UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA et al.,

Plaintiffs,

v.

DEPARTMENT OF HEALTH & HUMAN SERVICES et al.,

Defendants.

Civil Action No. 20-3402 (TJK)

MEMORANDUM OPINION

The Department of Health and Human Services is considering allowing prescription drugs to be imported from Canada under a statute that has lain dormant for decades. Plaintiffs, a collection of organizations with various interests in American healthcare, say that decision would be mistaken and that it was started by unlawful processes. But no organization, nor any of their members, faces a concrete risk of harm from the inchoate importation program, as is required when suing. So the Court must dismiss this case for lack of standing.

I. Background

The challenged agency action is the first step on a path to legal importation of prescription drugs. To contextualize that development, the Court begins by explaining why it is significant. The Court is resolving a motion to dismiss, so the facts below are drawn from Plaintiffs' complaint.

A. Legal Background

Congress has prohibited the introduction of new drugs into interstate commerce without approval from the Food and Drug Administration. *See* 21 U.S.C. §§ 331(d), 355(a). The FDA

considers many factors before approving a prescription drug, including evidence of its safety and efficacy, its "composition," the method of its "manufacture, processing, and packing," and its proposed labeling. *See id.* § 355(b)(1)(A). A drug may not be introduced if it is "adulterated or misbranded." *Id.* § 331(a).

The FDA's approval is tied to a particular production-and-distribution process. A drug is not approved if it the manufacturer uses "unapproved production lines," even if the same facility produces another version of the same drug that is approved. *See* HHS Task Force on Drug Importation, Dep't of Health & Hum. Servs., *Report on Prescription Drug Importation* 3–4 (2004) ("HHS Drug Importation Report"). Such drugs likely share "significant similarities" with approved drugs, but they do not meet the exacting standards of FDA approval. *See id.* at 4.

Thus, the FDA has historically recognized only two ways to import prescription drugs legally. The first is to make the drug in a foreign-but-FDA-inspected facility and complete the ordinary approval process. *See* HHS Drug Importation Report at 3. The second is to make an approved drug in the United States, send it abroad, and reimport it. *See id.* The latter method requires the importer to be the original manufacturer. 21 U.S.C. § 381(d)(1)(A).

Proper labeling is another obstacle to importing prescription drugs. A drug's label must not be "false or misleading in any particular." *See* 21 U.S.C. § 352(a)(1). And an approved application for a new drug is based in part on "[t]he proposed text of the labeling" to be used. *See* 21 C.F.R. § 314.50(c)(2)(i). But "foreign labeling differs from domestic labeling." *In re Canadian Import Antitrust Litig.*, 470 F.3d 785, 790 (8th Cir. 2006). For that reason alone, even a foreign drug that is otherwise identical to an approved, domestic drug cannot be imported without special authorization. *Id.* at 790–91.

Moreover, the domestic drug supply chain is strictly monitored. *See generally* 21 U.S.C. § 360eee-1. Drug wholesalers and dispensers must, among other things, verify that the drugs they carry have unique product identifiers, that they have a product's transaction history, and that they trade only with approved partners. *Id.* § 360eee-1(c)(1)(A)(i), (c)(2)–(3), (d)(1)(A)(i), (d)(2)–(3). The idea, as the Eighth Circuit has explained, is to maintain a "closed system designed to guarantee safe and effective drugs for consumers in the United States." *Canadian Import*, 470 F.3d at 790 (quotation omitted). And that closed system "has effectively precluded importation of [prescription] drugs." *Id.* at 791.

Congress has, however, laid the groundwork for cutting through that red tape. It enabled HHS to promulgate "regulations permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States." 21 U.S.C. § 384(b). That authorization is subject to several limitations, including those related to testing of imported drugs and modified labeling, as well as many requirements that apply to applications for new domestic drugs. *See id.* § 384(c), (e), (h).

More importantly, that authorization is subject to a precondition. The statute "shall become effective only if the Secretary [of Health and Human Services] certifies to the Congress that the implementation" will satisfy two criteria. 21 U.S.C. § 384(*l*)(1). Importation from Canada must both "(A) pose no additional risk to the public's health and safety; and (B) result in a significant reduction in the cost of covered products to the American consumer." *Id.*

Several HHS Secretaries have declined to certify those conclusions. The first HHS Secretary to consider the problem explained to Congress, "I cannot make the determination called for in the statute because of serious flaws and loopholes in the design of the new drug reimportation system. . . . [It is] impossible for me to demonstrate that [importation from Canada] is safe and

cost effective."[1] Similarly, in 2004, an HHS task force concluded that "[l]egalized importation of drugs in such a way that creates an opening in the 'closed' system will likely result in some increase in risk." HHS Drug Importation Report at 35. And in 2018, HHS Secretary Alex Azar derided drug importation as a "gimmick" that would "have no meaningful effect" on drug prices.[2]

The statutory drug-importation scheme has thus lain dormant for most of its history, and importing drugs from Canada or elsewhere has remained effectively illegal.

B. Factual Background

1. The Agency Action

The challenged agency action began a potential change to that status quo. In 2019, HHS proposed partially implementing the drug-importation statute. *See generally* Importation of Prescription Drugs, 84 Fed. Reg. 70796 (Dec. 23, 2019) ("NPRM"). Its proposal was to "allow commercial importation of certain prescription drugs from Canada through time-limited programs sponsored by at least one non-federal governmental entity." *Id.* at 70798. That implementation is partial in one sense because the statute contemplates individual—not just commercial—importation. *See* 21 U.S.C. § 384(j). And it is partial in another sense because the implementation does not itself permit any drug to be imported—a point that requires further explanation.

HHS proposed implementing the statute via state- or tribal-run programs that would identify particular drugs that satisfy the statutory criteria and arrange to import them. *See* NPRM, 84 Fed. Reg. at 70797. That is, it proposed shifting the importation onus to "non-federal

[1] Letter from Donna E. Shalala, Sec'y of Health & Hum. Servs. to William J. Clinton, President of the United States (Dec. 26, 2000), *reprinted in* 149 Cong. Rec. 15490, 15528–29 (2003).

[2] *Hearing on the Department of Health and Human Services' Fiscal Year 2019 Budget Request Before the H. Comm. on Ways & Means*, 115th Cong. 85 (2018) (statement of Alex Azar, Sec'y of Health & Hum. Servs.).

governmental entities," perhaps joined by a "pharmacist" or "wholesaler," to find Canadian drugs that could safely and cheaply be imported. *See id.* Qualifying drugs would be approved for sale in Canada and would be approvable in the United States but for their labeling. *Id.* It called such a hypothetical program an "SIP" and an interested nonfederal governmental entity an "SIP Sponsor." *Id.*[3]

HHS did not suggest authorizing any particular SIP. Instead, it invited SIP proposals. *See* NPRM, 84 Fed. Reg. at 70801. A successful proposal would need to show that the selected drugs could satisfy the statutory preconditions—that "importation will pose no additional risk to the public's health and safety," and that it "would result in a significant [cost] reduction." *Id.* at 70802. Similarly, it would need to satisfy the remaining statutory criteria, including those related to testing, registration of foreign sellers, and labeling. *See id.*; 21 U.S.C. § 384(d)–(h). But even if a proposal satisfied the proposed rule's criteria, the rule made clear that the FDA would retain "discretion" to deny the proposal anyway. NPRM, 84 Fed. Reg. at 70802.

In other words, HHS announced that it was considering a *conditional* certification of the statutory precondition. *See* NPRM, 84 Fed. Reg. at 70803. The certification would be "conditioned on each authorized SIP meeting the relevant requirements." *Id.* Thus, although the proposal contained proposed regulations to implement the drug-importation statute—which could lawfully exist only after HHS had effected the statute by certifying the preconditions—HHS explained that it would consider comments it received on that proposal when deciding whether to certify the preconditions at all. *See id.* With that explanation, it invited public comment.

[3] "SIP" stands for "Section 804 Importation Program." NPRM, 84 Fed. Reg. at 70798. Section 804 is the relevant section of the Food, Drug, and Cosmetic Act, codified at 21 U.S.C. § 384.

Several months later, President Trump ordered the HHS Secretary to complete that "rule-making process" and "to allow importation of certain prescription drugs from Canada." Exec. Order No. 13938 § 2(c), 85 Fed. Reg. 45757, 45757 (July 24, 2020). Shortly after that order, the Secretary certified the preconditions of the drug-importation statute, and HHS issued a final rule inviting SIP proposals.

The Secretary's certification noted its conditional character. Although it explained that implementing the commercial portion of the statute would not increase risks and would significantly cut costs, it did so "limited to implementation . . . through the final rule." ECF No. 34-3 at 2. It refused to authorize "any other method of implementing" the statute. *Id.* And it explained the nature of the SIP programs for which the final rule would invite proposals. *Id.* at 2–3.

The final rule mirrors the proposed rule. *See generally* Importation of Prescription Drugs, 85 Fed. Reg. 62094 (Oct. 1, 2020) ("Final Rule") (codified at 21 C.F.R. § 251.1 *et seq.*). It contains two contingencies for any potential drug importation. First, as already explained, the FDA must approve an application to sponsor an SIP. *See id.* at 62094. Second, even if an SIP is approved, an importer must get the FDA's approval to bring any particular shipment of drugs into the country by filing a pre-import request. *See id.* at 62095; 21 C.F.R. § 251.5(a).

Under certain circumstances, the final rule imposes obligations on drug manufacturers—regardless of whether they endorse a drug's importation. A "complete Pre-Import Request" includes information that only a manufacturer can provide. *See* 21 C.F.R. § 251.5(c). So if an SIP is approved, and an importer wishes to submit a pre-import request, the importer must demand information from the manufacturer. *See id.* § 251.5(d), (e). After receiving such a demand, a manufacturer must respond within "30 calendar days." *Id.* For some responses, manufacturers have no choice—they must provide the information specified in the regulation. *See, e.g.*, *id.*

§§ 251.5(e)(2), 251.13(a). For others, they may choose among discrete options, for instance, whether to test imported drugs themselves at their own cost or to facilitate testing elsewhere by providing information. *See id.* §§ 251.5(c)(4)(xii), 251.5(d), 251.16(e). For those reasons, among others, HHS recognized that the final rule may impose costs on "manufacturers of imported drugs . . . if their drugs are imported." Final Rule, 85 Fed. Reg. at 62095.

As of the filing of Plaintiffs' operative complaint,[4] at least two SIP proposals have been filed, but none have been approved. Florida has applied to sponsor an SIP that would allow it to import "approximately 100 drugs" from Canada. ECF No. 31 ("Compl.") ¶ 94. It has also "contracted with a third-party, private logistics firm" to help it administer the proposed SIP and "identified a foreign seller" of at least some drugs it wishes to import. Compl. ¶¶ 92–93. The Florida legislature has appropriated funds to support an SIP, and Florida has constructed a warehouse "to store drugs imported under the SIP." Compl. ¶¶ 96, 98. And Florida's governor has explained in a press conference that he expects the state's application to be approved. Compl. ¶ 97. Similarly, New Mexico has applied to sponsor an SIP, although Plaintiffs do not note the number of drugs it wishes to import. Compl. ¶¶ 99–101.[5]

[4] Because the Court is resolving a motion to dismiss, it is concerned with the "legal sufficiency of the complaint." *See Carter v. Carson*, 241 F. Supp. 3d 191, 197 (D.D.C. 2017). So it may consider only "the state of things at the time of the action brought." *Mollan v. Torrance*, 22 U.S. (9 Wheat.) 537, 539 (1824). The Court's consideration of factual developments is thus frozen in time as of the date Plaintiffs' filed their amended complaint. *See Scahill v. District of Columbia*, 909 F.3d 1177, 1184 (D.C. Cir. 2018) (holding that allegations in an amended complaint control even if the allegations in an original complaint failed to establish subject-matter jurisdiction). ECF No. 31 at 86. That said, the parties have not informed the Court of HHS's approval of any SIP proposal since the amended complaint was filed.

[5] SIP proposals are not public, so details about their contents are available only if a would-be sponsor chooses to share them. *See* Compl. ¶ 106.

Four other states' legislatures have passed laws directing the state to apply to sponsor an SIP. Compl. ¶ 102. Colorado, Maine, and Vermont have released draft proposals that suggest what such a proposal may ultimately contain. Compl. ¶ 103. Colorado's draft, for example, foretells a proposal "to import 168 drugs." Compl. ¶ 104. But beyond those snippets, few details about potential SIPs are publicly available. *See* Compl. ¶ 106.

2. Plaintiffs

Plaintiffs are three organizations that each comprise other entities interested in the importation of prescription drugs. The first is Pharmaceutical Research and Manufacturers of America ("PhRMA"), an association whose membership includes drug manufacturers and other entities that have information that might be sought in a pre-import request. Compl. ¶¶ 1, 113–19. The second is the Partnership for Safe Medicines ("the Partnership"), an organization whose membership is "committed to the accessibility of safe prescription drugs[ ] and protecting consumers against counterfeit, substandard, or otherwise unsafe medicines." Compl. ¶¶ 2–3, 120–27. Among its members are other associations, including PhRMA, that represent drug manufacturers. Compl. ¶ 126. The third is the Council for Affordable Health Coverage ("the Council"), an organization that "promotes policies that lower health costs through increased competition, informed consumers, and more choices." Compl. ¶¶ 4, 128.

Plaintiffs oppose the Secretary's certification and the final rule for three broad reasons. First, they believe importing drugs from Canada is dangerous and unlikely to reduce costs to consumers. *See* Compl. ¶¶ 109, 113, 120–25, 128. Second, they are procedurally unsatisfied with the certification and rule—both in the procedures used to issue the certification and in the rule's implications for their ability to participate in future SIP proposals. *See* Compl. ¶¶ 110–12, 119, 127–28. Third, they object to burdens on drug manufacturers—both those that an approved SIP and subsequent pre-import request would impose and those that might result from importing unsafe

drugs. *See* Compl. ¶¶ 114–17, 126. Similarly, they point out that manufacturers "have already been forced to incur costs to ensure compliance" with future pre-import requests that they might receive, given the short notice that such requests would afford. Compl. ¶ 118.

Plaintiffs' concern about harms to their constituent drug manufacturers takes many forms. At the pre-import-request stage, they point to costs incurred in responding to requests and to the loss of trade secrets if they must divulge protected information. *See* Compl. ¶¶ 115(a), 118. During the importation process, they assert harms in the form of testing costs, trademark infringement in their being forced to authorize importers to use their labeling, and unlawful compelled speech via a required attestation about the drug's compliance with regulatory requirements. Compl. ¶¶ 115(b), 117–18; *see also* 21 C.F.R. § 251.5(c)(4)(xii). After importation, they fear increased competition, derogation of statutory exclusivity rights, reduced patent values, and, from dangerous drugs, eroded goodwill, potential products-liability suits, and increased expenditures on safety protections and consumer education. Compl. ¶¶ 114, 115(c), 116.

C. Procedural History

Plaintiffs sued seeking to vacate the certification and final rule. ECF No. 1 at 68. Defendants moved to dismiss the complaint for lack of subject-matter jurisdiction and, alternatively, for failure to state a claim. ECF No. 26. Plaintiffs then amended their complaint. ECF No. 31. That amendment mooted Defendants' original motion.

Defendants responded with a renewed motion to dismiss. ECF No. 34. They again contend that the Court lacks subject-matter jurisdiction over Plaintiffs' claims, ECF No. 34-1 at 27–52, and, alternatively, that two of Plaintiffs' procedure-based claims should be dismissed for failure to state claims, *id.* at 52–55. Plaintiffs, joined by an amicus, oppose that motion. ECF Nos. 35, 43. Another amicus supports Defendants' position. ECF No. 28.

II. Legal Standards

Defendants' Motion relies on Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6). Under Rule 12(b)(1), Plaintiffs have the burden to establish standing. *Little v. Fenty*, 689 F. Supp. 2d 163, 166–67 (D.D.C. 2010). That burden "grows heavier at each stage of the litigation." *Osborn v. Visa Inc.*, 797 F.3d 1057, 1063 (D.C. Cir. 2015). To survive a motion to dismiss, Plaintiffs need only allege a qualifying "injury resulting from [Defendants'] conduct." *Id.* (quoting *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992)). The Court must "assume the truth of all material factual allegations in the complaint and . . . grant[Plaintiffs] the benefit of all inferences that can be derived from the facts alleged." *Am. Nat. Ins. Co. v. FDIC*, 642 F.3d 1137, 1139 (D.C. Cir. 2011) (quotation omitted).

Still, factual allegations demand "closer scrutiny when resolving a Rule 12(b)(1) motion than would be required for a Rule 12(b)(6) motion." *Tex. Low Income Hous. Info. Serv. v. Carson*, 427 F. Supp. 3d 43, 52 (D.D.C. 2019) (quotation omitted). The Court cannot "accept inferences drawn by plaintiffs if such inferences are unsupported by the facts." *Trudeau v. FTC*, 456 F.3d 178, 193 (D.C. Cir. 2006) (quotation omitted). And the Court may consider the allegations in Plaintiffs' complaint, undisputed facts in the record, and, if necessary, its resolution of disputed facts. *Coal. for Underground Expansion v. Mineta*, 333 F.3d 193, 198 (D.C. Cir. 2003).

Under Rule 12(b)(6), Plaintiffs' complaint must "contain sufficient factual matter . . . to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quotation omitted). A claim is plausible if "it contains factual allegations that, if proved, would allow the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Hurd v. District of Columbia*, 864 F.3d 671, 678 (D.C. Cir. 2017) (quotation omitted). Again, the Court must "accept all the well-pleaded factual allegations of the complaint as true and draw all reasonable inferences from those allegations in the plaintiff's favor." *Id.* (quotation

omitted). But it must disregard "a legal conclusion couched as a factual allegation." *Cason v. NFL Players Ass'n*, 538 F. Supp. 3d 100, 109 (D.D.C. 2021) (quotation omitted).

III. Analysis

Plaintiffs bring seven claims. The first three contend that the certification violated the Administrative Procedure Act ("APA"), Compl. ¶¶ 129–152, and the last four assert that the final rule violates the APA and the First Amendment, Compl. ¶¶ 153–90.

But the Court cannot address any of those claims unless it determines that Plaintiffs have standing. *See Freedom Watch, Inc. v. McAleenan*, 442 F. Supp. 3d 180, 186 (D.D.C. 2020); *see also Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94 (1998). To establish standing, Plaintiffs' complaint must have "clearly allege[d] facts demonstrating" Plaintiffs have "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant[s], and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016) (alteration adopted). The alleged injuries must be particular to Plaintiffs; they may not raise a "generally available grievance." *Lance v. Coffman*, 549 U.S. 437, 439 (2007) (per curiam).

As membership-based entities, Plaintiffs' asserted injuries must be divided into two categories for standing purposes. The first category contains injuries that inure to Plaintiffs' members. Courts term standing based on such injuries "associational" and ask whether the entity has identified a particular member who would (1) "have standing to sue in his own right" based on (2) an interest "germane" to the entity's "purpose" and (3) whether the individual's personal participation in the suit is necessary. *Chamber of Commerce of the U.S. v. EPA*, 642 F.3d 192, 199–200 (D.C. Cir. 2011). The second category contains injuries directly to the plaintiff entities. Courts term standing based on such injuries "organizational" and treat the entity as they would "an individual plaintiff." *People for the Ethical Treatment of Animals v. U.S. Dep't of Agric.*, 797 F.3d 1087, 1093 (D.C. Cir. 2015).

Here, the parties focus their dispute on injuries to Plaintiffs' members. So the Court begins by addressing associational standing.

A. Plaintiffs Lack Associational Standing Because It Is Speculative Whether, When, and How Their Membership Will Suffer Injury

The first associational-standing question is whether any of Plaintiffs' members could sue in their own right. That is, Plaintiffs must "show that at least one specifically-identified member has suffered an injury-in-fact" or that such an injury is "imminent." *Am. Chemistry Council v. Dep't of Transp.*, 468 F.3d 810, 820 (D.C. Cir. 2006). Reliance on imminent injuries does not remove the need to allege "a specific harm to a specific party." *Id.* at 820–21.

An injury-in-fact is "an invasion of a legally protected interest" that is "concrete and particularized." *Lujan*, 504 U.S. at 560. An injury is concrete if it is "real, and not abstract." *Robins*, 578 U.S. at 340 (quotations omitted). An injury is particular if it "affects the party asserting standing 'in a personal and individual way.'" *Defs. of Wildlife v. Perciasepe*, 714 F.3d 1317, 1323 (D.C. Cir. 2013) (quoting *Lujan*, 504 U.S. 560 n.1). Thus, a particular injury cannot rest on "a statistical probability" that some unknown members will suffer a concrete injury. *See Summers v. Earth Island Inst.*, 555 U.S. 488, 497 (2009).

Plaintiffs assert three types of associational injuries. The first class of injuries hinges on, at least, the approval of an SIP and the filing of a pre-import request. ECF No. 35 at 31–32. Some of those injuries also depend on the importation of drugs, among other contingencies. *Id.* at 32. The second class comprises costs already incurred to prepare for the possibility of an SIP approval. *Id.* at 29–31. The third class contains procedural injuries. *Id.* at 26–29.

The cognizability of each of those injuries, as the Court will explain, depends on the likelihood that an individual member's drug or drugs will be the subject of a pre-import request under

an approved SIP.[6] Because it is impossible to do more than speculate about that likelihood, Plaintiffs have not established an injury-in-fact.

1. Injuries Contingent on the Preparation of a Pre-import Request

The FDA has yet to approve an SIP. *See* Compl. ¶ 106. So the alleged injuries in the first category are future injuries. And the Plaintiffs' burden to establish standing here is "significantly more rigorous." *Chamber of Commerce*, 642 F.3d at 200 (quotation omitted).

There are two alternative tests for cognizability of future injuries. The first asks whether a "threatened injury" is "certainly impending," rather than merely "possible." *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013) (quotations and emphasis omitted). The second asks whether "there is a substantial risk that the harm will occur." *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 158 (2014) (quotation omitted). Plaintiffs have shown an injury-in-fact if they can satisfy either test. *Attias v. Carefirst, Inc.*, 865 F.3d 620, 626–27 (D.C. Cir. 2017).

Neither an SIP authorization with definite terms nor a particular pre-import request is certainly impending. Momentarily setting aside the many potential defects in an SIP application, the FDA retains discretion to deny even an SIP proposal that meets the regulatory requirements. 21 C.F.R. § 251.4(a). That discretion alone "vitiates" any claim that an authorization is "certainly impending." *See de Ramirez v. Barr*, No. 18-1516 (PLF), 2019 WL 4750373, at *4 (D.D.C. Sept. 30, 2019) (quoting *Clapper*, 568 U.S. at 401). Plaintiffs cannot say that the certification or the final rule "will *certainly* cause" them any future harm because there is at least a possibility that no

[6] Recall that the FDA must approve a pre-import request before an importer can bring drugs into the country, 21 C.F.R. § 251.5(a), and that an importer's request to a manufacturer to help it complete a pre-import request triggers the manufacturer's obligations under the rule, *see id.* § 251.5(d), (e)(2). And a pre-import request cannot be made until the FDA authorizes an SIP. *See id.* § 251.5(b), (c)(2). Thus, the event relevant to assessing the likelihood of injuries to Plaintiffs' members is an importer's decision to prepare a pre-import request, which turns on a prior SIP approval.

SIP will ever win approval. *See Pub. Citizen, Inc. v. Trump*, 297 F. Supp. 3d 6, 21 (D.D.C. 2018). Indeed, Plaintiffs do not appear to contend otherwise. *See* ECF No. 35 at 33–35 (arguing under the "substantial-risk" test and asserting that "SIP approval is likely in the near future" (emphasis omitted)). So Plaintiffs must make their stand on the second test.

To show an injury from increased risk, Plaintiffs must "show both (i) a substantially increased risk of harm and (ii) a substantial probability of harm with that increase taken into account." *Food & Water Watch, Inc. v. Vilsack*, 808 F.3d 905, 914 (D.C. Cir. 2015) (quotation and emphasis omitted). That standard is not an end-run around the constitutional requirement that future injuries be imminent, but another way to assess imminence. *See id.* at 915. And the imminence requirement "compels a very strict understanding of what increases in risk and overall risk levels can count as substantial." *Id.* (quotation omitted). At the very least, substantiality requires that the "nature of the injury alleged" is not "speculative." *See Elec. Priv. Info. Ctr. v. FAA*, 892 F.3d 1249, 1255 (D.C. Cir. 2018) ("*EPIC II*"). If a court "can only speculate" about whether and how an injury will occur, that is "ordinarily fatal to standing." *See Elec. Priv. Info. Ctr. v. Presidential Advisory Comm'n on Election Integrity*, 878 F.3d 371, 379 (D.C. Cir. 2017) ("*EPIC I*").

To analyze Plaintiffs' "increased-risk-of-harm claim," the Court must "consider the ultimate alleged harm . . . as the concrete and particularized injury and then . . . determine whether the increased risk of such harm makes injury to an individual citizen sufficiently imminent." *Food & Water Watch*, 808 F.3d at 915 (quotation omitted). That standard is hard to meet where the harm-causing event is still "subject . . . to regulatory processes and approvals." *See Ctr. for Biological Diversity v. Bernhardt*, 490 F. Supp. 3d 40, 52 (D.D.C. 2020). In such cases, determining whether the agency will act and, if so, how, often requires speculation. *See, e.g.*, *id.*

The ultimate alleged harms here, if they materialize, are sufficiently concrete. That is because they are financial and, in the case of the compelled-speech claim, constitutional. *See, e.g.*, *Thole v. U.S. Bank N.A.*, 140 S. Ct. 1615, 1619 (2020) (explaining that a financial loss would, "of course," support standing); *Valley Forge Christian Coll. v. Ams. United for Separation of Church & State*, 454 U.S. 464, 485–86 (1982) (acknowledging that a "personal injury suffered . . . as a consequence of the alleged constitutional error" is sufficiently concrete to confer standing (emphasis omitted)). But even the least contingent of those alleged harms lacks a substantial probability of materializing, so none is imminent.

When a future injury depends on a pending agency approval, three questions shed light on the injury's imminence. First, will the agency approve an application? *See Teva Pharms. USA, Inc. v. Azar*, 369 F. Supp. 3d 183, 203 (D.D.C. 2019) (explaining that there was "no guarantee that the FDA [would] approve *any* existing" new-drug application); *Ipsen Biopharms., Inc. v. Becerra*, No. 20-2437 (DLF), 2021 WL 4399531, at *5 (D.D.C. Sept. 24, 2021) (similar). Second, if it approves the application, when will it do so? *See Teva*, 369 F. Supp. 3d at 203 ("[T]he Court has no means of assessing . . . when [an approval] is likely to occur."). Third, even if the agency will soon approve an application, what will the terms of the approval be? *See id.* at 204 (noting that a future amendment to a pending application might forfeit the right the plaintiff sued to assert).

Plaintiffs' allegations address only the first question—and they are weak even on that score. They ask the Court to infer the FDA will approve an SIP based on four facts: (1) that at least two SIP proposals are pending before the FDA; (2) that Florida's governor said, in a press conference, that he expected the state's application to be approved;[7] (3) that Florida has invested

[7] Plaintiffs claim the governor's comments reflect "what Biden Administration officials told him." ECF No. 35 at 34 (emphasis omitted). But this was the precise exchange on which they rely:

money in running an SIP; and (4) that President Biden has directed the FDA Commissioner to "work with States and Indian Tribes that propose to develop [SIPs]."[8] ECF No. 35 at 33–35 (citing Compl. ¶¶ 3, 92–94, 97, 106, 108). At most, those allegations establish that Florida's leadership *expects* its SIP proposal to be approved and that the FDA is considering doing so. But expectations may be wrong, and intentions may change. Plus "judicial experience and common sense" teach that the outcome of a complex bureaucratic processes—absent, for example, preexisting "tentative approval"—is difficult to predict. *See Teva*, 369 F. Supp. 3d at 195, 203–04 (quotation omitted).

In any event, no injury to the Plaintiffs is imminent even if the Court assumes an SIP will eventually be approved. That is because, on this record, the Court could only speculate about when such an approval will occur and, more importantly, on what terms.

Plaintiffs' allegations establish next-to-nothing about the timing of an SIP approval. Indeed, the only relevant allegations are the same used to establish that the FDA will authorize an

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> REPORTER: But the hurdle is getting the okay from the FDA under Biden?
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> GOVERNOR DESANTIS: From the Biden administration, yeah. And look, we were told, [our SIP proposal is] still under review, [and] if it's not nixed by [May 2021], then they said we were going to be okay. But we haven't gotten the affirmative to do it, and so that's one of the reasons why we just want to make sure it's clear to everybody that we've [satisfied the requirements for an SIP application].

WPBF 25 News, *Gov. DeSantis Holds News Conference*, YouTube 28:38–29:30 (May 28, 2021), https://www.youtube.com/watch?v=XiwRK5qh5i0. The Court considers the full exchange because statements at the press conference constitute "undisputed facts evidenced in the record," *Coal. for Underground Expansion*, 333 F.3d at 198, and the video is "incorporated by reference in the complaint," *Elec. Priv. Info. Ctr. v. IRS*, 575 F. Supp. 3d 84, 88 (D.D.C. 2021) ("*EPIC III*") (quotation omitted); *see also* Compl. ¶ 97. In full context, it is far from clear from the governor's remarks that "federal officials have informed . . . the State of Florida[ ] that authorization of its application was certain and imminent as of May 2021." Compl. ¶ 108. It is not even clear that the unnamed speaker who said Florida would "be okay" was a member of the administration or, if so, what his or her role in the approval process was.

[8] Exec. Order 14036 § 5(q), 86 Fed. Reg. 36987, 36997–98 (July 9, 2021).

SIP. For example, Plaintiffs say the Florida legislature's decision to allocate funds to implement its SIP is "[i]n keeping with [its] apparent belief that SIP approval was imminent." Compl. ¶ 98. But again, a third party's beliefs, without more, reveal barely anything about duration of a process outside that party's control. The final rule specifies no timeframe within which the FDA must act on an SIP proposal; it says only that a final decision must be conveyed in writing. *See* 21 C.F.R. § 251.4(c)(2). Even so, the rule obliquely suggests a long process by noting that a pending proposal may be denied if the would-be sponsor fails to find a foreign seller of drugs "within 6 months of the initial submission." *Id.* § 251.4(a). At bottom, it is nearly impossible to conclude anything about a decision's timing because no SIP has been authorized.

That difficulty undercuts Plaintiffs' standing arguments because imminence requires some temporal certainty. True, standing under an increased-risk theory "depends on the probability of harm, not its temporal *proximity*." *Orangeburg v. FERC*, 862 F.3d 1071, 1078 (D.C. Cir. 2017) (quotation omitted and emphasis added). That is, even a far-off harm is cognizable now if a court can determine when and how an injury will materialize. *See id.* at 1079 (explaining that a plaintiff would suffer the injury when it began negotiating a new contract, the timing of which was ascertainable based on "historical practice"). But to avoid stretching the imminence requirement "beyond its purpose," and neglecting components of the definition of imminence such as "immediate" and "not remote," the Court must be able to say *something* about a future injury's timing. *See Pub. Citizen, Inc. v. Nat'l Highway Traffic Safety Admin.*, 489 F.3d 1279, 1293–94 (D.C. Cir. 2007) (quotation omitted). For example, even if it is impossible to pinpoint when a harm will occur, the harm is imminent if it is likely to happen "*at any moment* and *with no notice*." *See Olympic Fed. Sav. & Loan Ass'n v. Director*, 732 F. Supp. 1183, 1187–88 & n.3 (D.D.C. 1990). In such cases, at least one aspect of an injury's timing is clear: The whole risk bears on the plaintiff.

Attias helps illustrate how a risk can have temporal certainty. There, the D.C. Circuit concluded that a risk of harm was imminent because hackers already had "accessed personally identifying data" and had "both the intent and the ability to use that data for ill." *Attias*, 865 F.3d at 628. The full risk was present when the complaint was filed—it did not depend on a "long sequence of uncertain contingencies." *Id.* at 629. The *Attias* plaintiffs were thus likely to experience identity theft at any moment. *Cf. also Olympic Fed. Sav. & Loan*, 732 F. Supp. 3d at 1187.

The same cannot be said here. Even the first potential harm to Plaintiffs will be experienced only when the FDA, at some point, authorizes an SIP, and then an importer decides, at some point, to prepare a pre-import request. So not only is there at least one "uncertain contingenc[y]" between Plaintiffs and the immediate risk of harm, *Attias*, 865 F.3d at 629, but there is also no certain date by which that contingency will be eliminated, *contra Orangeburg*, 862 F.3d at 1078, and no "historical practice" to inform even temporal guesswork, *see id.* at 1079. For those reasons, Plaintiffs' statement that the contingent harms will occur "in the near future," ECF No. 35 at 33, is mere speculation, which cannot support a finding of imminence, *see Chamber of Commerce*, 642 F.3d at 202.

But even if the Court were to set aside the "if" and "when" questions about SIP applications and pre-import requests, the remaining question—"how"—would defeat Plaintiffs' standing. Recall that associational plaintiffs cannot rest on the "statistical probability" that some of their members will suffer harm. *Summers*, 555 U.S. at 497. Courts in this district have divided over whether an association must "identify an injured member by name at the motion to dismiss stage" or instead a "lesser degree" of identification is enough. *Conf. of State Bank Supervisors v. Office of the Comptroller of the Currency*, 313 F. Supp. 3d 285, 298–99 (D.D.C. 2018) (collecting cases). But whether or not a name is needed, it must be possible to identify a specific member who faces the

risk of harm. *See id.* at 299. That "identification requirement serves an important gatekeeping role" where questions remain about which, if any, member of a plaintiff association will suffer injury. *See id.*

Plaintiffs cannot satisfy the identification requirement. That is because there is no way to know which drugs will be included in an approved SIP and which of those drugs an SIP sponsor will import. Plaintiffs explain that the SIP proposals with known contents—Florida's, New Mexico's, and, to a lesser extent, Colorado's—include requests to import drugs manufactured by members of PhRMA and the Council. *See* Compl. ¶¶ 94, 101, 104. Even that allegation includes the probabilistic qualifiers "most" and the "vast majority" regarding the subject drugs. *Id.* But more importantly, the final rule provides that one way for the FDA to act on an SIP proposal is to "modify" the SIP. *See* 21 C.F.R. § 251.4. The rule also contemplates an interactive process where the FDA may request "additional information" and the would-be sponsor may submit a "supplemental proposal." *Id.* § 251.4(c)(1). Because SIP proposals and the resulting deliberations are not public, *see* Compl. ¶ 106, the Court cannot surmise whether a drug's inclusion on an initial proposal will survive deliberations between the FDA and the would-be sponsor. And a drug might be eliminated from an SIP proposal for many reasons—for example, the inability to find a foreign seller. *See* 21 C.F.R. § 251.4(a).[9] Plaintiffs themselves have described to the FDA what they call "serious flaws with [existing SIP] proposals." Compl. ¶ 112. If they are right, remedying those flaws could require substantial revisions of unknown dimensions.

[9] Plaintiffs allege that Florida has "identified a foreign seller for its SIP." Compl. ¶ 93. But that allegation, which is based on another statement at the May 2021 press conference, *see id.*, need not mean that the foreign seller can or will provide every drug listed in an initial proposal. The final rule contemplates that it may be necessary "to add additional Foreign Sellers . . . to an authorized SIP." 21 C.F.R. § 251.8(c).

Plaintiffs, in other words, assert nothing more than the likelihood that some of their members face a risk of harm. But unless "*all* the members of the organization[s] are affected by the challenged activity," the Court cannot "dispense[ ] with" the identification requirement. *Summers*, 555 U.S. at 498–99. And the fact that the Plaintiffs cannot do more than identify an aggregate risk absent further regulatory developments shows that the identification requirement is not here an empty formality—it highlights fundamental uncertainty about the nature of the supposedly impending injury-in-fact. *Cf. Chamber of Commerce*, 642 F.3d at 203 (citing *Am. Chemistry Council*, 468 F.3d at 820). Given that uncertainty, "the identity of the party suffering an injury" in the form of a substantially increased risk of harm is far from "firmly established." *Am. Chemistry Council*, 468 F.3d at 820.

In resisting that conclusion, Plaintiffs point to cases in which, as they put it, courts have found "standing even when a plaintiff's theory of harm rests on future government action." ECF No. 35 at 36. They rely particularly on *Bennett v. Spear*, 520 U.S. 154 (1997), and *Sherley v. Sebelius*, 610 F.3d 69 (D.C. Cir. 2010). Of course, it is true that "the prospect of future government action poses no categorical bar to suit." ECF No. 35 at 37. But *Bennett* and *Sherley* illustrate why the future government action at issue here is too uncertain to confer standing.

The *Bennett* plaintiffs wished to challenge an agency opinion concluding that a water-reclamation project jeopardized endangered species. 520 U.S. at 158–59. The relevant agency had announced that it would "operate the project in compliance with the opinion." *Id.* at 159. The Court held that the plaintiffs had standing because they "receive[d] irrigation water" from part of the project and the opinion recommended restrictions that would "substantially reduc[e] the quantity of available irrigation water." *Id.* at 167 (quotation omitted). The government objected that "a diminution in the *aggregate* amount of available water [did] not necessarily establish . . . that

[the *plaintiffs* would] receive less water." *Id.* But the Court explained that it was "easy to presume specific facts under which [the plaintiffs would] be injured—for example [a] reduction pro rata among [project users]." *Id.* at 168.

Bennett is inapposite for two reasons. First, it was decided under the old, lower pleading standard under which a plaintiff could survive a motion to dismiss unless he could "prove no set of facts in support of his claim which would entitle him to relief."[10] Because a "plaintiff's showing of standing must be evaluated in light of the relevant stage of the proceeding," the Court's willingness in *Bennett* to presume facts under which the plaintiffs would suffer injury has less force under the contemporary, more demanding pleading requirements. *Teva Pharms.*, 369 F. Supp. 3d at 201. Second, the future government action was more definite than that here in two respects. For one thing, the relevant agency had already committed to act. *Bennett*, 520 U.S. at 159. For another, the future action would diminish a shared, fungible resource, and so it was natural to infer that all who used it would suffer harm. *See id.* at 167–68. By contrast, the inference Plaintiffs ask the Court to draw from their allegations is that the FDA will find importation of individual, distinct drugs safe, cost effective, and feasible, *see generally* 21 C.F.R. § 251.3—a conclusion that Plaintiffs emphatically claim would be wrong. So there is no "clear marker[ ]" from which this Court can safely predict how the FDA will "exercise [its] discretion." *Pub. Citizen*, 297 F.3d at 22–23 (quoting *Clapper*, 568 U.S. at 412).

The future injury in *Sherley* was much like that in *Bennett*. An agency action removed funding limits on a federal grant program. *Sherley*, 610 F.3d at 70–71. Two repeat applicants for grants under that program sued, alleging that the increased competition would make it harder for

[10] *Conley v. Gibson*, 355 U.S. 41, 45–46 (1957), *overruled by Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), *and Iqbal*, 556 U.S. 662; *see also Teva Pharms.*, 369 F. Supp. 3d at 201.

them to win grant money. *Id.* at 71. The D.C. Circuit held that they had standing because the increased competition "for a share in a fixed amount of money" meant that they would "have to invest more time and resources to craft a successful grant application." *Id.* at 74. So like in *Bennett*, an inference of harm was possible because of the relative diminution of a shared, fungible resource. For the same reason, then, *Sherley* does not support standing here.

In sum, even the least conjectural of Plaintiffs' allegations about the increased risk of future harm cannot satisfy the "rigorous burden" for establishing standing under such a theory. *Chamber of Commerce*, 642 F.3d at 201 (quotation omitted). To predict whether and when a particular one of Plaintiffs' members will receive an informational demand from an importer, the Court can only speculate. And the other forms of future injury they allege would require the Court to pile on still further speculations. That conclusion is "fatal" to this theory of Plaintiffs' standing. *EPIC I*, 878 F.3d at 379.

2. Injuries from Compliance Costs

Plaintiffs, however, assert past and present financial injuries too. Specifically, they allege that their members have already incurred "compliance costs" to prepare for future pre-import requests once an SIP is authorized. ECF No. 35 at 29–31. Their efforts have included "developing work flows and processes for responding to importer requests" and "identifying and compiling the information needed to conduct the testing." Compl. ¶ 118. They supplement those allegations with the declarations of executives at twelve member companies, who explain how their companies have prepared for a potential pre-import request. *See generally* ECF Nos. 35-2–35-13. Such preparation is reasonable, they explain, because the final rule gives them only 30 days to respond to such a request. Compl. ¶ 118; *see also* 21 C.F.R. § 251.5(d), (e)(2).

But Plaintiffs' members' efforts to mitigate potential future injury are inseparable from the imminence of the future injuries themselves. Undoubtedly, as Plaintiffs point out, "exacerbated

administrative costs [can] constitute a concrete and particularized injury." *New Jersey v. EPA*, 989 F.3d 1038, 1046 (D.C. Cir. 2021); ECF No. 35 at 30. Yet the cognizability of such costs depends on whether Plaintiffs have met the standard for alleging a "substantial increase in the risk of harm." *Food & Water Watch*, 808 F.3d at 919 (citing *Clapper*, 568 U.S. at 416). As the Court has just explained, that is not so. And that requirement retains force even if the Plaintiffs' compliance efforts are a "sensible" response to a tight turnaround. *See In re Sci. Applications Int'l Corp. (SAIC) Backup Tape Data Theft Litig.*, 45 F. Supp. 3d 14, 26 (D.D.C. 2014). If it were otherwise, anyone with reasonable fears of future harm could buy standing via self-inflicted expenditures, irrespective of whether a risk is constitutionally substantial. *See Clapper*, 568 U.S. at 416.

Indeed, Plaintiffs acknowledge that their compliance-costs theory depends on whether they have "adequately alleged a substantial risk of future harm." ECF No. 35 at 31 (quotation omitted and alterations adopted). Because they have not, this theory fails.

3. Procedural Injuries

The story is the same for Plaintiffs' alleged procedural injuries. Among their claims are contentions that the certification that effected the drug-importation statute should have happened before HHS proposed a rule to implement the statute, Compl. ¶ 150, that the certification was a rule that required an independent opportunity for notice and comment, Compl. ¶ 151, that the rule deprives interested parties of notice and the opportunity to comment on or participate in individual SIP proposals, Compl. ¶¶ 173–77, and that HHS failed to follow a statutory consultation requirement, Compl. ¶¶ 178–80. Those alleged procedural missteps, Plaintiffs say, independently confer standing because the procedures were "connected to the substantive result" and they implicate "concrete interests." ECF No. 35 at 27 (quotations omitted and alteration adopted).

But the cognizability of procedural injuries also depends on whether Plaintiffs have shown a "substantial probability" of future harm. *Ctr. for Biological Diversity v. EPA*, 861 F.3d 174,

184–85 (D.C. Cir. 2017) (quotation omitted). In other words, standing cannot be established by "deprivation of a procedural right without some concrete interest that is affected by the deprivation—a procedural right *in vacuo*." *Summers*, 555 U.S. at 496. To assess whether a concrete interest is cognizable, the Court must apply the same increased-risk-of-harm test it has already applied. *See Food & Water Watch*, 808 F.3d at 921.

Again, Plaintiffs acknowledge that their procedural-rights theory depends on whether they have shown a substantial probability of future harm. ECF No. 35 at 29 n.10. Because they have not, this theory fails too.

Plaintiffs, then, have not identified a particular member who would "have standing to sue in his own right." *Chamber of Commerce*, 642 F.3d at 199. So they cannot proceed on an associational-standing theory.

B. Plaintiffs Lack Organizational Standing Because the Certification and Rule Are, At Most, Setbacks to Their Abstract Social Interests

That leaves organizational standing. An organization pleads a concrete injury by alleging facts showing that the challenged action has "perceptibly impaired" its "activities," leading to a "drain on the organization's resources." *Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379 (1982). A "setback to the organization's abstract social interests," by contrast, is not enough. *Id.*

Courts in this Circuit use a two-part test to apply that standard. *Tex. Low Income Hous.*, 427 F. Supp. 3d at 52. First, they assess the alleged impairment to the organization's activities. *EPIC I*, 878 F.3d at 378. The impediment must frustrate the organization's "daily operations." *Food & Water Watch*, 808 F.3d at 919 (quotation omitted). And there must be a "direct conflict between the [defendants'] conduct and the organization's mission." *EPIC II*, 892 F.3d at 1255 (quotation and emphasis omitted). Second, courts ensure the organization "used its resources to counteract that harm." *EPIC I*, 878 F.3d at 378 (quotation omitted). That effort cannot be a "self-

inflicted budgetary choice." *Id.* at 379 (quotation omitted). So litigation costs or extra advocacy efforts do not count. *Food & Water Watch*, 808 F.3d at 919.

Plaintiffs do not advance a theory of organizational standing, but they do allege injuries to themselves—not just their members. Some of those injuries are not cognizable for the reasons already explained. For example, Plaintiffs count themselves among the entities injured by procedural deprivations. *See* Compl. ¶¶ 110, 112, 127–28. But the rules governing those alleged injuries are, of course, no different than for other entities, so they cannot create standing either.

The Partnership and the Council, however, also claim that the certification and rule will impede their and their members' advocacy efforts. They say, for instance, that drug importation will harm "member organizations with a shared interest in the safety of the U.S. drug supply." Compl. ¶ 120, 128. Organizations that "combat[ ] the use misuse of prescription drugs," they predict, "will be forced to expend additional resources to curtail the circulation of unapproved, misbranded, and adulterated drugs." Compl. ¶ 121.

Those allegations fail at the first step of the organizational standing test. They are prototypical statements of harm to "abstract social interests." *Havens Realty Corp.*, 455 U.S. at 379. Plaintiffs nowhere allege that their ability to provide services has been "perceptibly impaired" or describe any "inhibition" of their "daily operations." *Food & Water Watch*, 808 F.3d at 919 (quotation omitted). And simply put, "an organization's use of resources for . . . advocacy is not sufficient to give rise to an Article III injury." *Id.* So Plaintiffs can no more maintain an organizational theory of standing than they could an associational theory.

* * *

Without a plaintiff with standing to challenge the certification or final rule, the Court lacks subject-matter jurisdiction over this case. *Haase v. Sessions*, 835 F.2d 902, 906 (D.C. Cir. 1987).

It thus cannot address Plaintiffs' contentions on their merits. *Steel Co.*, 523 U.S. at 94. And it "must dismiss the complaint in its entirety." *Arbaugh v. Y&H Corp.*, 546 U.S. 500, 514 (2006).

IV. Conclusion

For all the above reasons, the Court will grant Defendants' motion to dismiss insofar as it seeks dismissal under Rule 12(b)(1). A separate order will issue.

/s/ Timothy J. Kelly
TIMOTHY J. KELLY
United States District Judge

Date: February 6, 2023