipt of federal funds on a cost-saving measure that requires drug manufacturers to participate in something called the Medicaid Drug Rebate Program. *See Walsh*, 538 U.S. at 649.

The Rebate Program specifies that for a prescription drug to be eligible for federal Medicaid dollars, its manufacturer must pay rebates to "participating states to reduce the costs of dispensed outpatient drugs that a state expends under its Medicaid plan." *Mallinckrodt ARD LLC v. Verma*, 444 F. Supp. 3d 150, 154, 158 (D.D.C. 2020). The idea behind the Rebate Program is straightforward: ensure that state Medicaid programs receive the same discounts that manufacturers provide to commercial purchasers. To achieve that end, the Medicaid statute provides that the amount a drug manufacturer must rebate to the states is the difference between a drug's "average manufacturing price" and the lowest available price for the drug on the commercial market, which is known as the "best price." 42 U.S.C. § 1396r-8(c)(1); 42 U.S.C. § 1396r(c)(1)(C).

Calculating the best price gets tricky when considering recent developments. Over the last several decades, high out-of-pocket costs in the form of large deductibles and co-payments for patients with commercial health insurance plans have kept some of those patients from purchasing the medications their doctors have prescribed. *See* Compl. ¶¶ 32–33. These "health-plan-imposed costs," as PhRMA sees it, "have a rationing effect" in that "they deter patients from purchasing

drugs" that they otherwise would have purchased but-for the high associated costs. *Id.* ¶ 3. In response, drug manufacturers offer financial assistance that helps patients with commercial health insurance plans afford the out-of-pocket costs their insurers set for certain drugs. *Id.* ¶ 2. These financial support programs are known as "patient assistance programs." *Id.*

According to PhRMA, commercial health insurers have caught on to the patient assistance programs and, seeking to pocket some of the financial support, have devised schemes known as "accumulator adjustment programs." *Id.* PhRMA alleges that accumulator adjustment programs enable insurers, working with companies that manage prescription drug benefits on their behalf, to refuse to count toward satisfaction of a patient's annual deductible and co-payment a drug manufacturer's financial assistance to that patient. *Id.* ¶¶ 4–5. From PhRMA's perspective, the accumulator adjustment programs result in "prescription abandonment, non-adherence to prescribed medication regimens, poor health outcomes, and unnecessary medical spending by patients." *Id.* ¶ 39.

In June 2020, the Department of Health and Human Services took up this issue. HHS published that month a proposed rule addressing, among other things, the impact of accumulator adjustment programs on the "best price" determination. *See Revising Medicaid Drug Rebate and Third Party Liability Requirements*, 85 Fed. Reg. 37286 (June 19, 2020). The proposed rule sought to revise the agency's regulations to require that a drug manufacturer ensure that "the full value of the assistance or benefit is passed on to the . . . patient" before the manufacturer may exclude the discount from its "best price" calculation. *Id.* at 37299. Put differently, manufacturers would have to include the value of assistance they provide to patients through the patient assistance programs in their best price determinations, unless they ensure that the full value of their assistance stays

with the patient and is not captured by the patient's health insurer through an accumulator adjustment program. *Id.*; 42 C.F.R. § 447.505(c)(8)-(11).

PhRMA submitted comments expressing its opposition to the proposed rule. *See* Compl. ¶ 42. The association noted that it is "a voluntary, non-profit organization representing the country's leading research-based pharmaceutical and biotechnology companies," and that the proposed rule "could potentially reduce the availability of patient assistance, which could, in turn, inhibit the ability of patients to pay their out-of-pocket costs." *Id.* Several of PhRMA's members submitted comments agreeing with the association's views and voicing opposition to the proposed rule.[1]

After reviewing the public comments, HHS adopted its proposal in a final rule published in December 2020. *See Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements*, 85 Fed. Reg. 87,000 (Dec. 31, 2020). The agency noted that the comments from drug manufacturers spanned an array of concerns, including (1) the rule's impact on patients, (2) the agency's legal authority to enact the rule, (3) mechanisms to assist manufacturers with compliance with the rule, (4) the viability of manufacturer assistance programs on an ongoing basis, and (5) the affect of the rule on other programs. *Id.* at 87049. In addition to addressing those concerns, the agency also explained that it would delay the rule's launch date until January

[1] Amgen, for instance, voiced its opposition to the "proposed modifications to the regulatory exclusions of manufacturer-sponsored co-payment assistance programs . . . because the proposal would harm patients, is based on incorrect factual assumptions, has no basis in the [] statute, and could not be operationalized by manufacturers even if finalized." Administrative Record ("AR"), ECF No. 19-1 at 9169. Bristol-Myers Squibb likewise commented that it opposed the "proposal to require manufacturers to include in their calculation of Best Price assistance provided to patients unless they can 'ensure' that the full value of this assistance goes solely to patients" in part because the "proposal would discourage manufacturers from providing patient assistance, to the detriment of patients." AR at 35289. And Eli Lilly noted its position that the proposed rule would prove "harmful to patients, could inhibit participation in [Medicaid programs], and is incompatible with the Medicaid statute." AR at 43419. The company further remarked that it did "not believe that subsequent attempts by others in the payment and supply chain to effectively 'steal' [] benefits from patients should somehow render those patient benefits constructive price concessions." *Id.*

1, 2023, in light of industry concerns about implementing the rule during the COVID-19 pandemic. *Id.* at 87053.

PhRMA filed this lawsuit soon after, asserting that the rule exceeds the agency's statutory authority and runs afoul of the Administrative Procedure Act. *See* Compl. ¶ 71; 5 U.S.C § 706(2)(A), (C). In particular, PhRMA alleges that the rule forces its members to "either risk paying higher Medicaid rebates . . . or forego offering financial assistance to patients," *id.* ¶ 65, and that it creates a new compliance burden on drug manufacturers, *id.* ¶ 66. PhRMA claims that the rule leaves its members with three choices: (1) design and implement operational changes to their patient assistance programs to ensure that the full value of the assistance stays with the patient rather than being passed to commercial health insurers, (2) retain their current assistance programs and accept the additional compliance costs that the rule imposes, or (3) stop offering patient assistance altogether, leaving some patients unable to afford the out-of-pocket costs required for manufacturers' products under their insurance plans. *See* Compl., ¶¶ 45–46.

The Government has moved to dismiss PhRMA's Complaint, arguing that PhRMA lacks Article III standing. *See* Def.'s Mot.

II. Legal Standard

Federal Rule of Civil Procedure 12(b)(1) requires dismissal of a complaint if the Court lacks "subject-matter jurisdiction." *See* Fed. R. Civ. P. 12(b)(1). When ruling on a motion filed under Rule 12(b)(1), the Court must "treat the complaint's factual allegations as true" and must afford the plaintiff "the benefit of all inferences that can be derived from the facts alleged." *Delta Air Lines, Inc. v. Export–Import Bank of U.S.*, 85 F. Supp. 3d 250, 259 (D.D.C. 2015) (quotation omitted). Although the Court need not accept inferences unsupported by the factual allegations, the Court "may consider such materials outside the pleadings as it deems appropriate to resolve

the question whether it has jurisdiction to hear the case." *XP Vehicles, Inc. v. Dep't of Energy*, 118 F. Supp. 3d 38, 56 (D.D.C. 2015) (quotation omitted). The Court may even consider the administrative record to determine whether the plaintiff has standing. *Am. Chemistry Council v. Dep't of Transp.*, 468 F.3d 810, 819 (D.C. Cir. 2006); *Haase v. Sessions*, 835 F.2d 902, 906 (D.C. Cir. 1987) (quotation omitted) ("In 12(b)(1) proceedings, it has been long accepted that the judiciary may make appropriate inquiry beyond the pleadings to satisfy itself on authority to entertain the case.").

III. Associational Standing

The Constitution of the United States limits the "judicial Power" to resolving "Cases" and "Controversies." U.S. Const. art. III, § 2. A plaintiff must establish standing to satisfy the case-or-controversy requirement. *See Lance v. Coffman*, 549 U.S. 437, 439 (2007) (per curiam). To establish standing, a plaintiff must demonstrate injury in fact, causation, and redressability. *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016); *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2203 (2021); *see also* Ann Woolhandler & Caleb Nelson, *Does History Defeat Standing Doctrine?*, 102 Mich. L. Rev. 689 (2004).

In this case, PhRMA seeks to invoke "associational standing." Associational standing refers to the doctrine that "sometimes permits an entity to sue over injuries suffered by its members even when . . . the entity itself alleges no personal injury." *Ass'n of Am. Physicians & Surgeons v. United States Food & Drug Admin.*, 13 F.4th 531, 537 (6th Cir. 2021) (applying the associational standing doctrine but questioning its basis and current framework).

For an association to bring suit on behalf of its members, it must meet three requirements. *Am. Chemistry Council v. Dep't of Transp.*, 468 F.3d 810, 815 (D.C. Cir. 2006). First, the association must show that the "interests" that the suit "seeks to protect are germane to the

organization's purpose." *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977). Second, it must show that "neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Id.*[2] And third, the association must show that "its members would otherwise have standing to sue in their own right." *Id.*; *Nat. Res. Def. Council v. E.P.A.*, 489 F.3d 1364, 1370 (D.C. Cir. 2007).[3]

The third requirement gives rise to the most judicial scrutiny and requires courts "to vigilantly ensure that an association's members have incurred a personal injury." *Ass'n of Am. Physicians & Surgeons*, 13 F.4th at 534. To satisfy the third requirement, the association must "identify a member who has suffered (or is about to suffer) a concrete and particularized injury from the defendant's conduct." *Id.* The remedy sought by the association must also redress the alleged harm. *Id.*; *see also* Brandon L. Garrett, *The Constitutional Standing of Corporations*, 163 U. Pa. L. Rev. 95, 138 (2014) (noting the importance of the association's requested remedy to the associational standing analysis).

IV. PhRMA Has Standing to Challenge the Final Rule

The Government asserts two reasons why PhRMA lacks standing. First, the Government argues that PhRMA has failed "to establish associational standing because it does not identify [by name in its Complaint] any specific members who have standing to challenge the" rule. Def.'s

[2] The Government does not challenge either the first or second requirements. *See* Def.'s Mot at 14. Nor could it. PhRMA sets out to protect interests germane to the association's purpose and does so via a facial challenge to a final rule based in large part on the administrative record.

[3] An association "may have standing in its own right to seek judicial relief from injury to itself and to vindicate whatever rights and immunities the association itself may enjoy." *Warth v. Seldin*, 422 U.S. 490, 511 (1975). An association, in other words, has standing when the challenged action itself injures the association's economic or missional interests. *See* Katherine Mims Crocker, *An Organizational Account of State Standing*, 94 Notre Dame L. Rev. 2057, 2069 (2019). This form of standing is known as organizational standing rather than associational standing. *Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379 n.19 (1982) ("[O]rganizations are entitled to sue on their own behalf for injuries they have sustained."). PhRMA has made clear that it does not rely on organizational standing to sue on its own behalf. *See* Pl.'s Response to Def.'s Mot. to Dismiss, ECF No. 16 at 13 n.2; *see California v. Texas*, 141 S. Ct. 2104, 2116 (2021).

Mot. at 14. Second, assuming that PhRMA overcomes the first hurdle, the Government contends that the association's "allegations would still be insufficient because the harms it asserts are not cognizable and not fairly traceable to the" rule. *Id.* at 16.

When it comes to the Government's first argument, it is hardly clear when an association has made sufficiently "specific allegations establishing that at least one identified member had suffered or would suffer harm." *Summers v. Earth Island Inst.*, 555 U.S. 488, 498 (2009). As the Government recognizes, courts "in this district have split on the issue of whether they must require an association to identify an injured member by name at the motion-to-dismiss stage of litigation." Def.'s Reply in Supp. of Mot. to Dismiss, ECF No. 18 at 7 n.2. Some courts require that an association identify *by name* in its complaint one of its members that has standing. *See Conf. of State Bank Supervisors v. Off. of Comptroller of Currency*, 313 F. Supp. 3d 285, 298 (D.D.C. 2018); *W. Wood Preservers Inst. v. McHugh*, 292 F.R.D. 145, 148 (D.D.C. 2013). Others require less, and permit suits to proceed even if the association does not identify "specific, injured members by name" in its complaint. *Ranchers-Cattlemen Action Legal Fund, United Stockgrowers of Am. v. United States Dep't of Agric.*, No. CV 20-2552 (RDM), 2021 WL 4462723, at *7 (D.D.C. Sept. 29, 2021); *Ass'n of Am. Physicians & Surgeons, Inc. v. Sebelius*, 901 F. Supp. 2d 19, 31 (D.D.C. 2012) ("[T]he plaintiff need not identify an affected member by name."). Courts of Appeals have also applied different tests. *See Bldg. & Const. Trades Council of Buffalo, New York & Vicinity v. Downtown Dev., Inc.*, 448 F.3d 138, 145 (2d Cir. 2006) ("[T]he defendants cite to no authority—nor are we aware of any—that supports the proposition that an association must 'name names' in a complaint in order properly to allege injury in fact to its members."); *Am. Coll. of Emergency Physicians v. Blue Cross & Blue Shield of Georgia*, 833 F. App'x 235, 241 n.8 (11th Cir. 2020) (per curiam) ("[R]equiring specific names at the motion to dismiss stage is

inappropriate."); *Hancock Cty. Bd. of Suprs v. Ruhr*, 487 F. App'x 189, 198 (5th Cir. 2012) ("We are aware of no precedent holding that an association must set forth the name of a particular member in its complaint in order to survive a Rule 12(b)(1) motion to dismiss based on a lack of associational standing."). *But see S. Walk at Broadlands Homeowner's Ass'n, Inc. v. OpenBand at Broadlands, LLC*, 713 F.3d 175, 184 (4th Cir. 2013); *New Jersey Physicians, Inc. v. President of U.S.*, 653 F.3d 234, 241 (3d Cir. 2011); *Waskul v. Washtenaw Cty. Cmty. Mental Health*, 900 F.3d 250, 257 (6th Cir. 2018); *Prairie Rivers Network v. Dynegy Midwest Generation, LLC*, 2 F.4th 1002, 1010 (7th Cir. 2021) ("On the face of PRN's complaint, we cannot assure ourselves that at least one individual member—and not those individual members as a group—has standing to sue.").

So must PhRMA identify by name in its Complaint at least one of its members that has standing to challenge the final rule? The Court concludes that when an association brings a lawsuit on behalf of its members the complaint, including material incorporated by reference (as well the administrative record), must identify by name at least one member that has standing to challenge the defendant's conduct. An association therefore need not "name names" within the four corners of the complaint itself. *See Fac. v. New York Univ.*, 11 F.4th 68, 76 (2d Cir. 2021) (noting that "[i]t is possible to be more specific—even if 'naming names' and submitting individual affidavits is not required"). But the complaint, together with materials incorporated by reference, must provide the Court with sufficient information to identify by name at least one member that possesses standing to sue. *Ctr. for Biological Diversity v. Nishida*, No. CV 21-119 (RDM), 2021 WL 827189, at *2 (D.D.C. Mar. 4, 2021); *Am. Petroleum Inst. v. Johnson*, 541 F. Supp. 2d 165, 176 (D.D.C. 2008). "[C]ryptic" reference to the identity of members of an association will not

suffice. *Coal. for ICANN Transparency Inc. v. VeriSign, Inc.*, 452 F. Supp. 2d 924, 934 (N.D. Cal. 2006).

PhRMA satisfies this test here. The Complaint includes a link to PhRMA's website, *see* Compl. ¶ 18, which lists its members, including Eli Lily, Bristol Myers Squibb, and Amgen, *see* https://www.phrma.org/About. Though none of those companies is expressly mentioned in the Complaint, the administrative record and the comments referenced in the Complaint tell a different story.[4] Eli Lily, Bristol Myers Squibb, and Amgen, among others, commented on the agency's proposed rule and stated that each would be harmed if the rule were to go into effect. *See* AR 035289 (noting that Bristol Myers Squibb warned the agency that the proposed rule could "discourage manufacturers from providing patient assistance"); AR 043419 (showing that Eli Lilly explained that the proposed rule would "[p]enaliz[e] manufacturers who seek to ameliorate deficiencies in commercial insurance benefit designs by forcing them to give away product to Medicaid"); AR 009179 (demonstrating that Amgen told the agency that compliance with the proposed rule would be "impossible to operationalize" from a compliance perspective). Based on those comments, PhRMA has explained how the "challenged agency action affects or injures one or more of its members," has identified at least one of those members, and has pointed to "evidence

[4] PhRMA references in its Complaint comments submitted in response to the proposed rule. *See* Compl. ¶ 44 (referencing "many comments received [by the agency] sounding the alarm about the [proposed rule]"); *Strumsky v. Washington Post Co.*, 842 F. Supp. 2d 215, 218 (D.D.C. 2012) (quotation omitted) (noting that "a document need not be mentioned by name to be considered 'referred to' or 'incorporated by reference' into the complaint"); *Mpoy v. Rhee*, 758 F.3d 285, 291 n.1 (D.C. Cir. 2014). Not only did PhRMA reference the comments in the Complaint, but they were submitted during the rulemaking process and are accessible to the public. What's more, the agency has full awareness of the comments referenced in the Complaint. One might even say that the public comments and the agency's response to them qualify as public records. And "[p]ublic records are subject to judicial notice on a motion to dismiss when referred to in the complaint and integral to the plaintiff's claim." *Owens v. BNP Paribas, S.A.*, 897 F.3d 266, 273 (D.C. Cir. 2018); *Kaspersky Lab, Inc. v. United States Dep't of Homeland Sec.*, 909 F.3d 446, 464 (D.C. Cir. 2018) (quotation omitted) ("A federal court may take judicial notice of a fact that is not subject to reasonable dispute if it . . . can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned."). Plus, the comments appear in the administrative record, which the Court may consider when deciding whether the plaintiff has standing. *Am. Chemistry Council*, 468 F.3d at 819.

in the administrative record" that shows the challenged agency action actually affects the identified member. *Hearth, Patio & Barbecue Ass'n v. EPA*, 11 F.4th 791, 803 (D.C. Cir. 2021). PhRMA therefore has associational standing to pursue this lawsuit on its members behalf. *Sierra Club v. E.P.A.*, 292 F.3d 895, 900 (D.C. Cir. 2002).[5]

But are the alleged harms to PhRMA's members sufficient to satisfy Article III? PhRMA asserts two harms allegedly attributable to the final rule. First, it claims that its members must "either risk paying higher Medicaid rebates . . . or forego offering financial assistance to patients." Compl. ¶ 65. Second, it claims that the rule will impose a "new compliance burden on manufacturers." *Id.* ¶ 23.

These allegations assert cognizable harms that can be traced to the final rule. If the rule goes into effect, manufacturers will have to either discontinue their financial assistance programs or risk paying higher Medicaid rebates. That choice constitutes an injury-in-fact traceable to the agency's rule sufficient to establish Article III standing. *See Grocery Mfrs. Ass'n v. E.P.A.*, 693 F.3d 169, 178 (D.C. Cir. 2012) (noting that the costs accompanying an agency's rule can give rise to Article III standing). Even HHS in the final rule acknowledged that "patient assistance programs

[5] The Complaint here is quite similar to the one in *Pharmaceutical Research and Manufacturers of America v. Walsh*, 538 U.S. 644, 652 (2003). In *Walsh*, the state of Maine had encouraged drug companies to enter into rebate agreements favorable to Mainers. *Id.* at 653–54. If a company refused, Maine subjected that company's Medicaid sales to "prior authorization," reducing the company's sales and market share in the Pine Tree State. *Id.* at 655–56. PhRMA sought injunctive and declaratory relief barring the implementation and enforcement of Maine's statutory scheme. *Id.* PhRMA's Complaint, however, did not mention *by name* any of the association's members. PhRMA instead specified that the association represents "leading research-based pharmaceutical and biotechnical companies" and serves those companies as their "principal policy advocate." PhRMA's Compl. in *Pharm. Rsch. & Manufacturers of Am. v. Concannon*, No. CIV. 00-157-B-H, 2000 WL 34290605 (D. Me. Oct. 26, 2000), at ¶¶ 6–7 (The Complaint is on file with Federal Records Center). The association further clarified that it brought "suit on behalf of its members," and that "[a]t least one of PhRMA's members possesse[d] standing to sue in its own right." *Id.* ¶ 8. Neither the district court, the court of appeals, nor the United States Supreme Court declined to entertain PhRMA's challenge on standing grounds. *See Pharm. Rsch. & Manufacturers of Am. v. Concannon*, No. CIV. 00-157-B-H, 2000 WL 34290605 (D. Me. Oct. 26, 2000), *rev'd sub nom. Pharm. Rsch. & Mfrs. of Am. v. Concannon*, 249 F.3d 66 (1st Cir. 2001), *aff'd sub nom. Pharm. Rsch. & Mfrs. of Am. v. Walsh*, 538 U.S. 644 (2003). That should come as no surprise. The record before the district court allowed for PhRMA's members to be specifically identified. *See Concannon*, 2000 WL 34290605 at *2 (mentioning Boehringer Ingelheim Pharmaceuticals, Inc. and Pfizer).

serve as important marketing tools for manufacturers to start a patient on a therapy, and to promote and maintain adherence once patients are taking their medications." 85 Fed. Reg. at 87099. Manufacturers will also have to implement new regulatory requirements and incur new compliance burdens in the face of the obligations imposed by the rule, especially if they wish to attempt to avoid the choice discussed above. *See* 85 Fed. Reg. at 37299 (specifying that the agency's rule excludes manufacturer-sponsored assistance from best price only if manufacturers "ensure[] the full value of the assistance or benefit is passed on to the consumer or patient").

The Government's argument that PhRMA attempts "to assert claims not on behalf of the unnamed drug manufacturers it represents, but on behalf of the patients with which the manufacturers do business," doesn't hold water. Def.'s Mot. at 17. PhRMA seeks to protect the interests of its members in continuing to operate patient assistance programs without the risk of having to pay higher Medicaid rebates, and also to be free from any increased compliance burdens that accompany the rule. Just because the patients with whom the manufacturers do business might benefit from PhRMA's challenge does mean that the only injury allegedly caused by the rule is suffered by patients.

The Government is also wrong to argue that "any manufacturer's decision to continue providing patient discounts . . . looks like a self-inflicted injury" not traceable to the final rule. Def.'s Mot. at 17. An injury counts as self-inflicted for purposes of standing "where the plaintiff's claimed injury [i]s clearly independent of agency action." *Scahill v. D.C.*, 271 F. Supp. 3d 216, 230 (D.D.C. 2017), *aff'd*, 909 F.3d 1177 (D.C. Cir. 2018); *Ciox Health, LLC v. Azar*, 435 F. Supp. 3d 30, 51 (D.D.C. 2020) (quotation omitted) ("To the extent that injury is self-inflicted, it must be so completely due to the complainant's own fault as to break the causal chain."). The manufacturers would not elect to eliminate or modify their patient assistance programs

"independent of" the final rule (or at least, the Complaint reasonably alleges that to be the case). It is rather the rule, PhRMA reasonably alleges, that could cause manufacturers to stop offering financial assistance to patients.

V. Conclusion

For the foregoing reasons, the Government's Motion to Dismiss for Lack of Standing is **DENIED**. PhRMA's Motion for a Briefing Schedule is **DENIED as MOOT**. The Parties are **ORDERED** to Confer and Propose a Briefing Schedule in wake of this Memorandum Opinion. An Order will be entered contemporaneously with this Memorandum Opinion.

DATE: December 1, 2021

CARL J. NICHOLS
United States District Judge