IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*,	)	
Plaintiffs,	)	
v.	)	No. 1:18-cv-02112-JDB
THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,	)	
Defendants.	)	

MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS

INTRODUCTION

Plaintiffs are (i) hospitals that buy drugs through a government-created drug discount program known as the 340B Program, and (ii) hospital associations whose members allegedly do the same. They contend that the U.S. Department of Health and Human Services (also "HHS" or the "Department") has violated the Administrative Procedure Act, 5 U.S.C. § 706, by delaying the implementation of a rule that would make changes to that program. And they filed an early summary judgment motion, seeking to focus attention on the merits of their complaint.

But federal courts cannot start with the merits. They must always determine their jurisdiction first. Indeed, "[n]o principle is more fundamental to the judiciary's proper role in our system of government than the constitutional limitation of federal-court jurisdiction to actual cases or controversies." *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 408 (2013). And "[o]ne element of the case-or-controversy requirement" is that plaintiffs "must establish that they have standing to sue." *Id.*

On this score, plaintiffs come up short: Plaintiffs have not properly demonstrated two of the essential components of standing. First, plaintiffs have not properly alleged that they have suffered a concrete injury in fact. Second, they have not established that their supposed injury is likely to be redressed by an order in their favor.

To start, plaintiffs allege that the current drug-price calculations are inaccurate. Compl. ¶ 26. But, even if true, an inaccurate calculation is not necessarily a harmful one. They also contend that "some and possibly many" of the association plaintiffs' members have been overcharged. Compl. ¶ 27. But an association cannot sue on behalf of its members without naming at least one member who would have standing to sue in its own right, and plaintiffs have not done so. Plaintiffs make a third allegation in a bid to secure standing, namely, that they have been deprived of information promised to them by statute. But as plaintiffs have not established that they have suffered the sort of injury that Congress intended to prevent through the dissemination of this information – i.e., they have not shown that they have been overcharged because they lack the information – this allegation also fails to establish standing.

Finally, plaintiffs have also failed to demonstrate that a favorable order from the Court would remedy any harm plaintiffs would suffer even if they have been overcharged. The government does not sell drugs to plaintiffs through the 340B Program, rather, drug manufacturers do. Thus, plaintiffs' allegations against the government are premised on its alleged failure to adequately regulate third parties

– the drug manufacturers. In other words, a favorable court order – e.g., one instructing the government to implement the drug pricing rule immediately – will not directly redress any alleged injury. Whether the Court's order would remedy any injuries depends on the discretionary choices and independent actions of third parties, the drug manufacturers, because they could choose to provide drugs using the pricing criteria included in the new rule (thereby remedying any injury) *or* they could decide to leave the 340B Program all together. Plaintiffs have offered nothing other than speculation to suggest that the manufacturers necessarily would act in a way that would remedy their injury. But speculation is not a sturdy enough foundation to support standing.

Thus, for the reasons stated above and more fully explained below, plaintiffs are not entitled to summary judgment, and their case should be dismissed for lack of jurisdiction.

BACKGROUND

In 1992, Congress created a program by which certain hospitals, community health centers and other federally funded entities serving low-income patients could receive drug discounts. The program is commonly known as the 340B Program, because it was created by section 340B of the Public Health Service Act. Drug manufacturers must offer their drugs for sale through the 340B Program in order to have their drugs covered through the separate Medicaid program. 42 U.S.C. 1396r-8(a)(1); 42 U.S.C. 256b(a). The program operates on a quarterly basis, *i.e.*, changes to prices and other conditions occur at the beginning of every quarter (January 1,

April 1, July 1, and October 1). 42 U.S.C. 256b(a) (indicating pricing is done on a quarterly basis); 77 Fed. Reg. 43342, 43343 (July 24, 2012) (indicating registration of covered entities is done on a quarterly basis).

In 2010, Congress modified the 340B Program in the Patient Protection and Affordable Care Act of 2010, Pub. L. 111-148, 124 Stat. 119 (March 23, 2010), 124 Stat. at 823-25 (codified at 42 U.S.C. § 256b(d)). More specifically, it instructed the Secretary of the Department to, among other things, develop "a system to enable the Secretary to verify the accuracy of ceiling prices calculated by manufacturers under subsection (a)(1) and charged to covered entities," provide "access through the Internet website of the Department of Health and Human Services to the applicable ceiling prices for covered outpatient drugs as calculated and verified by the Secretary in accordance with this section," and "impos[e] . . . sanctions in the form of civil monetary penalties which . . . shall be assessed according to standards established in regulations promulgated by the Secretary." 42 U.S.C. §§ 256b(d)(i), (iii), (vi).

On January 5, 2017, the Department issued a Final Rule, with an effective date of March 6, 2017, which "sets forth the calculation of the 340B ceiling price and application of civil monetary penalties." 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1,210 (Jan. 5, 2017) (the "340B Drug Pricing Rule"). Among other things, the rule implements a penny-pricing policy, under which manufacturers must sell certain drugs for a penny (such as when the price of a drug has increased at a rate greater than

inflation). The effective date of the Final 340B Rule has been delayed a handful of times over the ensuing months, most recently until July 1, 2019. 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 83 Fed. Reg. 25,943, 25,945 (June 5, 2018) [hereinafter the June 5 delay rule]; Admin. R. 309-313. But on November 2, 2018, the Department issued a notice of proposed rulemaking ("NPRM") in which it proposes that the effective date for the 340B Drug Pricing Rule be moved up to January 1, 2019, *see* 83 Fed. Reg. 55,135, which is the earliest possible effective date under the program's quarterly system.

On September 11, 2018, plaintiffs – hospitals that purportedly participate in the 340B Program and associations with members who do the same – filed a complaint alleging that the June 5 delay rule is arbitrary and capricious under 5 U.S.C. § 706(2), and that HHS has "unlawfully withheld or unreasonably delayed" agency action under 5 U.S.C. § 706(1). Compl.¶¶ 57-62, ECF No. 1. Plaintiffs filed their summary judgment motion, and the supporting memorandum, on the same day. *See* Motion for Summary Judgment ("SJ Mot."), ECF No. 2. In an order issued on November 2, 2018, the court consolidated briefing on plaintiffs' motion for summary judgment and defendants' motion to dismiss. Order, Nov. 2, 2018, ECF No. 19, at 5.

ARGUMENT

I. Plaintiffs Have Not Established Standing to Sue

Plaintiffs make three separate allegations in support of standing. None is adequate to furnish them with standing to sue. Accordingly, this Court lacks

jurisdiction and dismissal under Federal Rule of Civil Procedure 12(b)(1) is warranted.[1]

A court cannot exercise jurisdiction over a case unless a plaintiff has adequately established that it has standing to sue. *See Friends of Animals v. Jewell*, 828 F.3d 989, 992 (D.C. Cir. 2016) (noting that "at the pleading stage, a plaintiff must allege facts demonstrating each element" of standing). As a matter of pleading, plaintiffs must allege facts that, if true, would establish the following three elements: (1) they have suffered an "injury in fact" that is "concrete and particularized," and "actual or imminent, not conjectural or hypothetical"; (2) there exists "a causal connection between the injury and the conduct complained of"; and (3) it is "likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–61 (1992). And given that plaintiffs have filed a motion for summary judgment, it is important to recall that "each element [of standing] must be supported in the same way as any other matter on which the plaintiff bears the burden of proof, i.e., with the manner

[1] Since the Department has now proposed an effective date of Jan. 1, 2019 for the 340B Drug Pricing Rule, it does not challenge plaintiffs' arguments that there is no need to delay implementation of the 340B Drug Pricing Rule until July 1, 2019. But this decision does not mean that defendants concede that all of plaintiffs' merits arguments are correct: for example, plaintiffs incorrectly argue that courts apply a heightened standard of review under the APA to agency decisions to change course, *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 514 (2009) (rejecting that proposition), and they also errantly suggest that the Department acted in bad faith. Nor does this approach reflect any position on the content of the final rule that will be issued after the agency reviews comments on the NPRM.

and degree of evidence required at the successive stages of the litigation." *Id.* at 561.

Plaintiffs first allege that "[a]s to the ceiling price methodology, for example, the Hospital Plaintiffs and the Association Plaintiffs' members have been harmed by being charged ceiling prices calculated under inaccurate methodologies." Compl. ¶ 26. This does not constitute an allegation of a concrete injury. An inaccurate calculation is not necessarily a harmful one: The allegedly inaccurately calculated price could be either higher – or *lower* – than it should be. That is, plaintiffs could have been charged "inaccurate[ly]" low prices for drugs, in which case they would have been helped, not harmed. Indeed, as the Supreme Court recently explained, "not all inaccuracies cause harm or present any material risk of harm." *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1550 (2016), as revised (May 24, 2016). Accordingly, this allegation does not provide a basis for standing.

Plaintiffs also allege that "as to each Association Plaintiff, which collectively represent virtually every 340B hospital in the country, some and possibly many of the Association Plaintiffs' members have been overcharged by one or more drug companies." Compl. ¶ 27. Plaintiffs do not make this allegation as to the hospital plaintiffs.

This allegation of alleged harm does not support standing because associations cannot base their standing on alleged harm to unidentified members. An association can sue on behalf of its members. To do so, it must establish three elements. *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977).

Only the first element is relevant here, namely, that at least one of the association's "members would otherwise have standing to sue in [its] own right." *Id.* "At the threshold, the first element of the *Hunt* test requires that the plaintiff-association identify at least one specific member who has suffered, or is likely to suffer, an injury in fact." *Pub. Citizen, Inc. v. Trump*, 297 F. Supp. 3d 6, 18 (D.D.C. 2018) (citing *Summers v. Earth Island Inst.*, 555 U.S. 488, 498 (2009)). "[I]t is not enough" for an association plaintiff "to aver that unidentified members have been injured." *Chamber of Commerce v. E.P.A.*, 642 F.3d 192, 199 (D.C. Cir. 2011). And this identification requirement obligates plaintiff associations to identify an injured member *by name*. *Conference of State Bank Supervisors v. Office of Comptroller of Currency*, 313 F. Supp. 3d 285, 298-299 (D.D.C. 2018) (holding that the obligation attaches at the motion to dismiss stage); *Am. Ass'n of Cosmetology Sch. v. DeVos*, 258 F. Supp. 3d 50, 67-69 (D.D.C. 2017) (indicating that the obligation attaches at the summary judgment stage). Plaintiffs, however, have not named any member who has been overcharged, alleging only that "some and possibly many" have been. More is required. Plaintiffs' allegation of overcharging is not cognizable and so does not provide a basis for standing.

Finally, plaintiffs allege that "[a]s to the transparency-related rules, the Hospital Plaintiffs and the Association Plaintiffs' members have been deprived of access to ceiling price data." Compl. ¶ 26. This is an allegation of an informational injury. It too fails to establish standing, because plaintiffs have not properly alleged that they have suffered the type of harm that Congress sought to prevent.

"An informational injury can occur when a plaintiff is deprived of information that a statute entitles him to have." *New England Anti-Vivisection Soc'y v. United States Fish & Wildlife Serv.*, 208 F. Supp. 3d 142, 156 (D.D.C. 2016) "Under [] circumstances, which are exceedingly limited as a practical matter . . . an alleged informational injury can provide the necessary injury in fact to support Article III standing." *Id.* Specifically, "[a] plaintiff suffers sufficiently concrete and particularized informational injury where the plaintiff alleges that: (1) it has been deprived of information that, on its interpretation, a statute requires the government or a third party to disclose to it, and (2) it suffers, by being denied access to that information, the type of harm Congress sought to prevent by requiring disclosure." *Friends of Animals*, 828 F.3d at 992.

"The scope of the second part of the [informational injury standing] inquiry may depend on the nature of the statutory disclosure provision at issue. In some instances, a plaintiff suffers the type of harm Congress sought to remedy when it simply seeks and is denied specific agency records . . . In others, a plaintiff may need to allege that nondisclosure has caused it to suffer the kind of harm from which Congress, in mandating disclosure, sought to protect individuals or organizations like it." *Id.* Here, plaintiffs must do more to establish standing than claim a bare entitlement to the pricing information. Congress did not intend for the pricing information to be an end in and of itself, such that the deprivation of it alone could establish a concrete injury. Rather, the statute makes clear that Congress wanted entities participating in the 340B Program to have access to pricing

information to protect them from being overcharged. Indeed, the statute provides that "the Secretary shall provide for improvements in compliance by manufacturers with the requirements of this section *in order to prevent overcharges and other violations* of the discounted pricing requirements specified in this section." 42 U.S.C. § 256b(d)(1)(A) (emphasis added). And the statute adds that "the improvements described in subparagraph (A) shall include the following . . . The provision of access through the Internet website of the Department of Health and Human Services to the applicable ceiling prices for covered outpatient drugs as calculated and verified by the Secretary in accordance with this section." § 256b(d)(1)(B)(iii). In short, the statutory text demonstrates that the provision of website access is an improvement designed to "prevent overcharges and other violations" of the statute. *Id.* § 256b(d)(1)(B).

Thus, to have standing to raise their "transparency-related" claim, plaintiffs must allege that they have been overcharged because they have been deprived of the ceiling-price information. Compl. ¶ 27; *Friends of Animals*, 828 F.3d at 992. But plaintiffs have not made such an allegation, so their informational injury claim also fails to provide a basis for standing.

II. Plaintiffs Have Not Demonstrated That Their Injury Is Likely to Be Redressed by a Favorable Decision

Even if plaintiffs had adequately pleaded that they have been overcharged for drugs under the 340B Program, they have not demonstrated that it is "likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Lujan*, 504 U.S. at 561.

To adequately plead an injury, plaintiffs will have to allege that they have been overcharged for drugs under the 340B Program by manufacturers. *See* above. The last prepositional phrase, "by manufacturers," is important. The government does not sell drugs under the 340B Program – manufacturers do. So, plaintiffs' injury would arise, if at all, "from the government's allegedly unlawful regulation (or lack of regulation) of someone else," *Lujan*, 504 U.S. at 562 – the pharmaceutical companies. In this circumstance, "it becomes 'substantially more difficult' to establish standing." *Nat'l Wrestling Coaches Ass'n v. Dep't of Educ.*, 366 F.3d 930, 938 (D.C. Cir. 2004). Redressability would "hinge on the response of the regulated (or regulable) third party [*i.e.*, the manufacturers] to the government action," *i.e.*, on "unfettered choices made by independent actors not before the courts and whose exercise of broad and legitimate discretion the courts cannot presume either to control or to predict. " *Lujan*, 504 U.S. at 562 (internal quotations omitted). Thus, "it becomes the burden of the plaintiff to adduce facts showing that those choices have been or will be made in such manner as to . . . permit redressability of injury," and "mere unadorned speculation as to the existence of a relationship between the challenged government action and the third-party conduct will not suffice to invoke the federal judicial power." *Nat'l Wrestling Coaches*, 366 F.3d at 938 (internal quotation marks omitted). And of course, "each element [of standing] must be supported ... with the manner and degree of evidence required at the successive stages of the litigation." *Lujan,* 504 U.S. at 561.

In this case, plaintiffs have offered nothing other than "unadorned speculation" that a favorable decision will remedy the harm caused by any manufacturer overcharging. Plaintiffs contend "[o]n information and belief, [that] there would be fewer such overcharges if the accuracy, transparency and compliance rules set forth in the Final 340B Rule were in place." Compl. ¶ 27. But it is possible that a manufacturer may choose to leave the 340B Program, rather than to sell its drugs at prices mandated under the 340B Drug Pricing Rule. Indeed, plaintiffs attached to their summary judgment motion two letters from a drug company expressing its strong disagreement with HHS's penny-pricing policy, Exhibits A & B to SJ Mot., ECF Nos. 2-2, 2-3, a policy which will be codified in the 340B drug pricing rule. And if a manufacturer leaves the program, then plaintiffs could be in a worse position. Rather than paying more for an already discounted drug under the 340B Program, plaintiffs might not have access to the drug under the 340B Program at all, which means they might have to pay the drug's full market retail price. Admittedly, it is unlikely that most manufacturers will leave the program, if only because they must participate in the program to sell their products through the Medicaid program. But it is certainly possible that some might. A company with only a few drugs for sale might do so, for example, if one or more of them are subject to the penny pricing policy.

And since plaintiffs have not identified specific plaintiffs who have been overcharged for specific drugs, we do not even know which drug manufacturers might be at issue, much less have factual information (such as might be provided in

declaration) indicating how they intend to respond to the eventual enactment of the 340B Drug Pricing Rule. This information is required to demonstrate that *these plaintiffs* have standing to invoke this Court's jurisdiction. Dismissal is warranted.

CONCLUSION

For the reasons stated above, the Court should deny plaintiffs' motion for summary judgment and dismiss the case for lack of standing.

Date: November 13, 2018

Respectfully submitted,

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RESPONSE TO PLAINTIFFS' STATEMENT OF FACTS IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT

Plaintiffs filed a separate statement of facts in support of their motion for summary judgment. ECF No. 2-4. No such statement is appropriate in this case.

Local Civil Rule 7(h)(2) states that the Rule 7(h)(1), which requires the filing of a separate statement of facts in support of a summary judgment motion, "shall not apply to cases in which judicial review is based solely on the administrative record." LCvR 7(h)(2). This is a case in which review is based solely on the administrative record.

Claims of arbitrary and capricious agency action under 5 U.S.C. § 706(2), such as Count I of plaintiffs' complaint, *see* Compl. ¶¶ 57-59, are reviewed on the basis of the administrative record. *See Camp v. Pitts*, 411 U.S. 138, 142 (1973) ("In applying [the arbitrary and capricious] standard, the focal point for judicial review should be the administrative record already in existence...."). The other count of plaintiffs' complaint alleges, under 5 U.S.C. § 706(1), that the agency unlawfully withheld or unreasonably delayed an agency action. *See* Compl. 60-62. While there

is not always an administrative record to serve as the focal point of judicial review for such claims, *see generally Nat'l Law Ctr. on Homelessness & Poverty v. U.S. Dep't of Veterans Affairs*, 842 F. Supp. 2d 127, 130 (D.D.C. 2012), here there is, because the agency promulgated a rule – the rule challenged in this complaint, 83 Fed. Reg. 25,943 – explaining the basis for its delay in implementing the 340B Drug Pricing Rule. As such, this claim should also be reviewed on the basis of the administrative record. *See, e.g.*, *Stout v. U.S. Forest Serv.*, 869 F. Supp. 2d 1271, 1276 (D. Or. 2012) ("The court's review of this [§ 706(1)] claim is also limited to the administrative record.").

Thus, under the Local Rules, the parties should not file separate statements of fact, but rather should include in their briefs a statement of facts with any necessary references to the administrative record. LCvR 7(h)(2). Defendants have done so here.

Date: November 13, 2018

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