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Division of Docket Management (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Rm. 1061
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Second Supplement to Citizen Petition
Docket No. FDA-2023-P-1773-0001

Covington & Burling LLP, on behalf of the Pharmaceutical Research and Manufacturers of America ("PhRMA"), Morgan, Lewis & Bockius 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 second supplement to the Citizen Petition assigned Docket No. FDA-2023-P-1773-0001 ("Original Citizen Petition"). The Original Citizen Petition requested that the U.S. Food and Drug Administration ("FDA" or the "Agency") refrain from authorizing Colorado's December 5, 2022, Section 804 Importation Program Application to import prescription drugs from Canada.[1] On June 17, 2024, PhRMA, PSM, and CAHC filed a supplement to the Original Citizen Petition raising several concerns regarding Colorado's amended proposal, dated February 27, 2024 (the "First Citizen Petition Supplement").[2]

We submit this second supplement to respond to updates made to Colorado's proposal on August 28, 2024 (the "August 2024 Amended Proposal") and March 10, 2025 (the "March 2025 Amended Proposal").[3] The August 2024 Amended Proposal reflects a change of the importer from "Premier Pharmaceuticals Mid-America, LLC" located in Ohio to "Premier Pharmaceuticals LLC" located in Idaho. The most significant changes made via the March 2025 Amended Proposal were to (i) remove two drugs from the list of drugs to be imported and the cost analysis and (ii) incorporate additional discussion regarding oversight of the program, including by specifying and purportedly attaching additional standard operating procedures

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[1] *See* Original Citizen Petition, Docket No. FDA-2023-P-1773-0001 (May 3, 2023), https://www.regulations.gov/document/FDA-2023-P-1773-0001.

[2] *See* First Citizen Petition Supplement, Docket No. FDA-2023-P-1773-0004 (June 17, 2024), https://www.regulations.gov/document/FDA-2023-P-1773-0004.

[3] *See* August 2024 Amended Proposal (Aug. 28, 2024), https://hcpf.colorado.gov/sites/hcpf/files/August%202024%20SIP%20Drug%20Importation%20Amendment%208.28.24b.pdf; Mar. 2025 Amended Proposal (Mar. 10, 2025), https://hcpf.colorado.gov/sites/hcpf/files/March%202025%20SIP%20Amendment%20Submitted%203.10.25%20-%20AC.pdf.

("SOPs"), quality manuals, and work instructions. As discussed below, PhRMA, PSM, and CAHC maintain that, consistent with its statutory mandate, FDA must refuse to authorize the March 2025 Amended Proposal. We also wish to respond to the Colorado Department of Health Care Policy & Financing's ("HCPF's") comment to the docket.[4]

The amendments made in August 2024 and March 2025 do not address any of the significant concerns raised in the First Citizen Petition Supplement. Colorado continues to withhold from the public key portions of certain appendices, including all SOPs, quality manuals, and work instructions applicable to its SIP sponsor (i.e., HCPF), foreign seller, and importer. Indeed, the number of these withheld documents has expanded, as Colorado has added new information to purportedly fulfill federal requirements designed to protect the safety of the nation's drug supply.[5] For example, none of the four new SOPs governing HCPF's oversight measures is publicly available [6] Nor are the sixteen new SOPs and work instructions governing pharmacovigilance.[7] As we have previously articulated, these documents are crucial to the public's understanding of Colorado's SIP, as well as the compliance measures in place to ensure the importation does not pose additional risk to public safety and results in a significant cost reduction, both of which are prerequisites for not only Colorado's SIP but also for the certification by the Secretary of the Department of Health and Human Services ("HHS") in support of and to effectuate importation under Section 804 itself.

Colorado states that such documents are exempt in their entirety from disclosure under Colorado law but provides no analysis to support such a conclusion.[8] Additionally, the labeling information purportedly included in Appendix D is still, without explanation, absent from the

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[4] *See* Comment from HCPF, Docket No. FDA-2023-P-1773-0005 (July 30, 2024), https://www.regulations.gov/comment/FDA-2023-P-1773-0005.

[5] *See* March 2025 Amended Proposal SIP Appendices List at 1–3, publicly accessible version available at https://hcpf.colorado.gov/sites/hcpf/files/Colorado%20SIP%20Amended%20Appendices%20List%203.11.25.pdf (noting documents withheld from Appendices A–C).

[6] *See* March 2025 Amended Proposal, *supra* n.3, at 29–30 (stating the "[f]our primary SOPs govern HCPF's oversight activities" and stating that these and other documents, also redacted, demonstrate HCPF's "active oversight role in verifying compliance, detecting potential risks, and enforcing corrective measures across all aspects of the importation program among all contractors and subcontractors throughout the program"); *see also* March 2025 Amended Proposal SIP Appendices List, *supra* n.5, at 1 (noting documents withheld from Appendix A).

[7] *See* March 2025 Amended Proposal SIP Appendices List, *supra* n.5, at 2–3 (noting documents withheld from Appendices C).

[8] *See* March 2025 Amended Proposal SIP Appendices List, *supra* n.5, at 4.

publicly available version of that appendix.[9] We have repeatedly noted that drug labeling is unlikely to be confidential.[10]

Like the original proposal and the prior amendments, the March 2025 Amended Proposal fails to satisfy either of the primary criteria for authorization required by statute.[11] Colorado's updates do not address petitioners' concerns about the possibility that Colorado will import drugs through mail order pharmacies, and therefore Colorado does not demonstrate that importation will pose no additional risk to public safety.[12] Indeed, a recent executive order emphasized the importance of section 804 programs not "sacrificing safety or quality."[13]

As we previously noted, allowing distribution through mail-order pharmacies raises the very safety issues that precluded HHS from making its purported "certification" applicable to all of Section 804, as required by the statute.[14] In the proposed rule, FDA conceded that implementation of Section 804(j) would pose additional risk to the public's health and safety, finding that "[m]edications that are purchased online and imported through international mail, express couriers, and other means pose significant challenges for FDA and its ability to adequately safeguard the quality and safety of drugs taken by U.S. consumers."[15] Our First Citizen Petition Supplement provided a snapshot of the massive scale of illegal online pharmacy

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[9] *See* Amended Proposal, Appendix D, publicly accessible version available at https://hcpf.colorado.gov/sites/hcpf/files/Colorado%20SIP%20Appendix%20D%20for%20Web%203.10.25.pdf (missing labeling information included in list of materials available in the Amended Proposal SIP Appendices List).

[10] *See* Original Citizen Petition, *supra* n.1 at 27–28 ("The proposed labeling will become public once importation is initiated, and the existing FDA approved labeling to be included in the side-by-sides is already publicly available."); First Citizen Petition Supplement, *supra* n.2, at 5.

[11] *See* FDCA § 804(l). As previously noted, this failure compounds the fact that Section 804 requires the *Secretary* to consider importation's patient safety and cost implications prior to certification and to conclude that importation will pose no additional risk to public safety and will result in a significant reduction in costs for consumers. However, in September 2023, the Secretary delegated these assessments to future FDA proceedings, and FDA further punted them to SIP sponsors.

[12] *See* March 2025 Amended Proposal, *supra* n.3, at 10 ("Our importation program will provide consumers, carriers, PBMs, hospitals and doctors in Colorado with access to drugs imported from Canada through a variety of sources, including community pharmacies *and mail order pharmacies*.") (emphasis added); *id.* at 14 ("HCPF is also exploring a mail order pharmacy option as a potential solution to these issues.").

[13] *See* Executive Order No. 14273, Lowering Drug Prices by Once Again Putting Americans First, 90 Fed. Reg. 16441, 16443 (Apr. 18, 2025), https://www.govinfo.gov/content/pkg/FR-2025-04-18/pdf/2025-06837.pdf.

[14] First Citizen Petition Supplement, *supra* n.2, at 6 & n.20.

[15] 84 Fed. Reg. 70796, 70800 (Dec. 23, 2019).

networks and the ongoing enforcement challenges facing FDA and regulators worldwide.[16] If Colorado pursues a mail order pharmacy option, there is a substantial risk that unscrupulous actors will target consumers, advertise that they are part of Colorado's SIP program even if they are not, and distribute sub-potent, super-potent, or counterfeit drugs to the public. The March 2025 Amended Proposal further reveals that Colorado plans to allow imported drugs to not just enter the U.S. without a product identifier, but to transit across the country from Detroit to Boise without a product identifier, and then transit back to Detroit for release into the U.S. commercial market without any further testing, despite the elevated risk to product integrity associated with DSCSA non-compliant transport.

Colorado also fails to make a showing that importation will result in a significant reduction in the cost of prescription drug for consumers. All of petitioners' concerns regarding the cost analysis continue to apply, as Colorado has made no changes to its methodology since we filed our First Citizen Petition Supplement. It still remains unclear what portion of the calculated cost savings would be passed on to consumers; the calculation of potential cost savings still relies on a series of inadequately supported assumptions and data sources of dubious relevance; the analysis still applies projected average rebates by drug category and to assign drugs vastly different rebate rates based on undefined categories; and Colorado still fails to demonstrate how it will ensure participation from commercial plans, much less ensure that they will pass any savings to consumers.[17] Furthermore, because Colorado removed two drugs from the drug list, Colorado concedes the cost savings have declined, reducing its own inadequately supported projected cost savings from $51 million to $46.2 million.[18]

Other arguments previously raised by petitioners likewise preclude FDA from authorizing the March 2025 Amended Proposal. 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, our arguments in 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* are still applicable.[19] We note as well that Colorado has added no further detail on how it will ensure that that trade secrets and commercial or financial information that is privileged or confidential "are kept in strict confidence and used only for the purposes of

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[16] First Citizen Petition Supplement, *supra* n.2, at 6–8.

[17] *See* First Citizen Petition Supplement, *supra* n.2, at 8–13.

[18] *See* March 2025 Amended Proposal, *supra* n.3, at 4, 19–22; August 2024 Amended Proposal, *supra* n.3, at 4, 12–13, 19.

[19] *See* First Am. Compl., *PhRMA v. U.S. Dep't of Health & Human Servs.*, No. 1:20-cv-03402 (D.D.C. July 2, 2021); Original Citizen Petition, *supra* n.1, at 9–12. 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. Mem. Op. 13–14, *PhRMA v. U.S. Dep't of Health & Human Servs.*, No. 1:20-cv-03402 (D.D.C. Feb. 6, 2023).

testing or otherwise complying with" the Federal Food, Drug, and Cosmetic Act and the final rule.[20]

Finally, petitioners respond to HCPF's comment in response to our Original Citizen Petition, which was filed on July 30, 2024. HCPF accuses PhRMA of attempting to delay any FDA action on Colorado's proposal in order to prevent competition against brand-name drug companies and thereby "extract[] excessive profits from Coloradans."[21] PhRMA and the other petitioners support lawful competition including generic and biosimilar competition. The FDCA and FDA's implementing regulations provide manufacturers of generic drugs incentives to introduce generic competition.[22] Indeed, in 2023, generics and biosimilars accounted for more than 90% of U.S. prescriptions filled, resulting in $445 billion in savings in 2023 and more than $3.1 trillion in savings over the past 10 years.[23] Allowing entities to import foreign versions of drugs with remaining patents or exclusivities would upend the Hatch-Waxman Act's carefully constructed and successful balance between promoting innovation and fostering drug competition. Importing foreign versions of drugs with remaining patents or exclusivities could lower the incentives for manufacturers to innovate in certain disease areas and lower the incentives for generic manufacturers to develop and market generic and follow-on versions of innovative products, risking both sides of the Hatch-Waxman balance between innovation and low-cost generics. Most importantly, Colorado's importation scheme will undeniably pose additional risk to the public's health and safety by opening the closed U.S. distribution system—the very same system that FDA and Congress have otherwise bolstered in the name of public safety.

Colorado also indicates that petitioners are "misus[ing] the citizen petition process for the purpose of delaying FDA's review."[24] However, citizen petitions are intended to be used to petition FDA "to issue, amend, or revoke a regulation or order, *or to take or refrain from taking any other form of administrative action*."[25] Consistent with that regulatory provision, petitioners are asking FDA to refrain from authorizing the most recent SIP proposal. Petitioners agree that a citizen petition, while an appropriate pathway, is not an adequate pathway to

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[20] 21 C.F.R. § 251.3(e)(16); *see* First Citizen Petition Supplement, *supra* n.2, at 13–14.

[21] Comment from HCPF, *supra* n.4, at 1.

[22] *E.g.*, FDCA § 505(j)(5)(B)(iv).

[23] Ass'n for Accessible Meds., *The U.S. Generic & Biosimilar Medicines Savings Report* 7 (Sept. 2024), https://accessiblemeds.org/wp-content/uploads/2025/01/AAM-2024-Generic-Biosimilar-Medicines-Savings-Report.pdf.

[24] Comment from HCPF, *supra* n.4, at 1.

[25] 21 C.F.R. §§ 10.25(a), 10.30 (emphasis added).

comment on SIP proposals, but this is indeed the *only* pathway FDA provided for interested parties to participate in FDA's SIP review and approval process.[26]

For the reasons identified above and in our Original Citizen Petition and First Citizen Petition Supplement, petitioners respectfully request that FDA refrain from authorizing the March 2025 Amended Proposal.

Respectfully submitted,

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[26] *See* 85 Fed. Reg. at 62094, 62121–22 (Oct. 1, 2020) (stating that interested parties could submit a 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); *see also* First Citizen Petition Supplement, *supra* n.2, at 2–3 (emphasizing that the citizen petition process is inadequate and that the Administrative Procedure Act and principles of due process mandate that affected parties have the ability to comment on any SIP proposal before FDA makes a determination).