**UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF COLUMBIA**

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| Pharmaceutical Research & Manufacturers of America, *et al.*,<br><br>Plaintiffs,<br><br>v.<br><br>U.S. Department of Health and Human Services, *et al.*,<br><br>Defendants. | Case No. 1:20-cv-03402-TJK |

**Defendants' Motion to Dismiss For Lack of Subject Matter Jurisdiction And, Alternatively, For Failure to State a Claim Upon Which Relief Can Be Granted**

Defendants U.S. Department of Health and Human Services; Xavier Becerra, Secretary of Health and Human Services; U.S. Food and Drug Administration; and Janet Woodcock, M.D., Acting Commissioner of Food and Drugs, hereby move this Court under Federal Rule of Civil Procedure 12(b)(1) and 12(b)(6) to dismiss this action for lack of subject matter jurisdiction and, alternatively, for failure to state a claim upon which relief can be granted. The grounds for this motion are fully set forth in an accompanying memorandum.

May 28, 2021

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that this document, filed through the CM/ECF system, will be sent via electronic mail to the registered participants as identified on the Notice of Electronic Filing.

May 28, 2021

/s/ James W. Harlow
JAMES W. HARLOW

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**Memorandum in Support of Defendants' Motion to Dismiss For Lack of Subject Matter Jurisdiction And, Alternatively, For Failure to State a Claim Upon Which Relief Can Be Granted**

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## INTRODUCTION

Congress in 2000 and again in 2003 enacted a statutory pathway under which certain prescription drugs could be imported from Canada, 21 U.S.C. § 384. Congress, however, conditioned the statute's effectiveness on the Secretary of Health and Human Services' certification that it would: (1) pose no additional risk to the public's health and safety, and (2) result in a significant cost reduction to American consumers for covered drugs. In September 2020, the Secretary issued the certification necessary to bring the statute into effect ("the Certification"). Simultaneously, the U.S. Department of Health and Human Services ("HHS") and U.S. Food and Drug Administration ("FDA") promulgated a rule under 21 U.S.C. § 384 that established a novel regulatory scheme for States and other non-federal government entities to propose specific programs—known as Section 804 Importation Programs, or "SIPs"—to import eligible prescription drugs from Canada ("the Rule"). 85 Fed. Reg. 62,094 (Oct. 1, 2020).

Plaintiffs here challenge both the Certification and the Rule solely on behalf of their members. But neither action has harmed any of Plaintiffs' members. And no future harm could possibly arise unless and until FDA and other third parties, including State governments, take certain steps—eventualities that remain speculative.

Critically, no SIPs may operate without FDA authorization, and FDA has not authorized a single one. To even be eligible for authorization, a program must satisfy upfront (and continue to demonstrate thereafter) a host of stringent regulatory requirements related to patient safety and drug supply chain security, as well as show significant cost savings to American consumers. FDA possesses discretion to deny any proposal that does not facially meet the regulatory requirements. Even if a proposal is facially complete, the agency still may withhold authorization; for example, if the proposal inadequately protects the public health or insufficiently demonstrates

significant cost savings to American consumers. Unless and until FDA authorizes a SIP, neither the statute nor the implementing regulations require anything of anyone else.

Rather than wait until FDA authorized a SIP, Plaintiffs pre-emptively launched this wholesale attack on the Certification and the Rule. But the doctrines of standing and ripeness do not permit Plaintiffs to erase a Certification and Rule that have not yet affected their members in any concrete way and perhaps never will.

Specifically, Plaintiffs cannot establish any actual injury suffered by their members that is fairly traceable to the bare issuance of the Certification or the Rule. Plaintiffs filed suit before any SIP had even been proposed. To date, *no* SIPs have been authorized. Although two proposals have been submitted to FDA, *no* timeline exists for the agency to make a decision. Thus, the possible future injuries to Plaintiffs' members are overly speculative and not imminent, involving an attenuated chain of possibilities with independent third-parties and discretionary decisions of various government actors.

In addition, regulations ordinarily are not ripe for review until they are applied in a particular instance, providing a concrete factual setting and manageable scope for review. That is true here. Plaintiffs' challenge will not ripen at least until a SIP is authorized by FDA. Litigation of Plaintiffs' claims within the context of a particular, authorized SIP will allow the factual and legal issues to crystallize within manageable dimensions and permit FDA to bring its expertise to bear. Until then, the Certification and the Rule ask nothing of Plaintiffs' members, who are free to conduct their business as they see fit. This case is not justiciable and must be dismissed.

## BACKGROUND

The Federal Food, Drug, and Cosmetic Act ("FDCA"), which regulates drugs in interstate commerce, was twice amended by Congress to provide for importation of prescription drugs from Canada. That authority is contained in 21 U.S.C. § 384, which became effective through the Certification and eligible for implementation through the

Rule. But the survey below reveals how many steps must be taken before their impact could be felt by any of Plaintiffs' members, let alone the general public.

## I. The Statutory Framework for Importing Prescription Drugs from Canada

### A. The FDCA generally regulates access to new drugs.

The FDCA "generally prohibits access to new drugs unless and until they have been approved by . . . FDA." *Abigail All. for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 697 (D.C. Cir. 2007); *see* 21 U.S.C. § 355(a). Likewise, only drugs that meet the conditions of an FDA approval (but for their labeling) are potentially eligible for importation under the Rule. 85 Fed. Reg. at 62,094.

To obtain FDA approval, a drug sponsor submits a new drug application ("NDA") or abbreviated new drug application ("ANDA"), which must establish that the drug is safe and effective for each of its intended uses, through carefully controlled clinical trials and other data. 21 U.S.C. § 355(b), (d); 21 C.F.R. Part 314. During the review and approval process, FDA assesses the specific ingredients, strength and dosage form, specifications related to the drug's containers, exact labeling, and the facilities and processes for manufacturing and storing the drug. 21 U.S.C. § 355(b)(1)(D), (d); 21 C.F.R. § 314.50. For a particular article of drug to be an FDA-approved drug, it must be manufactured, processed, labeled, packaged, and held in strict accordance with the approved drug application. *Id*. Distribution of an adulterated drug in interstate commerce violates the FDCA. 21 U.S.C. §§ 331(a), (k); 351(a)(2)(B).

FDA approvals of NDAs and ANDAs are both manufacturer- and product-specific. 21 U.S.C. § 355; 21 C.F.R. § 314.50; *see also United States v. Generix Drug Corp.*, 460 U.S. 453, 461 (1983). Even if a manufacturer has FDA approval for a particular drug, a version of that drug produced for foreign markets would be unapproved for marketing in the United States unless the foreign version itself has been approved by FDA. *See* 21 U.S.C. § 331(a), (d); 21 C.F.R. § 314.50; *see also United States v. Genendo Pharm., N.V.*, 485

F.3d 958 (7th Cir. 2007); *In Re Canadian Imp. Antitrust Litig.*, 470 F.3d 785, 789-90 (8th Cir. 2006).

Drugs that appear to be adulterated, misbranded or unapproved generally may not be imported into the United States. *See* 21 U.S.C. § 381(a). With certain exceptions for manufacturers importing their own drugs, an entity may not import an unapproved foreign version of a drug, labeled for sale in the foreign market. *See* 21 U.S.C. § 381.[1] However, Congress twice amended the FDCA to create a specific pathway for entities other than manufacturers to import prescription drugs from Canada.

**B. Congress twice amended the FDCA to permit importation of prescription drugs from Canada.**

Two decades ago, Congress noted the rise in "[t]he cost of prescription drugs for Americans." Medicine Equity and Drug Safety Act of 2000, Pub. L. 106-387, § 745(b)(1), 114 Stat. 1549 ("MEDS Act"). Congress also observed that "[m]any life-saving prescription drugs are available in countries other than the United States at substantially lower prices, even though such drugs were developed and are approved for use by patients in the United States." *Id.* § 745(b)(3).

In response, Congress amended the FDCA, through the MEDS Act, to authorize the Secretary to "promulgate regulations permitting pharmacists and wholesalers to import into the United States" certain prescription drugs. *Id.*, § 745(c)(2), 21 U.S.C. § 384(a) (2001) (amended 2003). The goal was to allow Americans "to purchase medicines at prices that are comparable to prices for such medicines in other countries" without "endanger[ing] the gold standard for safety and effectiveness that has been established and maintained in the United States." *Id.*, § 745(b)(5). The Secretary, however, never

[1] These exceptions include when (1) a prescription drug that was manufactured in the United States and exported to another country, is now being imported by that same manufacturer; and (2) a prescription drug that was manufactured outside the United States, but which the manufacturer has authorized to be marketed in the United States and relabeled accordingly, is being imported. *See* 21 U.S.C. § 381(d)(1).

made the "demonstration" to Congress that was required to bring the statute into effect. Importation of Prescription Drugs, 84 Fed. Reg. 70,796, 70,799 (proposed Dec. 23, 2019); *see* 21 U.S.C. § 384(*l*) (2001).

In 2003, Congress superseded the MEDS Act through the Medicare Prescription Drug, Improvement, and Modernization Act ("MMA"), Pub. L. 108-173, § 1121, 117 Stat. 2464 (codified at 21 U.S.C. § 384). Like the MEDS Act, the MMA authorized the Secretary to promulgate regulations to permit wholesalers and pharmacists to import prescription drugs from Canada, subject to several requirements and limitations. 21 U.S.C. § 384(b)–(h).[2] Congress also provided HHS with significant instructions about the implementing regulations' content. *See id*. But before the statute could take effect, the Secretary would have to certify to Congress "that the implementation of this section will: (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." 21 U.S.C. § 384(*l*). Until recently, no such certification had been made.

## II. HHS and FDA establish the framework under which 21 U.S.C. § 384(b)–(h) could be implemented.

On July 31, 2019, HHS and FDA jointly released a "Safe Importation Action Plan to describe steps HHS and FDA will take to allow the safe importation of certain drugs originally intended for foreign markets." HHS, Safe Importation Action Plan, at 1 (July 31, 2019).[3] One of the steps described was a notice of proposed rulemaking to allow importation of drugs from Canada under 21 U.S.C. § 384. *Id.*

[2] The MMA also contains a provision, 21 U.S.C. § 384(j)(2)–(3), that gives the Secretary waiver authority for importation by individuals, but this personal importation provision was not implemented by the Certification or the Rule, and is not at issue here.

[3] https://go.usa.gov/xANKB.

**A. The Proposed Rule**

Consistent with the Safe Importation Action Plan, on December 23, 2019, FDA proposed a rule to implement 21 U.S.C. § 384(b)–(h) by allowing pharmacists and wholesalers to import certain prescription drugs from Canada. *See* 84 Fed. Reg. 70,796. The agency proposed to employ "time-limited Section 804 Importation Programs (SIPs), which would be authorized by FDA and managed by States or other non-federal entities, such as Tribes, in conjunction with co-sponsors like pharmacists or drug wholesalers." 84 Fed. Reg. at 70,797; *see* 21 U.S.C. § 384(a)(1) (permitting pharmacists or wholesalers to act as importers).[4]

On July 24, 2020, the President directed the Secretary to complete the proposed rulemaking process to implement 21 U.S.C. § 384(b)–(h). Exec. Order No. 13,938, § 2(c), 85 Fed. Reg. 45,757 (July 29, 2020). Accordingly, FDA reviewed more than 1,200 comments received on the proposed rule. *See* 85 Fed. Reg. at 62,096. Commenters included consumers and consumer groups, industry and trade organizations, as well as States and Canadian entities. *Id*. Two of the plaintiffs here—Pharmaceutical Research and Manufacturers of America ("PhRMA") and Partnership for Safe Medicines ("PSM")—were among the commenters. *See* Compl., ECF No. 1, at ¶ 55. The comments addressed nearly every aspect of the proposed rule.

**B. The Certification**

On September 23, 2020, the Secretary wrote to congressional leaders "to certify" under 21 U.S.C. § 384(*l*) that he had "determined that implementation of section 804(b)-(h) through the final rule Importation of Prescription Drugs, which [he] will sign immediately after this certification, poses no additional risk to the public's health and safety and will result in a significant reduction in the cost of covered products to the

[4] Section 804 of the FDCA is codified at 21 U.S.C. § 384. For convenience, this brief cites to the U.S. Code section.

American consumer." Compl. ¶ 81; *see* Ex. 1.[5] The Certification described the basic structure of the Final Rule, and how the Rule "includes requirements that provide control over and transparency into the supply chain." *Id*. It also clarified that it did not extend to the personal importation provisions in 21 U.S.C. § 384(j).

**C. The Final Rule**

On September 23, 2020, the Secretary also signed the Importation of Prescription Drugs Final Rule, 85 Fed Reg. 62,094 (Oct. 1, 2020) ("Rule" or "Final Rule"). The Final Rule, codified at 21 C.F.R. Part 251, largely tracks the proposed rule. States (including the District of Columbia and territories) and Indian Tribes may submit SIP proposals to FDA for review and, if warranted, authorization. *See* 85 Fed. Reg. at 62,094. If authorized, a SIP would manage, for renewable 2-year periods, the importation of certain prescription drugs that are approved in Canada and, but for the products' labeling, meet the conditions in an FDA-approved drug application.[6] *Id.*

Generally under a SIP, a Canadian "Foreign Seller" would purchase eligible prescription drugs *directly* from the manufacturer and sell them *directly* to the U.S. "Importer." *Id.* A Foreign Seller is a wholesaler licensed by Canadian authorities and also registered with FDA; an Importer is a wholesale distributor or pharmacist licensed in the United States. *Id.* This short supply chain, coupled with the Rule's other security provisions, is designed to ensure comparable safety to drugs approved by FDA. *See, e.g.*, *id.* at 62,098–99. For example, eligible prescription drugs imported under a SIP must undergo statutorily-prescribed testing to ensure that the drugs are authentic, not

[5] A copy of the Certification cited and quoted in the Complaint is attached hereto as Exhibit 1. *See Kaempe v. Myers*, 367 F.3d 958, 965 (D.C. Cir. 2004) (considering for purposes of motion to dismiss, "public records subject to judicial notice" and documents "referred to in the complaint [that] are integral to" the pleaded claims, "whose authenticity is not disputed").

[6] Eligible prescription drugs *exclude*, for example, biological products, controlled substances, and drugs with extra restrictions known as Risk Evaluation and Mitigation Strategies (REMS) to ensure their safety. *See* 21 C.F.R. § 251.2.

degraded, and meet established specifications and standards ("Statutory Testing"). *See* 21 C.F.R. § 251.2 (defining "Statutory Testing"). And if FDA accepts the testing results, then the drugs must be re-labeled with the required FDA-approved labeling. *See* 85 Fed. Reg. at 62,095.

However, as shown below, numerous steps must occur before a manufacturer incurs any obligations under the Rule, and even more before any drug could be imported and reach a consumer in the United States.

**1. SIP Proposals and FDA authorization**

First, a SIP Sponsor submits to FDA a proposed program to facilitate the importation of specific prescription drugs from Canada. *See* 21 C.F.R. § 251.3. Among many other things, a SIP Proposal must identify and provide detailed supporting information about the Canadian Foreign Seller and the U.S.-based Importer. *Id.* § 251.3(d); *see id.* § 251.2 (defining "Foreign Seller" and "Importer"). Due to the potential difficulties in finding a well-qualified Foreign Seller, a SIP Sponsor has six months after the initial submission to identify a Foreign Seller, but the Proposal cannot be authorized without it. *Id*. § 251.4; *see* 85 Fed. Reg. at 62,099–100. The Proposal must identify the eligible prescription drugs it seeks to import—namely, drugs that are approved by Canada's Heath Products and Food Branch ("HPFB") and, but for the fact that they bear the HPFB-approved labeling, would meet the conditions of an FDA-approved NDA or ANDA. *See* 21 C.F.R. § 251.3(e).

SIP Proposals also must include a detailed summary and importation plan that describe how the Sponsor will ensure, among other substantial criteria, that the imported eligible prescription drugs meet the Statutory Testing requirements; "the supply chain [in the SIP] is secure;" the labeling requirements of the FDCA and the Rule are met; and the post-importation pharmacovigilance and other requirements of the FDCA and the Final Rule are satisfied. *Id*. § 251.3(c)–(e). The Proposal must also contain

copies of the FDA-approved labeling and the proposed new labeling. *Id.* § 251.3(e)(8). Significantly, the SIP Sponsor must explain too how it "will ensure that the SIP will result in a significant reduction in the cost to the American consumer of the eligible prescription drugs that the SIP Sponsor seeks to import." *Id.* § 251.3(e)(9); 85 Fed. Reg. at 62,101–02 (explaining that Sponsors "should clearly articulate the mechanism by which the proposal will reduce costs to consumers" and the types of information considered for such a showing).

FDA "may" deny any SIP Proposal that "does not meet the requirements of" 21 C.F.R. Part 251. 21 C.F.R. § 251.4(a). And even if the Proposal "meets the requirements of" Part 251, FDA still retains discretion to "decide not to authorize the SIP Proposal," for a variety of reasons. *Id.* § 251.4(a). For example, FDA may deny a Proposal due to "potential safety concerns," uncertainty that it "would adequately ensure the protection of the public health," "the recommendation of another [HHS] component . . . [about] the relative likelihood that the SIP Proposal . . . would not result in cost savings to the American consumer," and the limitations of FDA's ability to "effectively and efficiently carry out its responsibilities under" 21 U.S.C. § 384. *Id.* § 251.4(a). The regulations provide no timeframe in which FDA must complete its review of a Proposal.

The Rule requires or requests *nothing* of a drug manufacturer before a SIP is authorized. *See, e.g.*, 85 Fed. Reg. at 62,100 ("Under the final rule, § 251.3(d)(5)–(6), (e)(5) and (7), manufacturers are not required to disclose information before a SIP is authorized."). And *no* SIPs have been authorized. *See, e.g.*, *id.* at 62,095 ("*If* such programs are authorized and implemented . . . .") (emphasis added).

**2. Pre-Importation Requests and another round of FDA review**

Only upon FDA authorization of a SIP would other regulatory provisions begin to apply. The Importer must submit a Pre-Import Request for FDA's authorization at least 30 days before the scheduled date of arrival or "entry for consumption" of a shipment

containing an eligible prescription drug covered by the SIP, whichever is earlier. 21 C.F.R. § 251.5(b). Among many other requirements, Pre-Import Requests must contain detailed information about each drug proposed for import, including its composition and manufacture, *id*. § 251.5(c)(4); a detailed "Statutory Testing Plan," *id*. § 251.5(c)(4)(xi); and the Importer's plan to ensure that the drug complies with all labeling requirements, *id*. § 251.5(c).

To compile this information, an Importer would request that the manufacturer either conduct the Statutory Testing itself, or supply the Importer with all information necessary for the Testing. *Id*. § 251.16(b), (e). The manufacturer would have 30 days to provide this information once requested. *Id*. § 251.16(e). Also upon an Importer's request, a manufacturer would either provide an "attestation and information statement . . . that establishes that the drug proposed for import, but for the fact that it bears the HPFB-approved labeling, meets the conditions in the FDA-approved NDA or ANDA," or notify FDA and the Importer of its inability to do so and explain why it cannot. *Id*. § 251.5(c)(4)(xii), (d). The manufacturer at this stage must also provide certain other manufacturing and transaction records to the Importer upon request. *Id*. §§ 251.5(e), 251.14(b). Again though, these provisions only begin to apply "*[a]fter* FDA has authorized a SIP Proposal." 85 Fed. Reg. at 62,095 (emphasis added).

All information received by an Importer from a manufacturer "must be kept in strict confidence" and used only for specific purposes. 21 C.F.R. § 251.16(g). SIP Sponsors are responsible for ensuring that "any trade secrets or commercial or financial information that is privileged or confidential . . . are kept in strict confidence." *Id.* § 251.3(e)(16); *see id.* § 251.16(h). Violations of these confidentiality obligations would constitute prohibited acts under 21 U.S.C. § 331(aa). 21 C.F.R. § 251.21(b).

After an Importer submits "a complete Pre-Import Request," FDA reviews the request for compliance with all applicable statutes and regulations. 21 C.F.R. § 251.5(a). No drug may be imported until FDA grants the request. *See id.*

**3. Statutory Testing, relabeling, and another round of FDA review**

If FDA grants a Pre-Import Request, the Importer may bring the drugs covered by the Request into the country, but the drugs may not be released until several more steps are completed. Samples of the drugs would be sent to a qualifying laboratory in the United States for the Statutory Testing. *Id*. §§ 251.16(c)–(f); 251.17(d), (e). Samples also would be sent to FDA, along with other information including laboratory records and testing protocols. *Id*. § 251.17(d). The Statutory Testing results would be submitted to FDA for review and acceptance. *Id.* § 251.17(f).

If FDA accepts the Testing results, the Importer may arrange for the drugs to be relabeled. *Id*. Upon request, manufacturers would provide written authorization to the SIP Sponsor or Importer for the use of the applicable, FDA-approved labeling, otherwise such authorization is deemed given. *Id.* § 251.13(a); *see* 21 U.S.C. § 384(h). The relabeling on the imported drug would include the information from the applicable FDA-approved labeling, as well as information about the Importer and a statement that the drug was "imported from Canada without the authorization of [the manufacturer] under" a SIP. 21 C.F.R. § 251.13(b). If "the eligible prescription drug has been shown by testing and relabeling to meet the requirements of" 21 U.S.C. § 384 and 21 C.F.R. Part 251, the Importer or the manufacturer would provide FDA with a certification "that the prescription drug . . . is approved for marketing in the United States and is not adulterated or misbranded" and "meets all labeling requirements" of the FDCA. *Id.* § 251.17(g); *see* 21 U.S.C. § 384(d)(1)(K). Only then could the drugs be distributed to end users in the United States. *See* 21 U.S.C. § 381(a).

**4. Post-Importation requirements**

FDA has wide authority to suspend a SIP, *see* 21 C.F.R. §§ 251.7(a), 251.18, and may do so "immediately" in some circumstances, *id.* § 251.7(b). FDA also may revoke a SIP authorization, in whole or in part, "at any time" for a variety of reasons, including if it determines that "continued implementation of the SIP is not reasonably likely to result

in a significant reduction in the cost of the drugs covered by the SIP to the American consumer." *Id.* § 251.7(c). Drugs that fail to comply with the FDCA and the Rule may be subject to importation refusal, and their importation would constitute a prohibited act under the FDCA. *Id.* § 251.21; *see* 21 U.S.C. § 331(aa).

### III. Post-promulgation developments further complicate the Rule's implementation.

The Final Rule was published on October 1, 2020, and went into effect on November 30. 85 Fed. Reg. at 62,094. Three days earlier, on November 27, 2020, Canada's Minister of Health issued an interim order "to help safeguard the Canadian drug supply by ensuring that bulk importation frameworks, such as the one recently established by the United States, do not cause or exacerbate a drug shortage in Canada." Health Canada, Explanatory note for safeguarding drug supply interim order (Nov. 27, 2020).[7] The interim order prohibits would-be Canadian Foreign Sellers from distributing certain drugs for consumption outside of Canada unless they have "reasonable grounds to believe that the distribution will not cause or exacerbate a shortage of the drug" in Canada. Health Canada, Interim Order Respecting Drug Shortages (Safeguarding the Drug Supply), § 2 (Prohibition) (Nov. 27, 2020).[8] The order also requires manufacturers and drug establishment license holders to inform the Ministry of Health about potential shortages of their drugs. *See id.* §§ 3–4.

Canada's interim order injects uncertainty into whether and to what extent the Rule could be implemented. Qualified Canadian entities also may be unwilling to serve as a Foreign Seller, a pre-existing concern. *See* 85 Fed. Reg. at 62,099. Even if a Foreign Seller

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[7] https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/importation-exportation/interim-order-drug-shortages-protecting-supply/note.html. The Court may take judicial notice of this action. *See Levinson v. Islamic Republic of Iran*, 443 F. Supp. 3d 158, 170 n.15 (D.D.C. 2020).

[8] https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/importation-exportation/interim-order-drug-shortages-protecting-supply.html.

is found and a SIP authorized, that Seller's ability to export the eligible drugs is now subject to the dynamics of the Canadian drug supply and the Ministry of Health.

To date, FDA has received two publicly announced SIP Proposals, from the States of Florida and New Mexico, and two citizen petitions from PhRMA, PSM, and The Council for Affordable Health Coverage ("CAHC"), requesting that the agency refrain from authorizing those Proposals. *See* Pls.' Fla. Citizen Pet., Dkt. FDA-2021-P-0034-0001, at 1–2 (Jan. 7, 2021);[9] Pls.' N.M. Citizen Pet., Dkt. FDA-2021-P-0307-0001, at 1–2 (Mar. 18, 2021);[10] *see also* 21 C.F.R. § 10.30 (citizen petition authority). Plaintiffs' petitions make a number of procedural and substantive arguments against authorization, including that the Proposals lack required elements. *See* Pls.' Fla. Citizen Pet. 2, 26; Pls.' N.M. Citizen Pet. 2, 10. Those SIP Proposals and Plaintiffs' petitions remain under review by FDA.

**IV. Plaintiffs' Lawsuit**

Plaintiffs PhRMA, PSM, and CAHC filed this action on November 23, 2020, seven days before the Final Rule went into effect, solely on behalf of their members. *See* Compl. ¶ 90. Plaintiffs allege six counts, which challenge the Certification and the Final Rule under the Administrative Procedure Act ("APA") and the First Amendment, *see id.* ¶¶ 100–45—but not the lawfulness of 21 U.S.C. § 384. They ask this Court to declare the Certification and Rule void in their entirety, and prevent Defendants from implementing them. *See id.* at 68.

After extension of their deadline to respond to the Complaint, Defendants now move to dismiss this action under Federal Rule of Civil Procedure 12(b)(1) and 12(b)(6) for lack of subject-matter jurisdiction and failure to state a claim upon which relief can be granted.

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[9] https://go.usa.gov/x6qFS. Florida's proposal was submitted on or around November 23, 2020. *See id*. at 2.

[10] https://go.usa.gov/x6qMx.

## LEGAL STANDARD

When considering a motion to dismiss for lack of subject matter jurisdiction under Rule 12(b)(1), the Court "presume[s]" to "lack jurisdiction" unless Plaintiffs meet their "burden of establishing it." *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 342 n.3 (2006) (quotation omitted). The Court accepts the complaint's "well-pleaded factual allegations" and any reasonable inferences drawn therefrom, but does "not assume the truth of legal conclusions" or "accept inferences that are not supported by the facts set out in the complaint." *Arpaio v. Obama*, 797 F.3d 11, 19 (D.C. Cir. 2015). "Additionally, '[t]he court must give the [Plaintiffs'] factual allegations closer scrutiny when resolving a Rule 12(b)(1) motion than would be required for a Rule 12(b)(6) motion because subject-matter jurisdiction focuses on the court's power to hear the claim.'" *Texas Low Income Hous. Info. Serv. v. Carson*, 427 F. Supp. 3d 43, 52 (D.D.C. 2019) (quoting *Adams v. U.S. Capitol Police Bd.*, 564 F. Supp. 2d 37, 40 (D.D.C. 2008)). The Court lacks subject-matter jurisdiction if Plaintiffs cannot establish their standing, *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992), and if their claims are not ripe, *Exxon Mobil Corp. v. FERC*, 501 F.3d 204, 207 (D.C. Cir. 2007).

Alternatively, some courts have considered questions of prudential ripeness under Rule 12(b)(6) rather than Rule 12(b)(1). *See, e.g., Matthew A. Goldstein, PLLC v. U.S. Dep't of State,* 153 F. Supp. 3d 319, 331 n.9 (D.D.C. 2016) (quotation omitted). But "even in its prudential aspect," ripeness remains "a threshold inquiry." *In re Aiken Cty.*, 645 F.3d 428, 434 (D.C. Cir. 2011).

## ARGUMENT

This case founders on the twin justiciability doctrines of standing and ripeness. *See, e.g.*, *Trump v. New York*, 141 S. Ct. 530, 535 (2020) (per curiam). Plaintiffs have not established that any member suffered an actual or imminent injury traceable to the

mere issuance of the Certification or the Rule. Instead, Plaintiffs point to possible future injuries that might arise from the Rule's implementation through a SIP, but their allegations are "riddled with contingencies and speculation that impede judicial review." *New York*, 141 S. Ct. at 535.

The Rule has never been implemented. And any future implementation, if it were to occur, may not occur as Plaintiffs speculate. Meanwhile, nothing is required of Plaintiffs' members. The complaint thus presents "abstract hypotheticals or requests for advisory opinions," which fall outside the bounds of Article III, *Irregulators v. FCC*, 953 F.3d 78, 82 (D.C. Cir. 2020), and would "entangl[e the Court] in abstract disagreements over administrative policies," *Nat'l Park Hosp. Ass'n v. Dep't of Interior*, 538 U.S. 803, 807–08 (2003) (quotation omitted). Because Plaintiffs cannot establish standing or ripeness, the Court cannot decide the case. *See DaimlerChrysler*, 547 U.S. at 341.

## I. Absent any actual or imminent injury, Plaintiffs' members lack both standing and constitutionally ripe claims.

Standing and ripeness are threshold issues that must be resolved before reaching the merits. *See, e.g.*, *Util. Air Regul. Grp. v. EPA*, 320 F.3d 272, 277 (D.C. Cir. 2003). Because Plaintiffs do not allege any direct injury to themselves as organizations, they must establish "for each of [their] claims, that at least one of [their] members has standing" to sue in its own right. *Elec. Priv. Info. Ctr. v. U.S. Dep't of Com.*, 928 F.3d 95, 101 (D.C. Cir. 2019) (quotation omitted). Plaintiffs must show that their member "suffered an injury in fact fairly traceable to the actions of the [Defendants] that is likely to be redressed by a favorable decision on the merits." *Food & Water Watch, Inc. v. Vilsack*, 808 F.3d 905, 913 (D.C. Cir. 2015) (quotation omitted).

The injury-in-fact must be "concrete and particularized" and "actual or imminent, not conjectural or hypothetical." *Lujan*, 504 U.S. at 560 (internal quotation omitted). To qualify as "imminent," an alleged future harm must be either "'certainly impending' or there is a 'substantial risk' that the harm will occur." *Susan B. Anthony List v. Driehaus*,

573 U.S. 149, 158 (2014) (quoting *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 414 n.5 (2013)). "[A]llegations of *possible* future injury are not sufficient;" nor is any future injury that depends upon "a highly attenuated chain of possibilities." *Clapper*, 568 U.S. at 409 (internal quotation omitted). Also, "Plaintiffs cannot rely on speculation about 'the unfettered choices made by independent actors not before the court.'" *Id.* at 414 n.5 (quoting *Lujan*, 504 U.S. at 562).

The standing doctrine's injury-in-fact requirement also comprises the constitutional component of the ripeness doctrine. *See Am. Petroleum Inst. v. EPA*, 683 F.3d 382, 386 (D.C. Cir. 2012). "Just as the constitutional standing requirement for Article III jurisdiction bars disputes not involving injury-in-fact, the ripeness requirement excludes cases not involving present injury." *Wyoming Outdoor Council v. U.S. Forest Serv.*, 165 F.3d 43, 48 (D.C. Cir. 1999); *see Chlorine Inst., Inc. v. Fed. R.R. Admin.*, 718 F.3d 922, 927 (D.C. Cir. 2013).

The allegations in the Complaint do not establish that Plaintiffs' members have standing or constitutionally ripe claims for three reasons. *First*, Plaintiffs have not demonstrated an actual or imminent injury to their members traceable to the Rule. Plaintiffs can only speculate whether a State will propose a SIP that substantively satisfies the extensive regulatory requirements, and whether FDA will authorize that SIP. If no such SIP is proposed or authorized, the Rule's obligations on drug manufacturers will never be triggered and they will never face the possibility of injury. The alleged injuries derivative of patient harm are even more attenuated, involving layers of speculation about future events and the actions of third parties not before the Court.

*Second*, Plaintiffs have not demonstrated an actual or imminent injury to their members traceable to the Certification. The Certification merely brought 21 U.S.C. § 384(b)–(h) into effect—a statute not challenged in this litigation—and required nothing of Plaintiffs' members. Moreover, Plaintiffs' members have not plausibly

alleged any procedural injury sufficient for standing related to the Certification's issuance. *Third*, Plaintiffs' inability to show any injury to their members also manifests in the failure of PhRMA and CAHC to specifically identify any injured member, as they must for associational standing.

### A. None of the injuries feared by Plaintiffs' members related to the Rule are actual or imminent.

"[S]tanding is assessed as of the time a suit commences," here, November 23, 2020. *Chamber of Com. of U.S. v. EPA*, 642 F.3d 192, 199 (D.C. Cir. 2011). Unquestionably, Plaintiffs' challenge to the Rule rests solely on feared future, rather than presently felt, injuries to their members. *See, e.g.*, Compl. ¶¶ 73 ("*would be* required to facilitate importation . . . and *would* face the Hobson's choice"); 74 ("*would be* required to turn over"); 76 ("*would be* required either to attest to"); 77 ("*what happens if* the manufacturer believes"); 78 ("*would* also be required to provide"); 79 ("*would* be required to bear"); 94 ("*will* intrude on. . . various intellectual property rights"); 143 ("*would* also restrict manufacturers' speech rights" and "*would* compel manufacturers to make attestations") (emphases added). Plaintiffs thus "bear[] a more rigorous burden to establish standing." *Arpaio*, 797 F.3d at 21. They cannot satisfy this burden because "the [Rule] may not prove feasible to implement in any manner whatsoever, let alone in a manner substantially likely to harm any of" their members. *New York*, 141 S. Ct. at 535.

#### 1. Plaintiffs' members could not possibly suffer harm until a SIP is authorized.

Of all Plaintiffs' members, the earliest alleged injuries stem from the Rule's provisions related to PhRMA members, *i.e.*, drug manufacturers or NDA and ANDA holders. *See* Compl. ¶¶ 94-96. *None* of the Rule's provisions actually required anything of a PhRMA member when the suit was filed; the same is true today. Before any PhRMA member would have to attest that the drug to be imported meets the conditions of an FDA approval, conduct the Statutory Testing or provide information necessary for

the Importer to conduct the Testing, authorize (or be deemed to have authorized) the use of its label for the imported drug, furnish any potentially confidential commercial information to anyone, or perform any of the other actions they claim the Rule requires of them, *see, e.g.*, Compl. ¶¶ 73–78, 94–95, 144, a State must submit a SIP Proposal that substantively meets the Rule's requirements and, after review, FDA must determine that the SIP should be authorized, *see supra* pages 7–12 (describing regulatory process). Plaintiffs can only speculate whether or when each of those eventualities might occur.

Any prediction about SIP authorization involves speculation about several events, including the independent choices of third-parties and the discretionary decisions of government actors. First, a putative SIP Sponsor must amass a significant amount of information to submit a facially complete Proposal. *See* 21 C.F.R. § 251.3(d)–(e); *see also id.* § 251.2; *supra* pages 8–9. The putative Sponsor also must find, within six months of its initial submission, a well-qualified Canadian drug wholesaler willing to act as a Foreign Seller. *See* 21 C.F.R. §§ 251.3(d)(7)–(8), 251.3(2)–(4), 251.4; 85 Fed. Reg. at 62,099–100. But the willingness and ability of Canadian wholesalers to serve as Foreign Sellers may be limited by the Canadian government's recent prohibition on exporting drugs based on Canada's domestic drug supply and imposition of additional reporting obligations. *See* Health Canada, Interim Order §§ 2–4.[11]

Assuming a SIP Sponsor can compile and submit to FDA a facially complete Proposal, Plaintiffs can only speculate whether it would receive FDA authorization. The agency's review is rigorous and multifaceted, and authorization ultimately is discretionary. FDA may deny any Proposal that "does not meet the requirements of" 21 C.F.R. Part 251 for any of various reasons. 21 C.F.R. § 251.4(a). "FDA may decide not to

[11] Similarly, a manufacturer could try to stymie any would-be SIP by declining to sell the drugs to a known Foreign Seller, or contractually prohibiting their re-sale through a SIP. *See* 85 Fed. Reg. at 62,107 ("each drug imported under [a] SIP must be sold by the manufacturer *directly* to a Foreign Seller."). Such sales, after all, are not compelled by the Rule.

authorize a SIP Proposal," for example, "because of potential safety concerns with the SIP," "because of the degree of uncertainty that the SIP Proposal . . . would adequately ensure the protection of public health," "because of . . . the relative likelihood that the SIP Proposal . . . would not result in significant cost savings to the American consumer," or due to the agency's internal resource constraints. *Id.*

The period for FDA to review a SIP Proposal is indeterminate. The SIP process, the Rule, and 21 U.S.C. § 384(b)–(h) only came into effect months ago. *See* 85 Fed. Reg. at 62,100 ("SIPs are new and unique programs which may be challenging to implement at first . . . ."). Even Plaintiffs agree this is a "novel and untested program." Pls.' Fla. Citizen Pet. 27. FDA's review also may include conferral with other HHS components, which would require additional time. 21 C.F.R. § 251.4(a). Therefore, if or when FDA may receive a qualifying SIP Proposal and then authorize such a proposal—the necessary predicate for any harm to Plaintiffs' members—remains unknown.

Courts repeatedly have found Article III not satisfied when an alleged injury turns on the speculative outcome of a third-party's licensing process. For example, in *Chlorine Institute, Inc. v. Federal Railroad Administration*, 718 F.3d 922 (D.C. Cir. 2013), the D.C. Circuit dismissed a challenge brought by the chlorine industry to a Federal Railroad Administration rule that required certain rail carriers to submit "implementation plans" regarding their use of positive train control ("PTC") systems, *id.* at 924. Although the plaintiff averred possible reductions in chlorine shipments by rail, the D.C. Circuit rejected this injury as speculative because the plaintiff did "not know which track segments will be fitted with PTC under the plans that are submitted by [rail] carriers and ultimately approved by" the agency. *Id.* at 928. Until "the PTC Implementation Plan process advances and its impact becomes clearer," *id.* at 928–29, the plaintiff had "not demonstrated . . . an imminent or certainly impending injury," *id.* at 927.

Likewise, in *Teva Pharmaceuticals USA, Inc. v. Azar*, 369 F. Supp. 3d 194 (D.D.C. 2019), the plaintiff-drugmaker's alleged injury would manifest only if FDA approved a

competitor's ANDA, *id.* at 200. The court found no imminent harm sufficient for standing because, among other reasons, "there is no guarantee that the FDA will approve *any* of the existing ANDAs." *Id.* at 200, 203. "Approval," the court observed, "is a demanding task" and "by no means a forgone conclusion." *Id.* Absent "any indication about the status of the FDA's review, the Court has no means of assessing whether any ANDA is likely to receive approval, and if so, when that is likely to occur." *Id; see also Conf. of State Bank Supervisors v. Office of Comptroller of Currency*, 313 F. Supp. 3d 285 (D.D.C. 2018) (dismissing suit by state regulators, who feared harms "contingent on whether the" Office of Comptroller of Currency chartered a financial technology company, because "[s]everal contingent and speculative events must occur before" a charter would issue); *see also Gulf Restoration Network, Inc. v. Nat'l Marine Fisheries Serv.*, 730 F. Supp. 2d 157, 167 (D.D.C. 2010) (dismissing challenge to fishery management plan for lack of injury-in-fact because plan "merely constructs a framework within which Defendants may permit an entirely new activity that has yet to occur" and thus is "too far removed from harmful conduct to establish injury").

Here too, the alleged injuries to Plaintiffs' members involve the kind of speculation that "is ordinarily fatal to standing." *Elec. Priv. Info. Ctr.*, 928 F.3d at 102 (quotation omitted). The SIP Proposal process is both extensive and novel. Plaintiffs can only speculate about how third-parties—including SIP Sponsors, potential Foreign Sellers, and the Canadian Government—will act. And "[a]ny prediction how" FDA "might eventually implement" the Rule and authorize a SIP "is no more than conjecture at this time." *New York*, 141 S. Ct. at 535. Although events may occur as Plaintiffs' envision, "that speculation does not suffice" and Plaintiffs lack the constitutionally required injury-in-fact. *Summers v. Earth Island Inst.*, 555 U.S. 488, 499 (2009).

**2. The alleged injuries to Plaintiffs' members that derive from patient harm are far too speculative.**

The remaining alleged injuries to PhRMA's members and all alleged injuries to PSM's and CACH's members require extending the chain of speculation even further. The precursor for these alleged injuries is the "increased risk" that consumers would be harmed from unapproved, misbranded, or adulterated drugs imported through a SIP. *See* Compl. ¶¶ 91–93, 97–98. But "the mere increased risk of some event occurring is utterly abstract—not concrete, direct, real, and palpable" and "everyone in the relevant population is hit with the same dose of risk, so there is no particularization." *Pub. Citizen, Inc. v. Nat'l Highway Traffic Safety Admin.*, 489 F.3d 1279, 1297–98 (D.C. Cir. 2007). The "ultimate alleged harm" to Plaintiffs' members rests atop this poor foundation. *Food & Water Watch*, 808 F.3d at 915.

Plaintiffs cannot establish, as they must, "*both* (i) a *substantially* increased risk of harm and (ii) a *substantial* probability of harm with that increase taken into account." *Id.* at 914 (quotation omitted). PhRMA claims that the possible harm to consumers from drugs imported under a SIP will "in turn, harm manufacturers," who allegedly will be blamed, Compl. ¶ 91–92; PSM and CAHC similarly allege "financial and reputational harms" to their members flowing from possible patient harm, *id.* ¶¶ 97–98. However, no injuries derivative of patient harm could be realized *at the earliest* until drugs are actually distributed to consumers under a SIP—the very *last* step in the process. To reach that point, a SIP Proposal must be submitted to and authorized by FDA; a Pre-Importation Request must be submitted to and granted by FDA; the drugs must be shipped to the United States and tested, with the results accepted by FDA; and the

drugs must be relabeled,[12] and then distributed, dispensed, and administered in the United States.[13] *See supra* pages 8–11.

Plaintiffs have not plausibly alleged a substantial probability that all of those steps will occur *and* that they will occur in a manner that leads to a substantial probability of patient harm (*i.e.*, drugs actually presenting a risk to patient safety will be imported). *See, e.g.*, *Food & Water Watch*, 808 F.3d at 918 ("Because Plaintiffs have failed to plausibly allege that the [challenged USDA regulation] substantially increases the risk of producing unwholesome, adulterated poultry compared to the existing inspection systems, they do not have standing."); *Food & Water Watch v. U.S. EPA*, 5 F. Supp. 3d 62, 74–75 (D.D.C. 2013) (plaintiffs failed to establish injury-in-fact because "[t]he creation of [pollution] 'hotspots' by the issuance of" EPA permits was "highly speculative" and not "an actual or imminent injury for purposes of Article III"). Because the risk of patient harm is itself "overly speculative," all alleged injuries deriving therefrom necessarily are too speculative to confer standing. *Arpaio*, 797 F.3d at 21.

Any "reputational" harm, "increased costs," or "litigation risks" that would allegedly befall Plaintiffs' members, Compl. ¶¶ 92, 97–98, further depend on subsequent independent actions of third-party consumers, who would have to suffer harm and choose to blame Plaintiffs' members for their harms. Given "this long chain of events" and "Plaintiffs' inability to establish that each event has a substantial likelihood of occurring," these allegations are "[in]sufficiently imminent to constitute an injury-in-fact" and "not fairly traceable to the challenged action." *Double R Ranch Tr. v. Nedd*, 284 F. Supp. 3d 21, 27 (D.D.C. 2018). Nor can Plaintiffs' members bootstrap their way into

[12] As for Plaintiffs' labeling concerns, they would suffer no injury at least "until [FDA] actually approves a label bearing the allegedly infringing or diluting name." *Sociedad Anonima Vina Santa Rita v. U.S. Dep't of Treasury*, 193 F. Supp. 2d 6, 25 (D.D.C. 2001).

[13] Likewise, no PhRMA member could possibly lose revenue to Importers, *see* Compl. ¶ 96, until after SIP authorization because only then could a Foreign Seller purchase their covered drugs.

standing through "self-inflicted injuries" like voluntary "investments in pharmacovigilance," supply-chain security, and educational campaigns in anticipation of forecasted patient harm. *Compare* Compl. ¶ 93, *with Clapper*, 568 U.S. at 416 (parties "cannot manufacture standing merely by inflicting harm on themselves based on their fears of hypothetical future harm that is not certainly impending"), *and Nat'l Family Plan. & Reprod. Health Ass'n, v. Gonzales*, 468 F.3d 826, 831 (D.C. Cir. 2006).

Because Plaintiffs' parade of horribles requires far too many inferential leaps about the possible downstream effects of SIP authorization and implementation, it does not constitute an actual or imminent injury-in-fact sufficient for standing or ripeness.[14]

**B. The Certification's mere issuance created no actual or imminent injury to Plaintiffs' members.**

Plaintiffs' challenge to the Certification likewise founders because they have "neither sufficiently alleged nor persuasively demonstrated any threat of injury in fact to any of [their] members that is 'fairly traceable to' the" Certification itself. *Nat'l Ass'n of Home Builders v. EPA*, 667 F.3d 6, 13 (D.C. Cir. 2011); *see* Compl. ¶¶ 99–122 (counts I–III). By its plain terms, the Certification, which was addressed to Congress, neither compelled nor prohibited any action by Plaintiffs' members. *See* Ex. 1, Certification. It simply permitted parts of 21 U.S.C. § 384 to "become effective." 21 U.S.C. § 384(*l*); *see* Ex. 1. This was "the only issue the [Certification] in fact resolved." *Nat'l Ass'n of Home Builders*, 667 F.3d at 13*; see also* 85 Fed. Reg. at 62,114 (observing that the "certification is a finding that functions as a procedural step" that permits the agency to engage in rulemaking and "has no independent effect on outside parties"). And Plaintiffs do not

[14] Because PSM's and CAHC's standing rests solely upon these deficient allegations of injury derived from patient harm, they should not receive "an automatic 'pass'" even if the Court finds that PhRMA otherwise has standing. *Ctr. for Biological Diversity v. Trump*, 453 F. Supp. 3d 11, 29 (D.D.C. 2020). Rather, because PSM and CAHC "have completely failed to establish organizational standing," the Court should, "in its discretion," dismiss them from the case. *Id.*

allege their members are injured by the mere "existence of the law." *United Pub. Workers of Am. v. Mitchell*, 330 U.S. 75, 91 (1947). They do not challenge the statute *whatsoever*.

Nonetheless, Plaintiffs contend that the Certification, like the Rule, "threaten[s] patient safety." Compl. ¶ 91; *see id.* ¶¶ 97–98. However, as shown above, this nebulous threat does not amount to an injury-in-fact. No harm to patients is even possible (nor to Plaintiffs' members themselves, as discussed above) until a SIP is authorized and any drugs imported under a SIP must clear several additional layers of discretionary FDA review—the likelihood of which is a matter of pure speculation.

In addition, Plaintiffs' Count III alleges that "the Secretary . . . deprived regulated parties of any opportunity to comment" on matters "required to substantiate the Certification" and that they "will [be] deprive[d]" of such opportunity in the future. Compl. ¶ 121. It is unclear whether Plaintiffs assert this "deprivation" as an independent procedural injury. *See* Compl. ¶¶ 90–98 (enumerating "Injuries Resulting From the Certification and the Final Rule" without mention of procedure). But to the extent Plaintiffs do, to survive a motion to dismiss for lack of standing on a procedural rights claim, they "must show *both* (1) that their [members'] procedural right has been violated, *and* (2) that the violation of that right has resulted in an invasion of their concrete and particularized interest." *Ctr. for Law & Educ. v. Dep't of Educ.*, 396 F.3d 1152, 1159 (D.C. Cir. 2005). Plaintiffs cannot satisfy either prong here.

Plaintiffs' procedural claim rests upon a legal conclusion—the Certification was a rule subject to the notice-and-comment procedures in 5 U.S.C. § 553—that enjoys no presumption of truth. *Arpaio*, 797 F.3d at 19; *see* Compl. ¶ 121. Indeed, it is not true. Section 553 only applies to "substantive, legislative rules," *Clarian Health W., LLC v. Hargan*, 878 F.3d 346, 356 (D.C. Cir. 2017); *see* 5 U.S.C. § 551(4) (defining "rule"), which the Certification was not.

*First*, as discussed above, the Certification was addressed only "to the Congress." 21 U.S.C. § 384(*l*)(1); Ex. 1. The Certification itself imposed no "legally binding

obligations or prohibitions on regulated parties," as would a legislative rule subject to 5 U.S.C. § 553. *Nat'l Min. Ass'n v. McCarthy*, 758 F.3d 243, 251–52 (D.C. Cir. 2014). The Certification neither compels nor precludes any action by regulated parties. A simple hypothetical illustrates the point. If FDA authorized a SIP but the manufacturer whose drugs would be imported under the SIP refused to provide the information needed to conduct the Statutory Testing, that refusal would not violate the *Certification*. Rather, it would run afoul of the regulation, 21 C.F.R. § 251.16(b), (e), and the statute, 21 U.S.C. § 384(e); *see* 21 C.F.R. § 251.21; 21 U.S.C. § 331(aa).

*Second*, although a rulemaking "generally involve[s] broad applications of more general principles," *Neustar, Inc. v. FCC*, 857 F.3d 886, 893 (D.C. Cir. 2017), the Certification was a one-time, particularized "finding" by the Secretary that led to 21 U.S.C. § 384(b)–(h) becoming effective, 85 Fed. Reg. at 62,114; *see* 21 U.S.C. § 384(*l*). In this way, it was more of a "case-specific individual determination[]." *Neustar*, 857 F.3d at 893. Indeed, the agency characterized the Certification as akin to a declaratory order. *See* 85 Fed. Reg. at 62,114 (citing *Wilson v. A.H. Belo Corp.*, 87 F.3d 393, 397 (9th Cir. 1996) and *Time Warner Entm't Co. v. FCC,* 240 F.3d 1126, 1141 (D.C. Cir. 2001)); *see also* 5 U.S.C. § 554(e) (agency "may issue a declaratory order to terminate a controversy or remove uncertainty"). Declaratory orders generally "belong[] to the genre of adjudicatory rulings," *Chisholm v. FCC*, 538 F.2d 349, 365 n.30 (D.C. Cir. 1976), and are not subject to notice-and-comment requirements, *see Cent. Texas Tel. Co-op., Inc. v. FCC*, 402 F.3d 205, 210 (D.C. Cir. 2005).

*Third,* a comparison between the statutory provisions for issuance and revocation of the Certification further confirms that the former is not subject to 5 U.S.C. § 553. Congress provided a process for *revoking* the certification "after a hearing on the record" under 5 U.S.C. §§ 556–57, 21 U.S.C. § 384(*l*)(2)(B), but in contrast, provided no process for the decision to issue the certification, *id.* § 384(*l*)(1); *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 544 (2012) ("Where Congress uses certain language in one part of

a statute and different language in another, it is generally presumed that Congress acts intentionally."). Thus, Plaintiffs have not plausibly alleged that the issuance of the Certification violated any member's procedural rights.

Even assuming the Certification was subject to 5 U.S.C. § 553, Plaintiffs also have not adequately alleged that "the violation resulted in injury to their [members'] concrete, particularized interest." *Ctr. for Law & Educ.*, 396 F.3d at 1157. "[T]he mere inability to comment effectively or fully, in and of itself, does not establish an actual injury." *Int'l Bhd. of Teamsters v. Transp. Sec. Admin.*, 429 F.3d 1130, 1135 (D.C. Cir. 2005) (internal quotation omitted). Yet beyond a generic inability of "regulated parties" to comment, Compl. ¶ 121, Plaintiffs do not allege their members suffered any "personal and particularized injury" therefrom, *Int'l Bhd. of Teamsters*, 429 F.3d at 1135 (quotation omitted).[15] Accordingly, Plaintiffs lack standing for any procedural-rights claim. *See Ctr. for Law & Educ.*, 396 F.3d at 1160.

### C. PhRMA and CAHC failed to specifically identify any members who will be injured.

Plaintiffs PhRMA and CAHC have further failed "to make *specific* allegations establishing that at least one *identified* member had suffered or would suffer harm." *Summers*, 555 U.S. at 498 (emphases added). Because PhRMA and CAHC invoke this Court's jurisdiction "solely as the representative[s] of [their] members," *Warth v. Seldin*, 422 U.S. 490, 511 (1975), associational standing doctrine precludes them from merely "aver[ring] that unidentified members have been injured," *Pub. Citizen, Inc. v. Trump*, 297 F. Supp. 3d 6, 18 (D.D.C. 2018) (quoting *Chamber of Com.*, 642 F.3d at 199).

[15] In any event, as FDA explained, the Certification explicitly relied on the Final Rule as its basis and was issued contemporaneously with it; therefore, Plaintiffs already received the opportunity to comment they seek. *See, e.g.*, 85 Fed. Reg. at 62,111–14 (FDA responding to comments questioning legality of certification); *id.* at 62,114 (FDA responding to comment on the lack of opportunity to comment).

Although the complaint contains web links to PhRMA's and CAHC's full lists of members, Compl. ¶¶ 1, 3, these do not "specifically 'identify members who have suffered the requisite harm'" traceable to the Certification and the Rule, *Chamber of Com.*, 642 F.3d at 199 (quoting *Summers*, 555 U.S. at 499); *see Conf. of State Bank Supervisors*, 313 F. Supp. 3d at 298–99 ("at least three courts in this district have required an associational plaintiff to identify an injured member *by name* at the motion to dismiss stage"). Nor is it "enough to show . . . that [Plaintiffs' members] are part of an industry being regulated by the Final Rule." *Am. Chemistry Council v. Dep't of Transp.*, 468 F.3d 810, 920 (D.C. Cir. 2006). This failure cannot be overlooked, otherwise PhRMA and CAHC would "make a mockery of" standing jurisprudence. *Summers*, 555 U.S. at 498. Indeed, this case highlights the "important gatekeeping role" served by the requirement, *Conf. of State Bank Supervisors*, 313 F. Supp. 3d at 299, because as PhRMA admits, some drug manufacturers "may approve . . . of importation," Compl. ¶ 143. Accordingly, with no allegations identifying a specific member with standing, PhRMA's and CAHC's claims should be dismissed for this reason as well.[16] *See Firearms Policy Coal., Inc. v. Barr*, 419 F. Supp. 3d 118, 125 (D.D.C. 2019) (dismissing action, in part, due to failure to specifically identify injured member); *Conf. of State Bank Supervisors*, 313 F. Supp. 3d at 299 (same); *Pub. Citizen*, 297 F. Supp. 3d at 18 (same).

**II. Plaintiffs' claims are not prudentially ripe.**

Even if Plaintiffs' claims are constitutionally ripe, they are not prudentially ripe. "Ripeness is a justiciability doctrine designed 'to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties.'" *Nat'l Park Hosp. Ass'n*, 538 U.S. at 807–08 (quoting *Abbott Labs.*

[16] Although PSM identified members, *see* Compl. ¶ 97, its standing allegations are otherwise deficient as explained herein.

*v. Gardner*, 387 U.S. 136, 148–149 (1967)). To this end, the Supreme Court has repeatedly recognized that "[a] claim is not ripe for adjudication if it rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all." *Texas v. United States*, 523 U.S. 296, 300 (1998) (internal quotation marks omitted); *see also, e.g.*, *New York*, 141 S. Ct. at 535.

In considering ripeness, courts must "evaluate both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." *Abbott Labs.*, 387 U.S. at 149. Here, Plaintiffs cannot establish either ripeness prong. The issues are not fit for review because the dispute would not take shape, at the earliest, until a State proposes a SIP that substantively satisfies all regulatory criteria, and FDA, in its discretion, authorizes it. Otherwise, adjudication of Plaintiffs' claims now would require the Court to resolve numerous complex factual questions and variables through a host of assumptions and further deprive it of the benefit of FDA's evaluation and assessment. Plaintiffs also will face no hardship from deferring review because neither the Certification nor the Rule requires *any* action from their members now.

### A. Plaintiffs' challenge is not fit for judicial review until FDA authorizes a SIP.

"Among other things, the fitness of an issue for judicial decision depends on whether it is 'purely legal, whether consideration of the issue would benefit from a more concrete setting, and whether the agency's action is sufficiently final.'" *Atl. States Legal Found., Inc. v. EPA*, 325 F.3d 281, 284 (D.C. Cir. 2003) (quoting *Clean Air Implementation Project v. EPA*, 150 F.3d 1200, 1204 (D.C. Cir. 1998)). Even where "the question presented [] is 'a purely legal one' and . . . constitutes 'final agency action'" a case may be not fit where "further factual development would 'significantly advance [a court's] ability to deal with the legal issues presented." *Nat'l Park Hosp. Ass'n*, 538 U.S. at 812 (internal quotation omitted). When an agency decision may never have "its effects felt in a concrete way by the challenging parties," *Abbott Labs.*, 387 U.S. at 148–49,

"the prospect of [a court] entangling [itself] in a challenge to such a decision is an element of the fitness determination," *Devia v. Nuclear Regul. Comm'n*, 492 F.3d 421, 424 (D.C. Cir. 2007).

As the D.C. Circuit has admonished:

> Even though the legal issues may be clear, a case may still not be fit for review: The question of fitness does not pivot solely on whether a court is capable of resolving a claim intelligently, but also involves an assessment of whether it is appropriate for the court to undertake the task. Federal courts cannot—and should not—spend their scarce resources on what amounts to shadow boxing. Thus, if a plaintiff's claim, though predominantly legal in character, depends on future events that may never come to pass, or that may not occur in the form forecasted, then the claim is unripe.

*Devia*, 492 F.3d at 424–25 (cleaned up). That prudential concern "is especially true when the issue is one of constitutional import." *See Full Value Advisors, LLC v. SEC*, 633 F.3d 1101, 1106 (D.C. Cir. 2011); Compl. ¶¶ 130, 139–44 (noting potential First and Fifth Amendment issues).

Here, Plaintiffs' ripeness quest fails because it rests upon "contingent future events that may not occur as anticipated, or indeed may not occur at all." *Texas,* 523 U.S. at 300. A putative SIP Sponsor may never amass a facially complete Proposal, as discussed above. Even if facially complete, such Proposal may not substantively satisfy all applicable requirements, including adequate protection of public health and significant cost savings to American consumers. *See* 21 C.F.R. § 251.4(a). Thus, "the prudential ripeness doctrine counsels in favor of allowing time to sharpen this dispute before deciding it" because "there may ultimately be no case to decide at all if the [FDA] does not [authorize] a [SIP]." *Conf. of State Bank Supervisors*, 313 F. Supp. 3d at 301; *see, e.g.*, *Gulf Restoration Network*, 730 F. Supp. 2d at 170 (challenge to fishery management plan

not fit for review because process may result in "the denial of any and all aquaculture permits" so "injury to Plaintiffs will not even be a possibility"); *see also AstraZeneca Pharm. LP v. Food & Drug Admin.*, 850 F. Supp. 2d 230, 243 (D.D.C. 2012).

The Supreme Court has recognized that "wholesale" challenges to "broad regulations" generally are unripe before "the scope of the controversy has been reduced to more manageable proportions, and its factual components fleshed out, by some concrete action applying the regulation to the claimant's situation in a fashion that harms or threatens to harm him." *Lujan v. Nat'l Wildlife Fed'n,* 497 U.S. 871, 891 (1991). Accordingly, the Supreme Court has repeatedly declined to find cases ripe where future administrative action lay between an agency rule or policy and its effect actually being felt on a plaintiff. *See, e.g.*, *Nat'l Park Hosp. Ass'n*, 538 U.S. at 810–12 (challenge to regulation unfit for review until submission of, and action on, National Park Service concession contract provided "a concrete dispute"); *Ohio Forestry Ass'n, Inc. v. Sierra Club*, 523 U.S. 726, 733–34 (1998) (challenge to Forest Service land management plan unripe until further Forest Service procedures authorizing logging occurred, which would afford the "benefit of the focus that a particular logging proposal could provide"); *Lujan*, 497 U.S. at 893 n.3 (case not ripe "before the grant of such a permit [to conduct mining operations], or (when it will suffice) the filing of a notice to engage in mining activities, or . . . actual mining of the land" because "it is impossible to tell where or whether mining activities will occur"); *Toilet Goods Ass'n v. Gardner*, 387 U.S. 158, 163–64 (1967) (deferring broad regulatory challenge until an actual FDA inspection, when case was "likely to stand on a much surer footing in the context of a specific application of this regulation").

Courts within this Circuit have followed the Supreme Court's lead. *See, e.g.*, *Ctr. for Biological Diversity v. U.S. Dep't of Interior*, 563 F.3d 466, 480 (D.C. Cir. 2009) (holding that challenge, under two environmental statutes, to leasing program for offshore oil and gas development was unripe because "[n]o lease-sales had yet occurred"); *Sprint Corp.*

*v. FCC*, 331 F.3d 952, 956, 958 (D.C. Cir. 2003) (awaiting FCC decision on a particular "specialized overlay proposal" before reviewing agency policy because "issues still may not be fit for review where the agency retains considerable discretion to apply the new rule on a case-by-case basis"); *Sierra Club v. U.S. Dep't of Energy*, 825 F. Supp. 2d 142, 155 (D.D.C. 2011) (dismissing NEPA claim as unripe where agency had not issued formal "Record of Decision on a [loan] guarantee" and thus was "not committed to making one"; collecting cases). So too here.

By deferring review here until FDA authorizes a SIP, the Court would "bring[] 'more manageable proportions' to the scope of the parties' dispute." *New York*, 141 S. Ct. at 536 (quoting *Nat'l Wildlife Fed'n*, 497 U.S. at 891). Further factual development in the form of an authorized SIP—and the administrative process surrounding it—would both aid the Court's analysis and allow FDA the opportunity to further apply its expertise.

Plaintiffs' claims involve numerous complex factual questions, including how a SIP could achieve cost savings for American consumers, how a SIP could maintain supply chain security, how the Statutory Testing would occur, and how a manufacturer's trade secrets would be protected. *See, e.g.*, Compl. ¶¶ 60–71, 91–92, 106, 112, 130. Each SIP Proposal must address in detail these same factual questions (and many others), within its own particular setting. *See* 21 C.F.R. §§ 251.3(d)–(e). Indeed, Plaintiffs recognize that a critical feature of the Rule's (and the Certification's) structure is that they are implemented *only* through specific SIPs. *See, e.g.*, Compl. ¶ 121 (arguing that "consideration of such facts" about "public health and safety" was "deferred . . . *until such time as FDA approves* one or more SIP proposals") (emphasis added). And Plaintiffs' citizen petitions challenge, among other things, Florida's and New Mexico's proposed safeguards to ensure the safety of imported drugs, assessment of significant cost savings to the American consumer, and labeling provisions. Pls.' Fla. Citizen Pet. 12–26; Pls.' N.M. Citizen Pet. 10–27. In other words, many of the issues Plaintiffs present to this Court in the abstract will be addressed and further fleshed out through the

administrative process surrounding particular SIP Proposals. *See Ohio Forestry Ass'n*, 523 U.S. at 736 (disapproving "time-consuming judicial consideration of the details of an elaborate, technically based plan . . . without benefit of the focus that a particular . . . proposal could provide").

FDA's considered determination on any SIP Proposal and any related citizen petition would offer the Agency further opportunity to apply its expertise as to them and conceivably correct any mistakes, possibly narrowing or even obviating the issues for the Court. *See* 21 C.F.R. §§ 251.4, 10.30; *Ohio Forestry Ass'n*, 523 U.S. at 735–36. At a minimum, FDA should be afforded an opportunity "to refine its policies . . . through application of the [regulations] in practice." *Ohio Forestry Ass'n*, 523 U.S. at 735; *see Finca Santa Elena, Inc. v. U.S. Army Corps of Eng'rs*, 873 F. Supp. 2d 363, 369 (D.D.C. 2012) ("[A] controversy is not prudentially ripe if further administrative processes would aid in the development of any facts needed by the court to decide the question presented.").

Thus, an authorized SIP provides the "concrete setting" necessary for review, *Atl. States*, 325 F.3d at 284, and would "significantly advance [the court's] ability to deal with the legal issues presented," *Nat'l Park Hosp. Ass'n*, 538 U.S. at 812. Accordingly, this case "presents the classic institutional reason to postpone review:" the Court "need[s] to wait for a rule to be applied [to see] what its effect will be." *La. Envt'l Action Network v. Browner*, 87 F.3d 1379, 1385 (D.C. Cir. 1996).

**B. Plaintiffs will suffer no hardship by deferring judicial review.**

Meanwhile, Plaintiffs' members will "suffer no concrete harm" from deferring judicial review because neither the Certification nor the Rule "require them 'to do anything or to refrain from doing anything.'" *New York*, 141 S. Ct. at 536 (quoting *Ohio Forestry Ass'n*, 523 U.S. at 733). "Generally speaking, hardship will establish ripeness only where 'postponing review . . . impose[s] a hardship on the complaining party that is *immediate, direct, and significant*.'" *Friends of Animals v. Haugrud*, 236 F. Supp. 3d 131,

135 (D.D.C. 2017) (quoting *Cronin v. FAA*, 73 F.3d 1126, 1133 (D.C. Cir. 1996)) (emphasis added). No hardship exists when a regulation does not "require[] the plaintiff to adjust [its] conduct *immediately*" and it remains "free to conduct its business as it sees fit." *Sprint*, 331 F.3d at 958 (quoting *Nat'l Park Hosp. Ass'n,* 538 U.S. at 808, 810) (emphasis added). By contrast, courts have found hardship when "promulgation of the challenged regulations presented plaintiffs with the *immediate dilemma* to choose between complying with newly imposed, disadvantageous restrictions and risking serious penalties for violation." *Reno v. Cath. Soc. Servs., Inc.*, 509 U.S. 43, 57–58 (1993) (emphasis added).

Here, "the source of any injury to the plaintiffs is the action that" third-parties and FDA "*might* take in the future . . . not the [Certification or the Rule] itself in the abstract." *New York*, 141 S. Ct. at 536 (internal quotation omitted). As discussed above, the mere issuances of the Certification and Final Rule do not pose a hardship on Plaintiffs' members, where *nothing* is required of them today and they are free to conduct their business as they see fit. *See, e.g., New York,* 141 S. Ct. at 536; *Sprint*, 331 F.3d at 958. Because Plaintiffs' alleged harms—such as the potential disclosure of trade secrets or the use of drug labeling, *see* Compl. ¶¶ 93–94, 98—all are contingent on at least SIP authorization, they do not support any present hardship, *see, e.g.*, *Full Value Advisors*, 633 F.3d at 1107 (when no "allegedly proprietary information" has been disclosed publicly, company "has not yet suffered any hardship as a result of the . . . disclosure requirements"); *Pfizer Inc. v. Shalala*, 182 F.3d 975, 979 (D.C. Cir. 1999) (competitive harm claim not ripe before FDA approves competitor's product); *Sociedad Anonima*, 193 F. Supp. 2d at 25 (finding "trademark claims are not ripe" until agency "actually approves a label bearing the allegedly infringing or diluting name"). The most Plaintiffs can complain is that they "*would* face [a] Hobson's choice" *if* certain events occurred as they fear. Compl. ¶ 73 (emphasis added). But without an immediate impact

on their "day-to-day affairs," Plaintiffs' members are not burdened by deferring review. *Toilet Goods*, 387 U.S. at 164–65.

Moreover, Plaintiffs' members "may protect all of their rights and claims by returning to court when the controversy ripens." *Atl. States Legal Found.*, 325 F.3d at 285. Any future SIP authorization would be an agency "order" that could be administratively challenged in a citizen petition or request for stay of administrative action. *See* 21 C.F.R. §§ 10.30 (citizen petition), 10.35 (administrative stay); 85 Fed. Reg. at 62,121–22. Plaintiffs' citizen petitions regarding the Florida and New Mexico SIP Proposals vouch for the utility of that process. And should Plaintiffs suggest "there may not be time for judicial review in the future," that would "ignore[] the possibility of judicial stays and expedited review." *Sprint*, 331 F.3d at 958.

This case exemplifies "the usually unspoken element of the rationale underlying the ripeness doctrine: If [the Court] do[es] not decide it now, [it] may never need to." *Nat'l Treasury Emps. Union v. United States*, 101 F.3d 1423, 1431 (D.C. Cir. 1996). Because Plaintiffs' case demonstrates neither fitness nor hardship, it is not ripe. The prudent and legally required course is to defer review.

## CONCLUSION

For the foregoing reasons, the Court should grant Defendants' motion to dismiss for lack of subject matter jurisdiction, or in the alternative, for failure to state a claim, and dismiss this action.

May 28, 2021

Respectfully submitted,

/s/ James W. Harlow
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**CERTIFICATE OF SERVICE**

I hereby certify that this document, filed through the CM/ECF system, will be sent via electronic mail to the registered participants as identified on the Notice of Electronic Filing.

May 28, 2021

/s/ James W. Harlow
JAMES W. HARLOW

# Exhibit 1

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

SEP 2 3 2020

The Honorable Kevin McCarthy
Minority Leader
U.S. House of Representatives
Washington, DC 20515

Dear Represenative McCarthy:

I am writing to certify, under section 804(l) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 384(l)), that I have determined that implementation of section 804(b)-(h) through the final rule Importation of Prescription Drugs, which I will sign immediately after this certification, poses no additional risk to the public's health and safety and will result in a significant reduction in the cost of covered products to the American consumer. The final rule (Regulation Identifier Number (RIN) 0910-AI45) includes conditions under which certain prescription drugs can be imported from Canada to the United States under section 804 of the FD&C Act. This certification is limited to implementation of section 804(b)-(h) through the final rule and does not authorize any other method of implementing section 804.

The final rule implementing section 804(b)-(h) of the FD&C Act includes requirements that provide control over and transparency into the supply chain. The final rule allows States, the District of Columbia, territories, and Indian Tribes, and in certain future circumstances pharmacists and wholesalers, to submit "Section 804 Importation Program" (SIP) proposals to the Food & Drug Administration (FDA) for review and authorization. An importation program could be co-sponsored by a pharmacist, a wholesaler, a State, the District of Columbia, a territory, or an Indian Tribe. These programs, authorized by FDA for renewable 2-year periods, will manage the importation of certain prescription drugs that are approved in Canada and, but for the products' labeling when marketed in Canada, meet the conditions in an FDA-approved new drug application or abbreviated new drug application. Under these importation programs, a "foreign seller" that is licensed to wholesale drugs in Canada and registered with FDA will purchase eligible prescription drugs directly from the manufacturer. An importer that is a wholesale distributor or pharmacist licensed in the United States will buy the drugs directly from the foreign seller. Both the foreign seller and the importer are subject to certain requirements under the rule, including serialization and recordkeeping requirements. In addition, eligible prescription drugs must undergo statutorily prescribed testing to ensure that the drugs are authentic, are not degraded, and meet established specifications and standards. If FDA accepts the testing results, then the drugs must be re-labeled with the FDA-approved labeling. Biological products, controlled substances, and certain other categories of drug products, such as drugs subject to Risk Evaluation and Mitigation Strategies (REMS), will not be eligible for importation under the final rule. The final rule also includes post-importation requirements, including safety reporting and recall requirements. Importation programs must also demonstrate a significant cost reduction to the American consumer. An importation program may be terminated by FDA at any time for the reasons outlined in this final rule.

The personal importation provisions of section 804(j) of the FD&C Act are not being implemented through this rulemaking, and thus section 804(j) is not currently in effect. Any implementation of section 804(j) and any other implementation of section 804 outside the scope of the Importation of Prescription Drugs rulemaking would occur through a separate certification.

I look forward to continuing our work together to help American patients access safe, effective, and high-quality prescription drugs. A copy of this letter is also being sent to President of the Senate Pence, Speaker Pelosi, Majority Leader McConnell, Minority Leader Schumer, Chairmen Alexander and Pallone, Senator Murray, and Representative Walden.

Sincerely,

Alex M. Azar II

**UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF COLUMBIA**

| | |
|---|---|
| Pharmaceutical Research & Manufacturers of America, *et al.*,<br><br>Plaintiffs,<br><br>v.<br><br>U.S. Department of Health and Human Services, *et al.*,<br><br>Defendants. | Case No. 1:20-cv-03402-TJK |

**[Proposed] Order Granting Defendants' Motion to Dismiss**

Before the Court is Defendants' motion to dismiss under Federal Rule of Civil Procedure 12(b)(1) and 12(b)(6) for lack of subject matter jurisdiction and, alternatively, for failure to state a claim upon which relief can be granted. Having considered the parties' arguments in light of the governing standard, it is hereby ORDERED that Defendants' motion to dismiss is GRANTED. The Clerk shall close the case.

SO ORDERED.

Dated: _____.

_____
Timothy J. Kelly
United States District Judge