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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 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 ("Original Proposal").

Through this supplement, PhRMA, PSM, and CAHC raise several concerns regarding Colorado's recent amendment to the Original Proposal (the "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 Section 804 Importation Program ("SIP") proposal prior to the Agency making a determination.[1] This process has proven inadequate and unworkable. Although Colorado has made portions of the Amended Proposal publicly available, important documents remain undisclosed.

Based on the content that is publicly available, petitioners have identified several ways by which the Amended Proposal fails to satisfy the criteria for authorization. The Amended Proposal relies on questionable assumptions and faulty constructs that undermine any assertion that Colorado's SIP program will result in a significant reduction in costs for American consumers. Additionally, the proposed program continues to present an unreasonable risk to patients living in Colorado and to the confidentiality of information requested from manufacturers. Lastly, the Amended 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).

I. Background

The Original Citizen Petition, filed on May 3, 2023, 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. § 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 & Human Servs.*, No. 1:20-cv-03402 (D.D.C.); and
- Colorado's submission of the Original Proposal to FDA on December 5, 2022.

On February 27, 2024, Colorado posted its Amended Proposal to its website. The Amended Proposal reveals that Colorado and FDA engaged in substantial back-and-forth regarding the state's Original Proposal both before and after the Original Citizen Petition was filed.[2] The Colorado Department of Health Care Policy & Financing subsequently hosted a virtual stakeholder meeting regarding the Amended Proposal.[3]

II. Key aspects of the Amended Proposal remain outside the public's view, illustrating the inadequacy of the citizen petition process.

Since 2019, petitioners have emphasized that the Administrative Procedure Act ("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

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[2] *See* Amended Proposal, Appendix H.

[3] *See* Stakeholder Meeting Presentation (Mar. 12, 2024), https://hcpf.colorado.gov/sites/hcpf/files/Drug%20Importation%20Public%20Stakeholder%20meeting%203-12-2024.pdf; Webinar Recording (Mar. 12, 2024), https://www.youtube.com/watch?v=BK5Adu4KOPU.

opportunity to comment.[4] In the final rule, FDA rejected PhRMA's proposal, 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.[5]

For the reasons that 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 substitutes 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 choose to disclose only portions of their proposals and amendments thereto.[6] We incorporate by reference the APA procedural challenge to the final rule in the amended complaint (Count VI) and associated briefing.[7]

Colorado's publication of the Amended Proposal illustrates this point. As discussed further below, key aspects of Colorado's Amended Proposal were redacted by the State before public release. To our knowledge, FDA has published none of Colorado's proposals or the Agency's communications with the State regarding the same.

III. Lack of access to certain appendices makes it impossible to submit complete and informed comments on the Amended Proposal.

The public remains unable to completely evaluate Colorado's proposed SIP because the State has not disclosed key portions of certain appendices to its Amended Proposal. While Colorado has published certain portions of its proposed SIP online, it has importantly withheld from public view all of the standard operating procedures ("SOPs") and quality manuals applicable to its SIP sponsor, foreign seller, and importer, as well as the proposed labels for each of the drugs included in the "Final Drug List."[8] These documents provide critical information

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[4] 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.

[5] 85 Fed Reg. at 62121–22.

[6] 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.").

[7] 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).

[8] Amended Proposal, SIP Appendices List at 1–3, publicly accessible version available at https://hcpf.colorado.gov/sites/hcpf/files/SIP%20Appendices%20List%20Final%202-27-2024.pdf (noting documents withheld from Appendices A–C and content of Appendix D); Amended Proposal, Appendix D, publicly accessible version available at
(continued...)

about how Colorado intends to protect the safety of the drug supply and ensure compliance with the regulatory requirements for a SIP program.[9]

For example, Appendix A supposedly contains a "Quality Manual [that] details the overall compliance plan for the program,"[10] along with seven SOPs for the SIP sponsor addressing topics including safety reporting, drug evaluation, and Corrective and Preventative Action ("CAPA") procedures.[11] However, the publicly-available Appendix A appears to be a series of empty compliance checklists for the foreign seller, importer, and qualified lab. Appendix B, meanwhile, purportedly contains nine SOPs relevant to the foreign seller's processes for topics including labeling, shipping, receiving, storing, packing, and recalling product, as well as supply chain security—none of which is included in the publicly-available version.[12] Similarly, Appendix C purportedly contains 22 SOPs covering the importer's procedures for topics such as inventory management, pharmaceutical deviation reporting, adverse event investigations, temperature controls, sampling and statutory testing, recall and return processes, relabeling, drug supply chain security, field action reports, and material specifications.[13] All of these documents, however, have been withheld from publication.[14] These documents are crucial to the public's understanding of Colorado's SIP, as well as the compliance measures the foreign seller and importer have 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 HHS (the "Secretary") in support of and to effectuate importation under Section 804 itself.

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https://hcpf.colorado.gov/sites/hcpf/files/Appendix%20D%20FDA%20Required%20Data%20Elements%20-%20WEB%20only%202.23.24_accessible.pdf (missing labeling information included in list of materials available in Appendix D).

[9] *See* Amended Proposal at 29–30 (referring FDA to the various SOPs and SIP sponsor Quality Manual contained in appendices for information relevant to the state's compliance and oversight plan, as part of its compliance with 21 C.F.R. § 251(e)(10), (15)).

[10] *See id.*

[11] Amended Proposal, SIP Appendices List at 1, publicly accessible version available at https://hcpf.colorado.gov/sites/hcpf/files/SIP%20Appendices%20List%20Final%202.27.24.pdf.

[12] *Id.*

[13] *Id.* at 2.

[14] *Id.* at 3.

Additionally, the labeling information purportedly included in Appendix D is, without explanation, absent from the publicly available version of that appendix.[15] As we noted in the Original Citizen Petition, the proposed drug labeling is unlikely to be considered confidential.[16]

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

Colorado's 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. And it does not demonstrate that importation will result in a significant reduction in costs for consumers.

This failure compounds one of the key deficiencies of Congress's purported "certification." 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. Colorado continues to fail to make either showing.

A. The Amended Proposal does not demonstrate no additional risk to public safety.

The Amended Proposal continues to hint at the possibility of a "mail order pharmacy option" as a potential solution to initial hesitancy on behalf of pharmacies to participate in importation, notwithstanding the risks that FDA itself has expressed regarding such entities.[17,18] If Colorado permits mail-order pharmacies to distribute product under its SIP, there is a substantial risk that unscrupulous actors will target consumers, advertise that they are part of

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[15] *Compare* Amended Proposal at 46 ("A side-by-side comparison of FDA approved labeling for the source drug and the proposed patient labeling for the imported drug with differences annotated and explained, ensuring all changes proposed can be found in Appendix D."), *and id.*, SIP Appendices List at 3, publicly accessible version available at https://hcpf.colorado.gov/sites/hcpf/files/SIP%20Appendices%20List%20Final%202.27.24.pdf (including a section in Appendix D on "Labels for FDA Per Drug"), *with id.*, Appendix D, publicly accessible version available at https://hcpf.colorado.gov/sites/hcpf/files/Appendix%20D%20FDA%20Required%20Data%20Elements%20-%202.23.24.pdf (lacking any labeling).

[16] Original Citizen Petition 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.").

[17] Amended Proposal at 10, 14.

[18] *See* Original Citizen Petition at 21–22.

Colorado's SIP program even if they are not, and distribute sub-potent, super-potent, or counterfeit drugs to the public.[19]

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.[20] Former HHS Secretary Azar expressly declined to certify Section 804(j), which, if implemented, would establish a broad, personal importation scheme.[21] 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."[22] FDA then cited real-world examples where consumers were deceived into believing they were buying safe and effective medications when, in fact, they were buying adulterated, counterfeit, and unsafe drugs from pharmacies in Canada.[23] The Secretary's ultimate purported "certification" was premised from the outset on not implementing personal importation due to safety concerns associated with entities like mail-order pharmacies, which Colorado now proposes to use.

Unlawful sale of unapproved and misbranded drugs by online pharmacy networks continues to pose a problem for FDA and regulators worldwide. Many such networks are "complex, global operations that include hundreds—even thousands—of websites," making enforcement challenging.[24] Over the past five years, FDA has issued warning letters to companies that act as brokers between foreign pharmacies and employee-sponsored health

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[19] *Id.*

[20] *See* 21 U.S.C. § 384(l) ("*This section* shall become effective only if the Secretary certifies to the 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." (emphasis added)).

[21] Alex M. Azar, II, Sec'y, HHS, Letter to Kevin McCarthy, Minority Leader, U.S. House of Representatives (Sept. 23, 2020), Exhibit 1 to Defendants' Motion to Dismiss, No. 1:20-cv-3402, ECF No. 26-1 (May 28, 2021) ("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.").

[22] 84 Fed. Reg. 70796, 70800 (Dec. 23, 2019).

[23] *Id.*

[24] Nat'l Ass'n of Boards of Pharmacy, *RogueRx Activity Report, Injectable Weight Loss Drugs: How Illegal Online Drug Sellers Are Taking Advantage of Patients* at 4 (2024), https://nabp.pharmacy/wp-content/uploads/2024/04/RogueRx-Activity-Report-Injectable-Weight-Loss-Drugs-2024.pdf.

insurance plans, stating that unapproved versions of FDA-approved drugs do not carry the same assurances of safety and that such drugs may be contaminated, be counterfeit, contain varying amounts of active ingredients, or contain different ingredients altogether.[25] Such brokers have attempted to justify illegal personal importation from Canada and other countries by citing Section 804, even though the Final Rule did not certify personal importation under Section 804(j).[26]

FDA has also issued multiple warning letters related to the unlawful online sale of unapproved and misbranded glucagon-like peptide-1 receptor agonists (GLP-1 agonists),[27] the majority of which products appear to be counterfeits imported from outside the United States.[28] A 2023 article in the Wall Street Journal identified more than 50 websites selling semaglutide and tirzepatide, nearly all of which included disclaimers that the substances were "not for human consumption."[29] Importation of counterfeit drugs remains an important concern. For instance, "[m]edicine regulators around the world have identified substandard and falsified GLP-1 agonists in the supply chain."[30] In some cases, bad actors intentionally misspell or nickname the product to avoid detection, including one illicit seller that described tirzepatide as "Tirz."[31] In the U.S., FDA recently seized thousands of units of counterfeit semaglutide and

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[25] *See* FDA, Warning Letter to ElectRx and Health Solutions, LLC (Mar. 2, 2023); *see also* FDA, Warning Letter to CanaRx Services Inc. (Feb. 26, 2019) (stating that "the substitution of FDA-approved prescription drugs with unapproved drugs poses significant health risks to U.S. consumers.").

[26] *See e.g.*, ElectRx, *FDA Response*, https://electrx.com/index.php/fda-response/ (stating that "[y]our personal importation of medications directly from specific Tier 1 Countries, including Canada, are within the permissive acts established under the proposed regulations and the intent of the numerous executive orders, postal regulations, and language of the Medicare Modernization Act").

[27] *See* FDA, Warning Letter to www.dashpct.com (Apr. 24, 2024); FDA, Warning Letter to Synthetix Inc. DBA Helix Chemical Supply (Feb. 7, 2024); FDA, Warning Letter to US Chem Labs (Feb. 7, 2024); FDA, Warning Letter to www.gorillahealing.com (Oct. 2, 2023); FDA, Warning Letter to www.semaspace.com (Oct. 2, 2023).

[28] Nat'l Ass'n of Boards of Pharmacy, *FDA Warns of Fraud Pertaining to Distribution of Ozempic, Other Medications* (Oct. 20, 2023), https://nabp.pharmacy/news/blog/regulatory_news/fda-warns-of-fraud-pertaining-to-distribution-of-ozempic-other-medications/.

[29] Rolfe Winkler & Sara Ashley O'Brien, *How Dozens of Websites Sell Knock-Off Drugs, No Prescription Required*, Wall St. J. (Aug. 16, 2023), https://www.wsj.com/health/healthcare/ozempic-mounjaro-no-prescription-websites-726b3928.

[30] *Supra* n.24, at 9–10.

[31] *Id.* at 7.

alerted pharmacists and patients about fake lot numbers.[32] The fake GLP-1 medicines have reportedly resulted in patient harm, including hospitalizations and even death.[33]

B. The Amended Proposal does not demonstrate significant reduction in costs for consumers.

The Amended Proposal fails to explain how Colorado would ensure that its SIP program will result in a significant reduction in prescription drug costs to the American consumer. As discussed in the Original Citizen Petition, Section 804 requires a demonstration that importation will lead to a "significant reduction in the cost of covered products to the American consumer."[34]

First, it is unclear from the Amended Proposal what portion of the calculated cost savings would be passed on to consumers. The latest revisions suggest that Colorado's SIP program is designed to "reduc[e] drug costs for consumers, employers, and the state." Only the first of these beneficiaries—consumers—is relevant under the statute.[35]

Second, Colorado's calculation of potential cost savings relies on a series of inadequately supported assumptions and data sources of dubious relevance. To identify Canadian pricing for its cost analysis, Colorado "primarily us[ed] data from the . . . Quebec Province's 'List of Medications,'" which provides the price at which a product is sold by an accredited manufacturer or wholesaler to pharmacies.[36] When "Quebec data was unavailable," the Amended Proposal uses the wholesale prices supplied by its foreign seller.[37] Yet, states may only import drugs from their foreign seller, and Colorado's foreign seller is located in the province of Ontario.[38,39] The Amended Proposal does not explain why the prices in Quebec would more accurately represent the prices available to the foreign seller in Ontario than the wholesale

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[32] *See* FDA, *FDA Warns Consumers Not to Use Counterfeit Ozempic (semaglutide) Found in U.S. Drug Supply Chain* (Jan. 10, 2024), https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-consumers-not-use-counterfeit-ozempic-semaglutide-found-us-drug-supply-chain.

[33] *Supra* n.24, at 9–10.

[34] Original Citizen Petition at 3 (quoting section 804(l)(1) of the FDCA).

[35] *See* Amended Proposal at 5 ("A prompt SIP approval will help address some of these barriers by demonstrating progress and will help our state advance our goal of reducing drug costs for consumers, employers, and the state.").

[36] *Id.* at 16.

[37] *Id.*

[38] *See* 21 U.S.C. § 384(j)(3) (allowing the Secretary of HHS to permit the importation of drugs from Canada only from a registered seller); 21 C.F.R. § 251.3(b) (restricting an SIP sponsor to only one foreign seller per initial proposal).

[39] *Id.* at 11.

prices available through said foreign seller or even how the prices would be relevant to one another.

In addition, Colorado's actuarial cost savings analysis attempts to extrapolate data regarding a subset of its target population to the entire target population, without taking any steps to address any differences between the groups. Colorado predicts purported savings under its proposed SIP program for the State's commercial insured population.[40] To do so, the State relied on cost and utilization data from the Colorado All Payer Claims Database ("APCD").[41] The APCD data set, however, covers only about 60% of the commercial insured population—it does not include all data on employer self-insured plans.[42] To address this, Colorado "extrapolated APCD data to the full market" using a multiplier derived from the percentage of the state's commercial insured population covered by the APCD data set.[43] Thus, the projected cost-savings "assumethat the utilization and cost of the entire market is similar to that for the population in the APCD."[44]

This assumption is critical to the state's entire cost savings analysis. Yet, government agencies, think tanks, and academics have questioned the generalizability of APCDs, since self-funded plans are not required to report data.[45] According to research performed in

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[40] *See, e.g.*, Amended Proposal, Appendix E at 7.

[41] *See id.* at 9.

[42] *See id.* at 7 (noting that "[o]ur APCD dataset included 2,111,558 commercial average lives per month in 2022," which is approximately 60% of the "Colorado Commercial Insured Population, which we calculated at . . . 3,474,756 persons"). Research from the Kaiser Family Foundation indicates that 56.4% of private sector employees are in self-insured plans. *Id.* at 9.

[43] *Id.* at 7 ("Therefore, the expected drug use for the entire market is assumed to be a factor of the APCD amount, represented by the (Colorado Commercial Insured Population) ÷ (Commercial Population in APCD) . . . .").

[44] *Id.* at 10.

[45] *See* Colo. Dept of Labor, *State All Payer Claims Databases Advisory Committee Final Report and Recommendations*, at 8 (2021), https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/about-us/state-all-payer-claims-databases-advisory-committee/final-report-and-recommendations-2021.pdf ("The resultant loss of a significant amount of ERISA self-funded plan data in APCDs has impacted the ability of State APCD data users to fully understand the health care marketplace and its population."); RAND Health Care, *The History, Promises, and Challenges of State APCDs*, at 7 (June 2, 2021), https://aspe.hhs.gov/sites/default/files/migrated_legacy_files/200696/apcd-background-report.pdf ("The voluntary nature of these submissions represents an important challenge for research, benchmarking, and price transparency because ERISA plans represent a large portion of the commercial insurance market."); Ctr. for Am. Progress, *Policy Options to Encourage All-Payer Claims Databases*, at 3 (Apr. 20, 2018) ("Without data from these plans, APCDs will be at (continued...)

Massachusetts, spending and utilization by enrollees of self-funded plans may be higher, since enrollees are more likely to be female and tend to be older and less healthy; enrollees of self-funded plans also are more likely to be enrolled in preferred provider organizations, which often provide more robust healthcare options leading to higher spending.[46] Moreover, those self-funded plans that do report may not be representative and may therefore skew the APCD data: "It is easy to imagine, for instance, that an employer cutting costs due to business challenges or changes in management might simultaneously reduce the generosity of coverage and stop submitting APCD data."[47]

Despite these limitations, the lack of generalizability of APCD data is not even mentioned as a potential "Source of Uncertainty" in Section 3(D) of the cost analysis or in the Amended Proposal.[48] Failure to account for or even acknowledge the potential differences between these two groups calls into question the accuracy of Colorado's cost savings analysis. This is especially so given that the APCD excludes approximately 40% of the State's entire commercial insured population. Furthermore, the APCD data use "allowed cost," which includes both the covered amount and amounts paid directly by the covered individuals in the form of deductibles, copays, and coinsurance. Deductible payments are highly variable, lending additional, unaccounted-for uncertainty to the data.

Colorado's cost analysis also includes significant, unsupported assumptions regarding the impact of patent expiry on the cost of drug products. To calculate the impact of the loss of exclusivity associated with patent expiry, the cost analysis looks to a study of *generic* product prices relative to pre-expiration branded product prices over time.[49] Colorado assumes that the price of *branded* products will decrease at half the rate that the *generic* product prices were shown to decrease in the study,[50] applies this "assumed market cost impact to both the US and Canadian cost per unit,"[51] and compares the estimations of post-expiration brand prices to

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best less comprehensive and less useful; at worst, they will be potentially misleading."), https://www.americanprogress.org/wp-content/uploads/sites/2/2018/04/AllPayerClaims-brief2.pdf.

[46] Am. Coll. Of Employee Benefits Counsel, *All or Nothing: Mandating Self-Funded Employee Sponsored Health Plan Reporting to State All-Payer Claims Databases*, at 10 (2021), https://www.acebc.com/public-docs/writing-comp-papers/2021-Kizer-Sara-All-or-Nothing.pdf.

[47] RAND Health Care, *The History, Promises, and Challenges of State APCDs*, at 8.

[48] *Id.* at 18–19; Amended Proposal at 22.

[49] Amended Proposal, Appendix E at 13 & n.14.

[50] *Id.* at 13–14.

[51] *Id.* at 13.

determine whether importation would be cost-effective.[52] This approach is unsupported: Once there is generic entry, utilization in the "baseline scenario" would predominantly shift to generics, as authorized under Colorado law.[53] In other words, the relevant comparison is the price of the U.S. generic to the Canadian product. No explanation or justification is provided for using the estimated post-expiration brand prices rather than the generic price.

Even looking at the analysis on its own terms, Colorado provides no explanation or citation to justify the relevant assumptions. The assumption that the price of branded products will decrease at half the rate of generic product prices is seemingly concocted out of thin air. Moreover, Colorado applies this "assumed market cost impact to both the US and Canadian cost per unit."[54] The study from which the "assumed market cost impact" is derived, however, is based solely on U.S. data.[55] Colorado provides no basis for assuming the same rate applies to both U.S. and Canadian prices. Indeed, the cited study undermines this assumption, stating that the United States' healthcare system is more efficient than the Canadian healthcare system at capturing the benefits of generic product entry.[56] If this is true, assuming that Canadian prices would fall in lock-step with domestic prices would artificially reduce the drug unit costs in Colorado's estimated "plan scenario," inappropriately inflating the State's estimated cost savings.

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[52] Amended Proposal, Appendix E at 15–16 (stating that "the patent expiration effect . . . (for individual drugs going off patent during the protection period)" was applied to the estimated cost and utilization data to project cost and utilization for U.S. and Canadian product for future years).

[53] Colo. Rev. Stat. § 12-280-125(1)(a) & (4) (2024) (authorizing pharmacists to "substitute" approved generic versions of brand drugs when "filling a prescription order for a specific drug by brand or proprietary name" so long as the generic "costs the purchaser less" and is therapeutically equivalent to and interchangeable with the brand product).

[54] *Id.* at 13.

[55] IMS Institute for Healthcare Informatics, *Price Declines After Branded Medicines Lose Exclusivity in the U.S.*, at 1 (Jan. 2016) ("Sales data was obtained from the IMS National Sales Perspectives (NSP)™, a near census level audit of the *U.S.* pharmaceutical market.") (emphasis added), https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/price-declines-after-branded-medicines-lose-exclusivity-in-the-us.pdf; *see also* Amended Proposal, Appendix E at 13 n.14 (citing same).

[56] IMS Institute for Healthcare Informatics, *supra* note 34 at Introduction ("With the world's highest generic efficiency rate – the extent to which patients switch from the brand to a generic medicine following loss of exclusivity – the U.S. healthcare system captures maximum cost benefit from" price decreases following generic entry.); *see also* Amended Proposal, Appendix E at 13 n.14 (citing same).

Third, to calculate the impact of rebates, Colorado "projected average rebates for SIP Selected Drugs by drug category."[57] Each drug was assigned a category: brand, specialty, or brand & specialty. Brand drugs were then assumed to have the highest rebate rate, followed by brand & specialty products, and specialty products.[58] The cost analysis, however, does not provide any justification for applying average rebates for entire drug categories to the drugs that will be imported under Colorado's SIP, nor does it explain how or why the selected drugs were assigned to their designated category. Rebates may vary significantly on a drug-by-drug basis;[59] thus, applying an average rebate based on the drug's general category could significantly misstate the true net price of the drug. So, too, could mis-categorizing a product—the assigned rebate for specialty drugs is less than half that for brand drugs and roughly two-thirds the rebate for specialty & brand drugs.[60] Even a ten percent difference between the applied average rebate rates and the drugs' actual rebate rates (i.e., 1.4 to 3 percentage points depending on the assigned product category[61]) would decrease Colorado's projected savings by more than 26 percent.[62] Colorado's decision to apply projected average rebates by drug category to the products to be imported under its SIP and to assign drugs vastly different rebate rates based on undefined categories raise significant concerns regarding the ability of Colorado's SIP to generate cost savings for American consumers.

Notably, Colorado concedes that "[c]urrent statistics [from IQVIA] show aggregate rebate percents across all NDCs to be as high as 37–42%."[63] Colorado nonetheless assumes a much lower rebate specific to the Colorado commercial market (20.8% average for brand and specialty drugs in 2021).[64] Although the analysis cites the brand/specialty mix among selected drugs to justify this choice, Colorado does not explain how this mix differs from that in the IQVIA analysis. Colorado analyzed alternative scenarios where rebates were 10% higher or 5%

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[57] Amended Proposal, Appendix E at 10.

[58] *Id.* at 11.

[59] *See* Medicare Payment Advisory Commission (MedPAC), *Health Care Spending and the Medicare Program*, Section 10: Prescription Drugs, at 160 (showing negotiated rebates as a share of gross spending ranging from under 10% to 50% or greater), https://www.medpac.gov/wp-content/uploads/2023/07/July2023_MedPAC_DataBook_Sec10_SEC.pdf.

[60] *Id.*

[61] *Id.*

[62] *Id.* at 19 (indicating that a 10 percent increase in brand and specialty rebates would decrease the projected cost savings from $50.9 million to $37.5 million).

[63] Amended Proposal, Appendix E at 11.

[64] *Id.* at 10–11.

lower, but rebates would need to be 100% higher to reach the levels observed in the IQVIA analysis.[65]

Fourth, Colorado's assumptions about commercial plan participation leave critical questions unanswered. Colorado has no mechanism to force commercial plans to participate in the SIP.[66] Indeed, elsewhere, Colorado acknowledges that commercial payers have incentives *not* to participate because they profit from the rebates and discounts they receive from manufacturers and indicates that information on such rebates and discounts are difficult to estimate.[67] Colorado's estimate of 6 to 22.3% participation is wholly unsupported.

In addition, Colorado does not adequately establish that commercial plans will pass savings to consumers. Colorado observes that consumers pay 6.5% of the allowed cost of drugs and assumes that consumers will enjoy the same share of any savings realized by the commercial plans. Absent a legal requirement, it is possible that all cost savings will go the insurer's bottom line.[68]

V. The Amended Proposal continues to suffer from additional flaws that will harm manufacturers and raise doubts about Colorado's ability to comply with regulatory requirements.

The Amended Proposal suffers from additional flaws that will harm manufacturers and raise questions about Colorado's ability to comply with the regulatory requirements for an importation program. The Final Rule requires a SIP proposal to explain how the SIP sponsor will ensure 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 testing or otherwise complying with" the Food, Drug, and Cosmetic Act ("FDCA") and the Final Rule.[69] Like the Original Proposal, the Amended Proposal falls short of this requirement.[70] Compared to the Original Proposal, the Proposal adds only two short sentences on this topic, stating that its importer and qualified laboratory have signed a non-disclosure agreement and "drafted" a confidentiality agreement, and asserting, without explanation or justification, that "[t]hese documents or similar versions can be used between the manufacturer, [qualified lab], and [the

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[65] *Id.* at 11.

[66] *Id.* at 8 ("Not all health insurance payers . . . will offer imported SIP Selected Drugs to their members.").

[67] *Id.* at 11.

[68] *Cf.* Nick McGee, *Insurance Data: PBM Reform Has No Material Impact on Premiums* (Apr. 24, 2024), https://phrma.org/Blog/Insurance-data-PBM-reform-has-no-material-impact-on-premiums#:~:text=Even%20though%20PBMs%20negotiate%20significant,medicines%20to%20pay%20high%20costs.

[69] 21 C.F.R. § 251.3(e)(16).

[70] Original Citizen Petition at 26.

importer] in the future."[71] Yet, the State's importer and qualified laboratory have not actually entered a confidentiality agreement.[72] Additionally, the "drafted" confidentiality agreement does not appear to be included in the Amended Proposal or its appendices. Moreover, the Amended Proposal remains entirely silent on how the importer will meet its obligation to protect manufacturers' information.

The Amended Proposal also lacks adequate information regarding how and where drug products will be secured when they enter the United States. The Final Rule requires that a state's designated importer have a "secured warehouse or other secure distribution facility . . . within 30 miles of the authorized Port of Entry."[73] Although Colorado states that its importer will store drug product at a secure warehouse within 30 miles of the authorized port of entry,[74] it fails to disclose any specific information regarding that warehouse, including its location, calling into question whether the State and its importer are actually prepared to comply with the regulatory requirements for an importation program.

VI. FDA cannot authorize the Amended Proposal for the reasons set forth by petitions 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*.[75]

VII. Conclusion

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

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[71] Amended Proposal at 45–46.

[72] *Id.* at 45.

[73] 21 C.F.R. § 251.17(b).

[74] Amended Proposal at 10, 40.

[75] *See* n.5, *supra*.

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