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Supplement to Citizen Petition
Docket No. FDA-2021-P-0034-0001

Covington & Burling LLP, on behalf of the Pharmaceutical Research and Manufacturers of America ("PhRMA"), Ballard Spahr LLP, on behalf of the Partnership for Safe Medicines ("PSM"), and Sidley Austin LLP, on behalf of the Council for Affordable Health Coverage ("CAHC"), respectfully submit this supplement to the Citizen Petition Assigned Docket No. FDA-2021-P-0034-0001 ("Original Citizen Petition"). The referenced Citizen Petition requested that the U.S. Food and Drug Administration ("FDA" or the "Agency") refrain from authorizing Florida's November 23, 2020 Section 804 Importation Program Proposal for the Importation of Prescription Drugs from Canada ("Original Proposal").

Through this supplement, PhRMA, PSM, and CAHC raise several concerns regarding what appears to be the most recent amendment to the Original Proposal (the "April 2023 Amended Proposal"). The first is procedural. In the final rule on importation of prescription drugs, FDA identified the citizen petition process as the only way for interested parties to engage with the Agency about a SIP proposal prior to the Agency making a determination.[1] This process has proven inadequate and unworkable—Florida and FDA have engaged in substantial back-and-forth regarding the scope and substance of Florida's Section 804 Importation Program Proposal, which has been outside the public view and impedes the ability for affected stakeholders to submit public comment.

Turning to the substance of the April 2023 Amended Proposal, the content that is publicly available is incomplete, obfuscating a comprehensive assessment whether the proposed importation scheme meets statutory and regulatory requirements. However, based on its review of both the April 2023 Amended Proposal and the attachments, FDA identified numerous substantive deficiencies. Petitioners have identified additional ways in which the April 2023 Amended Proposal fails to satisfy the criteria for authorization, such that importation of prescription drugs from Canada under the April 2023 Amended Proposal would present an unreasonable risk to patients living in Florida. Finally, the April 2023 Proposal cannot be authorized because it was submitted pursuant to an invalid certification and unlawful final rule.

[1] 85 Fed Reg. 62094, 62121-22 (Oct. 1, 2020).

For the reasons identified herein and in our Original Citizen Petition, petitioners respectfully request that FDA refrain from authorizing the April 2023 Amended Proposal.

I. Background

The Original Citizen Petition, filed on January 7, 2021, discussed:

- The requirements for commercial importation under section 804 of the Federal Food, Drug, and Cosmetic Act;
- Then-Secretary of the Department of Health and Human Services ("HHS") Alex M. Azar's letter to Congress purporting to certify that implementation of the commercial importation provisions will not pose any 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;
- Publication by HHS and FDA of a final rule permitting commercial importation of certain prescription drugs from Canada without the manufacturer's authorization (the "final rule," codified at 21 C.F.R. Part 251);
- Litigation filed by PhRMA, PSM, and CAHC in the U.S. District Court for the District of Columbia on November 23, 2020, challenging the certification and the final rule, *PhRMA v. U.S. Dep't of Health and Human Servs*. No. 1:20-cv-03402 (D.D.C.); and
- Florida's submission of the Original Proposal to FDA on November 23, 2020.

Below, petitioners provide information on events that have occurred since the filing of the Original Citizen Petition.

In August 2022, the State of Florida and the Florida Agency for Health Care Administration ("AHCA") (collectively "Florida" or the "State") filed a complaint and amended complaint against FDA, HHS, FDA Commissioner Califf, and HHS Secretary Becerra (collectively "FDA"), alleging that FDA has unreasonably delayed acting on Florida's Original Proposal, as subsequently amended, in violation of the Administrative Procedure Act ("APA"), and seeking immediate review and action by FDA.[2] Court filings in *Florida v. U.S. Food & Drug Admin.* (M.D. Fla.) reveal that Florida has amended its SIP Proposal at least three times and

[2] First Amended Compl. ¶¶ 86-103 (Count I), *Florida v. U.S. Food & Drug Admin.*, No. 8:22-cv-1981 (M.D. Fla. Aug. 29, 2022). Florida also seeks to compel FDA to respond to AHCA's pending July 6, 2022 Freedom of Information Act ("FOIA") request seeking documents related to Canadian importation, including information about Florida's SIP Proposal and proposals from Colorado, New Hampshire, Vermont, and Maine. *Id.* ¶¶ 104-14 (Counts II and III). Count IV seeks declaratory relief. *Id.* ¶¶ 115-16. AHCA subsequently submitted two similar FOIA requests in March 2023 and May 2023, which are at issue in a separate case. *See Florida v. U.S. Food & Drug Admin.*, No. 8:23-cv-0877 (M.D. Fla. Apr. 21, 2023). Hereinafter, references to *Florida v. U.S. Food & Drug Admin.* relate to the 8:22-cv-1981 case.

that it has engaged in substantive back-and-forth with FDA regarding the proposal's scope and substance.

On December 29, 2022, FDA filed the administrative record,[3] which included amended proposals—not previously public—submitted by Florida to FDA on April 19, 2021 (the "April 2021 Amended Proposal");[4] September 15, 2021 (the "September 2021 Amended Proposal");[5] and November 11, 2021 (the "November 2021 Amended Proposal").[6] The administrative record also included letters from FDA to Florida documenting missing information and requesting additional information, including a request for information (RFI) letter sent on November 16, 2022 (the "November 2022 RFI"), seeking additional information related to the November 2021 Amended Proposal.[7]

The 15-page November 2022 RFI highlighted numerous deficiencies in the November 2021 Amended Proposal, many of which were emphasized in our Original Citizen Petition. Among other things, FDA stated that the November 2021 Amended Proposal did not adequately demonstrate cost savings and failed to describe how Florida would meet its statutory responsibilities to test imported product. FDA also requested additional information on the steps that Florida will take to ensure applicable supply chain security requirements are met and asked Florida to provide relevant policies, procedures, and protocols consistent with the final rule.

On April 7, 2023, FDA moved to stay the case as to the APA claim and corresponding request for declaratory judgment, until 60 days after the date on which Florida submitted an amendment to its SIP Proposal.[8] In its April 21 memorandum in opposition, Florida appended an amended proposal dated April 7 (the "April 2023 Amended Proposal" defined above), which Florida stated "responds to the November 2022 RFI."[9]

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[3] Filing of Administrative Record, *Florida v. U.S. Food & Drug Admin.*, No. 8:22-cv-1981 (M.D. Fla. Dec. 29, 2022).

[4] *Id.* at FDA-FLORIDA-000142 through FDA-FLORIDA-000266.

[5] *Id.* at FDA-FLORIDA-000273 through FDA-FLORIDA-000401.

[6] *Id.* at FDA-FLORIDA-004455 through FDA-FLORIDA-004580.

[7] *Id.* at FDA-FLORIDA-004602 through FDA-FLORIDA-004616. The administrative record also included a letter sent on August 20, 2021, detailing missing information from the Original Proposal and the April 2021 Amended Proposal, *see id.* at FDA-FLORIDA-000267 through FDA-FLORIDA-000269, and questions relayed via email in September and November 2021 regarding the September 2021 Amended Proposal, *see id.* at FDA-FLORIDA-000402 through FDA-FLORIDA-000404.

[8] First Motion to Stay the Case as to Counts One and Four, *Florida v. U.S. Food & Drug Admin.*, No. 8:22-cv-1981 (M.D. Fla. Apr. 7, 2023).

[9] Memorandum in Opposition to Motion to Stay, *Florida v. U.S. Food & Drug Admin.*, No. 8:22-cv-1981 (M.D. Fla. Apr. 21, 2023); Exhibit A, Memorandum in Opposition to Motion to Stay, *Florida v. U.S. Food & Drug Admin.*, No. 8:22-cv-1981 (M.D. Fla. Apr. 21, 2023) (hereinafter cited as "April 2023 Amended Proposal").

On May 26, 2023, FDA submitted a status report, stating that FDA had "immediately initiated its review" process for the April 2023 Amended Proposal and that it anticipated completing its review and issuing a decision on Florida's SIP Proposal by October 31, 2023.[10] Following a case management conference, on June 8, 2023, U.S. District Judge Thomas Barber entered an order partially granting FDA's request for a stay, stating that "[t]he potential for the APA claims to become moot upon a decision from the FDA prior to trial weighs heavily in favor of staying the proceedings as to these claims to conserve judicial resources."[11] The order further directed FDA to "submit a status report on or before August 8, 2023, to apprise the Court of the status of the decision-making timeline for the updated SIP proposal."[12]

On August 8, 2023, FDA updated the court that it "still anticipates issuing a decision on Florida's SIP proposal by October 31, 2023."[13] In an August 15, 2023 supplemental status report, FDA stated that it had "determined that Florida's proposal still does not contain certain information that is required under the SIP regulations."[14] FDA appended an August 14 letter outlining substantive deficiencies in the April 2023 Amended Proposal ("August 2023 Letter").[15] FDA requested that Florida provide "additional or clarifying information to address the deficiencies" by August 28. Florida submitted a status report on August 29, 2023, raising a variety of complaints regarding the deficiencies cited by FDA. The State attached an August 28, 2023 letter it sent to FDA in which it requested additional time to respond to the August 2023 Letter and a conference call.[16]

II. The Original Proposal has been largely rewritten outside the public's view, illustrating the inadequacy of the citizen petition process.

Since 2019, petitioners have emphasized that the APA and principles of due process mandate that affected parties have the ability to comment on any SIP proposal before FDA makes a determination. In comments submitted on the proposed rule, PhRMA proposed that authorization should not proceed until application holders have the opportunity to comment.[17] In the final rule, FDA rejected PhRMA's proposal, stating that interested parties could submit a

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[10] Defendants' Status Report for the APA Claim, *Florida v. U.S. Food & Drug Admin.*, No. 8:22-cv-1981 (M.D. Fla. May 26, 2023).

[11] Endorsed Order, *Florida v. U.S. Food & Drug Admin.*, No. 8:22-cv-1981 (M.D. Fla. June 8, 2023).

[12] *Id.*

[13] Defendants' Status Report for the APA Claim (Counts 1 and 4), *Florida v. U.S. Food & Drug Admin.*, No. 8:22-cv-1981 (M.D. Fla. Aug. 8, 2023).

[14] Defendants' Supplemental Status Report for the APA Claim, *Florida v. U.S. Food & Drug Admin.*, No. 8:22-cv-1981 (M.D. Fla. Aug. 15, 2023).

[15] Exhibit A, Defendants' Supplemental Status Report for the APA Claim, *Florida v. U.S. Food & Drug Admin.*, No. 8:22-cv-1981 (M.D. Fla. Aug. 15, 2023) (hereinafter cited as "August 2023 Letter").

[16] Plaintiffs' Status Report for APA Claims, *Florida v. U.S. Food & Drug Admin.*, No. 8:22-cv-1981 (M.D. Fla. Aug. 29, 2023).

[17] PhRMA, Comment Letter on NPRM, Docket No. FDA-2019-N-5711, at 73 (Mar. 9, 2020), https://www.regulations.gov/document?D=FDA-2019-N-5711-1236.

citizen petition under 21 C.F.R. § 10.25, but that application holders would not otherwise be entitled to participate in FDA's review of a SIP proposal.[18]

For the reasons PhRMA, PSM, and CAHC identified in *PhRMA v. U.S. Department of Health & Human Services*, No. 1:20-cv-03402 (D.D.C.), citizen petitions are not a substitute for the APA right to timely notice and an opportunity to comment. As an initial matter, petitioners and their members have no means of obtaining information in a timely fashion or submitting timely and informed citizen petitions when SIP sponsors do not choose to make their proposals and amendments thereto publicly available.[19] We incorporate by reference the APA procedural challenge to the final rule in the amended complaint (Count VI) and associated briefing.[20]

The lack of transparency into the significant changes made to Florida's SIP Proposal over the past two and a half years illustrates why relying on interested parties to submit citizen petitions is unworkable. To our knowledge, none of the amended proposals has been published by FDA outside of the court filings referenced above. Petitioners have learned of these submissions only by diligently monitoring the docket for *Florida v. U.S. Food & Drug Admin*. Except where states have voluntarily chosen to disclose their SIP proposals, interested parties have no means of learning about the existence of the proposals, much less whatever changes may be made and the reasons for such changes. The result is an iterative regulatory process with substantial public health implications conducted almost entirely behind closed doors.

The April 2023 Amended Proposal demonstrates why citizen petitions are not an effective substitute for a true APA process. Through the April 2023 Amended Proposal, Florida made multiple substantive changes to the Original Proposal. For example:

- Florida changed the identity of the importer in the April 2023 Amended Proposal. The Original Proposal named the Department of Health Central Pharmacy as the importer and stated that LifeScience Logistics, LLC ("LSL") would "assist the state and importer" with critical tasks, including negotiating drug prices, transporting drugs into the U.S., and distributing drugs to the end user.[21] The April 2023 Amended Proposal, however, lists LSL as the importer, rather than as a "designee" of the Department of Health Central Pharmacy.[22]

- Only five of the 17 drugs included in the April 2023 Amended Proposal were included in the Original Proposal. The Original Proposal included a list of 47 drugs, which was winnowed down to 27 drugs in the November 2021 Amended Proposal. Between

[18] 85 Fed Reg. at 62121-22 (Oct. 1, 2020).

[19] First Amended Compl. ¶ 112, *PhRMA v. U.S. Dep't of Health & Human Servs.*, No. 1:20-cv-03402 (D.D.C. July 2, 2021); *see also id.* at ¶ 175 ("Plaintiffs have access only to information that the SIP Sponsor chooses to make public, including the existence of the SIP, details of the proposal and amendments thereto, and its status with the agency.").

[20] The court dismissed the case solely on standing grounds on February 6, 2023, and did not consider the merits of any of the plaintiffs' claims. Memorandum Opinion 13-14, *PhRMA v. U.S. Dep't of Health & Human Servs.*, No. 1:20-cv-03402 (D.D.C. Feb. 6, 2023).

[21] Original Proposal at 6.

[22] April 2023 Amended Proposal at 9.

November 2021 and April 2023, Florida removed 22 drugs and added 12 entirely new drugs, including several with multiple strengths.

- Between November 2021 and April 2023, Florida largely rewrote the section on cost savings, stating that it had worked with an actuarial contractor, Milliman, Inc., to prepare baseline and plan scenarios. Florida also made significant changes to sections describing qualifying laboratory testing techniques; storage, handling, supply chain, and reporting guidelines; education and outreach plans; and compliance plans. Notably, as discussed in the next Section, Florida did not include any attachments to the April 2023 Amended Proposal filed with the court, though the table of contents indicates that the attachments were rewritten.

To our knowledge, none of these changes was announced by FDA or Florida other than in a multi-thousand page administrative record posted in December 2022 and an exhibit to a Memorandum in Opposition to Motion to Stay submitted in April 2023 (which, in turn, was incomplete, as discussed in the next Section). The lack of transparency from FDA and the State into these significant changes has impeded our ability to provide comment with respect to a novel and untested program. Nor have Florida citizens been provided with an opportunity to comment.

III. Lack of access to the attachments makes it impossible to submit complete and informed comments on the April 2023 Amended Proposal.

Turning to the substance of the April 2023 Amended Proposal, the content posted to the docket is incomplete, obfuscating a comprehensive assessment whether the proposed importation scheme meets statutory and regulatory requirements. Much of the meat of the proposal still has not been made available to the public. Florida appears to have added new Attachments A through J in support of its submission, but these attachments were not included in the court filing and do not appear to be otherwise publicly posted.[23] These attachments provide critical information about how Florida intends to protect the safety of the drug supply, and how cost savings have been estimated, both vitally important for Florida's patients.

For example, Attachment G is supposed to provide critical information about laboratory testing entities and standard operating procedures ("SOPs") governing testing. Attachments H and I, meanwhile, are supposed to set forth the relevant SOPs governing, among other things recalls, removals, and corrections; handling, storage, packaging, and distribution; pharmacovigilance; track and trace; and relabeling requirements. The lack of such SOPs was identified by FDA as a key deficiency in FDA's November 2022 RFI. But without seeing the actual documents, petitioners cannot plausibly comment on whether there are any gaps that threaten the drug supply or otherwise pose an unreasonable risk to the State's public health and safety. Similarly, petitioners cannot comment on the cost estimates without reviewing Attachment E, which includes the Milliman narrative, the Milliman Canadian drug importation analysis, and the SIP methodology and data for cost analysis. In the body of the April 2023 Amended Proposal, Florida states that it projects savings of $130,885,890.70 in the first year and $140,722,659.82 in the second year, but provides no drug-specific cost information, and no insight into how Milliman arrived at those figures.

Petitioners were able to obtain copies of Attachments A through J through records requests to AHCA. However, Attachments G, H, and I are so heavily redacted that they are not

[23] *Id.* at 52-54.

reviewable. With respect to Attachment E, petitioners obtained a letter from Milliman to AHCA entitled "Analysis of the Canadian Drug Importation Program," but did not receive the two exhibits referenced in the letter demonstrating "Net Projected Savings for the Program" and "Rebate/Dispensing Fee Inputs." Petitioners also received a document entitled "Methodology and Data for Cost Analysis," but the tables therein redact all drug-specific information on rebates, estimated total net costs for Florida Medicaid, and projections under the Baseline Scenario and the Plan Scenario.

Responses from AHCA represent the only insight petitioners have into the attachments. Covington has not received a response from FDA in response to its July 14, 2023, FOIA request seeking attachments to the April 2023 Amended Proposal.

IV. FDA cannot authorize the April 2023 Amended Proposal because it does not satisfy statutory and regulatory requirements.

Florida's April 2023 Amended Proposal fails to satisfy either of the primary criteria for authorization required by statute. It does not demonstrate that importation will pose no additional risk to public safety or that importation will result in a significant cost reduction for consumers. These failures are profoundly concerning for Florida patients.

Based on its review of both the April 2023 Amended Proposal and the attachments, FDA identified numerous substantive deficiencies. In the August 2023 Letter, FDA stated that the April 2023 Amended Proposal does not adequately describe how Florida will assure drug supply chain security for imported product, because it:

- Lacks clarity with respect to the Foreign Seller's plan to meet applicable requirements for determining whether a product in its possession is a suspect foreign product or illegitimate foreign product, investigating such product, and providing information about its transactions with the manufacturer or importer upon request by FDA or other appropriate Federal or State officials;

- Does not demonstrate that the product identifier would meet the definition of "product identifier" in section 581(14) of the FDCA;

- Lacks documentation regarding the importer's ability to retain required records, compare records from a foreign seller with information received from the manufacturer, and otherwise meet requirements for product tracing, verification, and ensuring that trading partners are authorized;[24] and

- Does not adequately explain how the return plan will prevent the exportation of returned eligible prescription drugs.[25]

[24] As FDA states, "[u]ncertainty with respect to whether the Importer will affix or imprint a product identifier that contains each element of the product identifier as defined in section 581(14) raises concerns about whether the Importer and subsequent trading partners will be able to effectively identify and trace the product imported under the SIP throughout the supply chain after it is relabeled for the U.S. market, thereby potentially putting the supply chain and patients at risk." August 2023 Letter at 5.

[25] *Id.* at 2-6.

FDA also determined that the April 2023 Amended Proposal does not adequately explain how Florida will ensure that the SIP will result in a significant reduction in the cost to the American consumer. Specifically, the April 2023 Amended Proposal:

- Does not provide price, quantity, and expenditure projections for each drug, making it impossible to determine whether the product of the price and quantity projections equals the drug-specific expenditure projections or whether the drug-specific expenditure projections are consistent with total expenditure projections;

- Identifies several assumptions underlying the Baseline Scenario's projections without providing specific estimates; and

- Does not address whether drugs proposed for importation meet Florida Medicaid requirements, even though the proposal states that "Florida's Medicaid program will constitute most consumers."[26]

FDA highlighted numerous other ways in which the April 2023 Amended Proposal falls short of statutory and regulatory requirements. For example, Florida has not provided information to confirm that the proprietary name, the name and quantity of the active ingredient, the inactive ingredients, and the dosage form are the same for both the Canadian Health Products and Food Branch (HPFB)-approved product and the FDA-approved product.[27] Moreover, two of the drugs Florida lists for importation do not appear to be eligible for importation. Based on information available, relabeling such products would require breaching their container closure systems.[28] The above deficiencies are not exhaustive of those included in FDA's letter.

Petitioners have identified further ways in which the information they could access does not adequately demonstrate that Florida's SIP will not pose an additional risk to public health and safety and will result in a significant reduction in the cost to the American consumer. For example, the April 2023 Amended Proposal:

- Contains only vague assurances that drugs will be stored, handled, and distributed in a compliant manner outside Florida state lines, as required by 21 C.F.R. § 251.3(e)(11)(i), including at the importer's facility in Whitestown, Indiana[29] and abroad;

- Provides no guidelines for ensuring that each supply chain participant complies with storage instructions included in each drug's labeling, as required by 21 C.F.R. § 251.3(e)(11)(i);

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[26] *Id.* at 6.

[27] *Id.* at 7.

[28] *Id.* at 8.

[29] Moreover, in the August 2023 Letter, FDA noted that the "SIP proposal does not indicate that the secured warehouse or other distribution facility is within 30 miles of the authorized Port of Entry for examination as required by 251.17(b)" because "[a]t this time, the only authorized Port of Entry is Detroit, Michigan" and "[t]he Whitestown facility is not within 30 miles of Detroit." *Id.* at 8.

- Does not indicate how Florida plans to ensure that drug supply chain participants screen the eligible prescription drugs for evidence that they are adulterated, counterfeit, damaged, tampered with, or expired, as required by 21 C.F.R. § 251.3(e)(11)(iii), beyond a vague assurance that LSL will "physically inspect each drug shipment received from Methapharm Inc. against shipping paperwork and a set of specifications developed for each drug imported";

- Purports to rely on the Drug Supply Chain Security Act (DSCSA) to ensure a secure supply chain to satisfy 21 C.F.R. § 251.3(e)(11)(ii), even though (1) Canada lacks a track and trace system, as LSL itself acknowledges in an email obtained via a FOIA request;[30] (2) products imported under the final rule are *exempt* from key provisions of the DSCSA; and (3) Florida's proposal to require a *lot-specific* machine-readable bar code in the product identifier violates the DSCSA, which requires package specific bar codes.

- Purports to rely on an actuarial analysis that "d[id] not include prescription drug rebates under the Medicaid Drug Rebate Program (MDRP)" and that expressly acknowledges "that the impact of those rebates could fully offset the projected 'savings' attributable to this program,"[31] while redacting all rebate information that the State supposedly incorporated into the analysis; and

- Does not provide any detail on "administrative costs" that likely will be borne by the State, does not address potential markups by the foreign seller or the burden on law enforcement, and does not justify the 75% uptake estimate, making it impossible to rely on the projected total savings provided.

Furthermore, there remains significant ambiguity about why Florida made such radical changes to the list of drugs to be imported. Florida states that these drugs will yield "the highest potential savings."[32] This is the *same* language Florida used in describing the list included in the Original Proposal, despite the fact that the April 2023 Amended Proposal includes only five of the 47 drugs included in the Original Proposal. While a table submitted to the court indicates that certain products were removed due to concerns raised in the November 2022 RFI that they could not be relabeled without breaching the container closures systems, Florida does not explain why other drugs were omitted or why it decided to add 12 new drugs more than two years after submitting the Original Proposal.

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[30] In an email dated April 5, 2023, Chris Mizener at LSL wrote an email to AHCA stating that the "we will be relabeling the product in the U.S. which will be the start of the DSCSA trail in association with the lab testing," and that "Methapharm would be excluded from DSCSA as they do not have the same requirements currently in Canada." AHCA 0000992 (received on July 25, 2023, in response to PSM records request dated June 23, 2023, seeking various communications among AHCA, Methapharm, AdiraMedica, and other agencies of the State of Florida).

[31] Letter from Andrew L. Gaffner, FSA, MAAA, Principal and Consulting Actuary, Milliman, to Matt Cooper, Assistant Deputy Secretary, Bureau of Medicaid Data Analytics, AHCA at 2 (Apr. 14, 2023) (received on August 24, 2023, in response to records request submitted on June 20, 2023)

[32] April 2023 Amended Proposal at 7, 12.

V. FDA cannot authorize the April 2023 Amended Proposal for the reasons set forth by petitioners in *PhRMA v. U.S. Department of Health & Human Services* (D.D.C.).

In our Original Citizen Petition, we stated that FDA should refrain from authorizing the Original Proposal for the reasons set forth in *PhRMA v. U.S. Department of Health & Human Services* (D.D.C.), which was filed on November 23, 2020. Because the Secretary of HHS has yet to make a valid certification, and FDA and HHS have not promulgated a valid rule pursuant to section 804, these arguments continue to hold true. We incorporate by reference Section III of the Original Citizen Petition and Counts I, II, III, IV, V, and VII of the amended complaint and associated briefing in *PhRMA v. U.S. Department of Health & Human Services*.[33]

VI. Conclusion

For the reasons identified above and in our Original Citizen Petition, petitioners respectfully request that FDA refrain from authorizing the April 2023 Amended Proposal.

[33] *See* n.20, *supra*.