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What's Next for Drug Importation? Potential Next Steps after FDA Authorizes Florida's Section 804 Importation Program

Attorneys
Margaux Hall
Beth Weinman
Jenna McCarthy
Alexandra Kaye
Will Shefelman

Introduction

On January 5, 2024, the U.S. Food and Drug Administration ("FDA") approved Florida's Section 804 Importation Program ("SIP"), pursuant to FDA's authority under Section 804 of the Federal Food, Drug, and Cosmetic Act ("FDCA") and the final importation rule the agency promulgated in September 2020 (the "Final Rule"). The approval of Florida's SIP marks the first time that the FDA has approved a program that would enable the importation of Canadian prescription drugs under Section 804.[1] The state of Florida is, therefore, closer to implementing a Canadian drug importation program than any state has been before, although there are a series of hurdles yet to surmount before drug importation would commence, including requisite buy-in from the Canadian government.[2] In this article, we summarize the remaining steps that will need to be completed before importation can begin under the Florida SIP, the likelihood of renewed litigation challenging both the Final Rule as well as FDA's determination that the Florida SIP meets the requirements of Section 804, and the larger legal, policy and market-based implications of Florida's authorized importation program, assuming importation does indeed begin.

Background

Section 804 of the FDCA (21 U.S.C. § 384), enacted in its current form in 2003, requires the U.S. Department of Health and Human Services ("HHS") Secretary to certify to Congress that drug importation will result in both "no additional risk to the public's health and safety" and "significant cost savings" to the American people in order for statutorily permitted importation to take effect.[3] For 17 years, no HHS Secretary was willing to make that certification. However, on September 24, 2020, HHS released the Final Rule, which enables states and Indian tribes to develop and seek FDA approval of programs that facilitate the importation of certain prescription drugs from Canada.[4] This rulemaking reflected the culmination of efforts by the Trump administration to produce an importation program as detailed in the Safe Importation Action Plan unveiled in July 2019.[5] As discussed in a prior Ropes & Gray alert, the Final Rule raised various legal questions, including questions regarding whether the agency could make the statutorily required showing that the rule would result in significant cost savings, when the agency itself admitted that it could not estimate the amount of any cost savings. As we anticipated, the Final Rule was quickly challenged by three associations, Pharmaceutical Research and Manufacturers of America, the Partnership for Safe Medicines, and the Council for Affordable Health Coverage, although the case was ultimately dismissed by the U.S. District Court for the District of Columbia in February 2023 for lack of standing.[6] In dismissing the case, the court said that the plaintiffs could not demonstrate a concrete risk of harm at a time when no state importation program had yet been approved.[7] FDA's recent authorization of Florida's importation program fundamentally changes the status of state drug importation programs in this regard. In its Letter of Authorization dated January 5, 2024, FDA determined that Florida's SIP Proposal met the statutory obligation of ensuring that importation would reduce consumer costs without posing additional risk to public health and safety.[8] Several other states have submitted similar proposals but those have yet to be approved. The approval of Florida's SIP Proposal provides one benchmark of a proposal that the agency viewed as meeting the requisite criteria.[9]

The Final Rule Provisions on Importation

While FDA has long taken the position that foreign market versions of FDA-approved drugs cannot be distributed in the United States, the Final Rule provides a pathway for importation of "eligible prescription drugs" through an authorized SIP.[10] Eligible prescription drugs are those that have been approved and have received a Notice of Compliance and Drug Identification Number ("DIN") from the Health Products and Food Branch of Health Canada ("HPFB") and, but for their labeling, meet the conditions in an FDA-approved new drug application ("NDA") or abbreviated new drug application

("ANDA") for a currently marketed prescription drug, including requirements relating to the "drug substance, drug product, production process, quality controls, equipment and facilities," and that are not otherwise excluded from the definition under the Final Rule.[11] The Final Rule explicitly excludes the following categories of prescription drugs from eligibility for import under an authorized SIP:[12]

- controlled substances, as defined by 21 U.S.C. § 802.
- biological products, as defined by 42 U.S.C. § 262(i)(1).
- drugs that are infused, intravenously injected, inhaled during surgery, or injected intrathecally or intraocularly.
- drugs subject to a risk evaluation and mitigation strategy ("REMS") under 21 U.S.C. § 355-1.
- drugs that are not prescription drugs in a finished dosage form that meet the definition of a "product" under 21 U.S.C. § 360eee(13).

A state or Indian Tribe that wishes to serve as a SIP Sponsor and thereby import eligible prescription drugs under the Final Rule must submit a proposal for its importation program to FDA for authorization.[13] The proposal must include all of the information laid out in the Final Rule, including a description of how the SIP Sponsor will ensure that (1) the imported eligible drugs meet the Statutory Testing requirements (described further below), (2) the supply chain will be secure, (3) the applicable labeling requirements will be met, (4) pharmacovigilance and other FDCA requirements will be met following importation, and (5) 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.[14] Authorized SIPs are valid for two years unless an extension is granted.[15]

Hurdles That Still Need to Be Crossed before Importation Can Begin

While the Florida SIP has now been approved, there are still a number of hurdles to cross before importation can begin. Specifically, once a state's SIP is authorized, the Importer must then submit to FDA a Pre-Import Request containing, among other information, an identification and description of each drug to be imported at least 30 calendar days before the drug's scheduled date of arrival.[16] Such imports will be required to be filed as formal entries with U.S. Customs and Border Protection ("CBP").[17] Importers are responsible for buying Canadian drugs directly from the Foreign Seller, which, in turn, purchases the eligible prescription drugs from the manufacturer.[18] An Importer is defined by regulation as a state-licensed pharmacist or a state- or FDA-licensed wholesale distributor wholesaler that is "the U.S. owner of an eligible prescription drug at the time of entry into the United States."[19] Additionally, the Importer's pharmacist license or wholesale distributor license (if issued by a state and not FDA) must be issued by a state that is a SIP Sponsor or Co-Sponsor, and that license must be in effect and in good standing with the licensor.[20] FDA must grant the Pre-Import Request before a shipment can be imported.[21]

The Importer or its authorized customs broker must file "entries for consumption"[22] with CBP for each eligible prescription drug imported. In addition, before an eligible prescription drug imported from Canada can be distributed in the United States, it must undergo and meet statutory testing requirements to establish its authenticity, ensure that it has not suffered degradation, and confirm that the prescription drug complies with established specifications and standards in the NDA and ANDA for the FDA-approved version of the drug.[23] The results of testing are subject to FDA's review and acceptance. Each drug also must be relabeled so that it matches the FDA-approved labeling, except that it must include additional information described in 21 C.F.R. § 251.13(b) (such as the Importer's National Drug Code ("NDC"), lot number, Importer's name and place of business, and a statement of importation).[24] The labeling of an eligible prescription drug imported under a SIP must also include the following statement on the immediate container label and outside package: "[This drug was/These drugs were] imported from Canada without the authorization of [Name of Applicant] under the [Name of SIP Sponsor] Section 804 Importation Program."[25] Further, manufacturers are required to provide an attestation that, but for the fact that the drug bears the HPFB-approved labeling, it meets the conditions in the

FDA-approved NDA or ANDA.[26] Additionally, upon request from a SIP Sponsor or Importer, the manufacturer must provide written authorization for the Importer to use the FDA-approved labeling of the drug within 30 calendar days or, if the manufacturer fails to do so, FDA may deem the authorization granted.[27]

Following importation, SIP Sponsors must submit quarterly reports to FDA that include detailed information regarding the drugs that have been imported (including but not limited to information regarding the point of origin and destination for imported drugs, the quantity of drug imported and shipped, the per-unit price the Importer paid for the drug, cost savings information, complete data derived from required testing showing that drugs imported are in compliance with established specifications and standards, and certifications that the imported drugs are not adulterated or misbranded and that they comply with all applicable labeling requirements).[28] Importers also must submit adverse event, field alert, and other reports to a drug's manufacturer and FDA.[29] SIP Sponsors also must effectuate any recalls (whether initiated by FDA or a SIP Participant); to that end, each SIP must have a written recall plan describing recall procedures and parties responsible for performing such procedures.[30]

Though the Final Rule still stands, and the first SIP has been authorized, there are still significant practical and political challenges that must be overcome before the start of importation of prescription drugs from Canada, and there are lingering questions regarding whether any importation would result in significant cost savings:

- From a policy and fiscal savings perspective, the Final Rule categorically excludes many of the most expensive drugs marketed, *e.g.*, by wholly excluding biological products from eligibility for importation, thereby calling into question the extent to which it could facilitate significant drug cost savings.
- The Canadian government has made it clear that it will not permit the export of Canadian drugs to meet the supply and pricing needs of the American public when doing so will cause or worsen drug shortages in Canada.[31] Various Canadian stakeholders, including the health minister, have already raised concerns in this regard.[32] Notably, the Canadian market for prescription drugs is much smaller than the U.S. market, and Canadian manufacturers may not be able to satisfy demand under the program.[33] U.S. drug manufacturers could establish quotas on the amount of drugs they will supply to Canadian wholesalers and distributors, and this could complicate efforts to export drugs to the United States under Canadian regulations.[34]
- There are numerous post-importation requirements with which SIP Sponsors and Importers must comply. Their ability to do so to FDA's satisfaction will influence whether their SIPs are renewed or revoked before the end of the two-year statutory term.
- Meeting the logistical requirements for importation is no easy task, requiring significant resources from the SIP Sponsor and coordination with multiple parties, including the manufacturers that hold the NDAs and ANDAs for the FDA-approved versions of "eligible prescription drugs" intended for importation. Manufacturers are subject to several deadlines: for instance, manufacturers must provide the required attestation that but for the fact that the drug bears the HPFB-approved labeling, it meets the conditions in the FDA-approved NDA or ANDA to Importers within 30 calendar days of receiving the Importer's request.[35]
- Litigation challenging the Final Rule, one iteration of which was dismissed on standing grounds, is reasonably foreseeable now that FDA has authorized the first SIP.
- A manufacturer also could refuse to sell its drug to a Foreign Seller, either because it perceives participation in the program as too risky, or because its Canadian contracts forbid them from exporting products to the United States.[36]

Legal Challenges

As noted above, several trade associations brought a challenge to the Final Rule in November 2020, which was dismissed on standing grounds in February 2023.[37] In that case, the plaintiffs argued that the plan contemplated by the Final Rule to

permit pharmacists and wholesalers in the United States to import certain prescription drugs from Canada would present safety risks: namely that the SIP program would open the "closed" regulatory system currently in place; increase the risk of unapproved, misbranded and adulterated drugs entering the market; and undermine protections established by the Drug Supply Chain Security Act ("DSCSA").[38] The complaint also alleged that both the HHS certification leading to the issuance of the rule and the Final Rule violated the Administrative Procedure Act ("APA"), 5 U.S.C. § 551 *et seq.*, asserting that both the certification and Final Rule were contrary to existing law and arbitrary and capricious.[39] The plaintiffs further argued that the Final Rule would deprive its members of speech rights protected by the First Amendment by compelling them to make statements about drugs with which they may disagree and preventing them from including additional statements in their labels about the differences between their drug and imported drugs.[40] On February 6, 2023, the court dismissed the Complaint on procedural grounds for lack of standing, finding that because FDA had not yet approved the SIP, the injuries would be future injuries, and did not meet the standard of certainly impending harm or a certain cause of future harm.[41] The court did not evaluate the merits of the plaintiffs' arguments.

After the FDA's approval of Florida's importation program, it is reasonably foreseeable that some aggrieved party concerned about importation will file suit to challenge the Florida SIP authorization or to challenge the Final Rule now that a SIP has been authorized. Should this occur, a court could be asked to stay the implementation of the Florida SIP and prevent authorization of other SIP proposals while the case is litigated. A ruling that the Final Rule violates the APA or the First Amendment also could delay importation pending FDA amendment of the Final Rule (or perhaps an agency decision not to reissue a new version). The upcoming presidential election also could impact the fate of the Final Rule, although both the Biden and Trump administrations have taken steps to facilitate the Final Rule and SIP programs in the past.[42]

Implications

If the Final Rule survives any potential legal challenges, and Florida or other SIP Sponsors can overcome the logistical hurdles the Final Rule imposes, the question remains as to whether the program will actually result in cost savings to the United States government and American consumers. Experts have estimated that drug prices in the United States are, on average, more than double Canadian drug prices.[43] Florida estimates that it will save up to $183 million annually once the program is implemented.[44] But others are more dubious that true savings will materialize. As mentioned, Section 804 prohibits the importation of certain types of drugs such as biologics and injectable drugs, which would prevent individuals from seeing savings from products such as insulin and often costlier cell and gene therapies.[45] Further, Canada is committed to preventing certain wholesale drug exports that would deplete its own supply, and its population of 38 million is close to that of Florida's alone, which has approximately 22 million residents. Thus, Canada could take action to prevent or increase the cost of exportation.

The Final Rule and potential SIP programs also present potential safety and security challenges and significant risk for participants. The Final Rule requires a SIP Sponsor to explain in its proposal how the SIP Sponsor will comply with the requirements of Section 804 and describe procedures used to ensure that, among other things, the supply chain is secure. However, Importers are exempt from specific requirements under the DSCSA.[46] The exemption could make it easier for counterfeit or substandard products to enter the market.[47] Manufacturers are likely to be wary of SIPs for many reasons: lost revenues from higher prices in the U.S., concerns about counterfeit or misbranded drugs and of potential liability or reputational harm if substandard versions of their drugs are imported, and the significant potential enforcement risks associated with non-compliance with the Final Rule's requirements.[48] Thus, manufacturers may choose to significantly limit the quantity of product they supply to the Canadian market to reduce the availability of product for export to the U.S.

Any importation program could have multiple, potentially contradictory impacts on the U.S. market and pricing for prescription drugs. Advocates of drug importation have posited that drug importation will lower consumer costs for drugs and potentially result in downward pressure on drug prices in particular therapeutic areas.[49] However, there is

ample skepticism that drug importation programs will ever reach the size or scope to result in meaningful savings.[50] Further, the supply chain may have other new costs on account of any importation program – including greater administrative costs in administering a state-based program and in addressing safety risks related to counterfeit or misbranded products, as well as compliance costs associated with new regulatory requirements.[51] Further, and significantly, drug importation could lower manufacturer revenue or otherwise have a chilling effect on incentives to pursue research and development of new or improved versions of drugs. The Congressional Budget Office estimates that reductions in revenue to manufacturers as a result of the program would lead to cuts in research and development that would cause approximately eight fewer new drugs to be introduced to the U.S. market over the next 10 years and roughly 30 fewer drugs over the following decade.[52]

Ropes & Gray will continue to monitor developments related to Section 804 Importation Programs. If you have any questions, please contact any of the authors or your usual Ropes & Gray advisor.

[1] Letter of Authorization for Florida's Section 804 Importation Program, U.S. FOOD & DRUG ADMIN. (Jan. 5, 2024), https://www.fda.gov/media/175237/download?attachment.

[2] On November 27, 2020, the Canadian Minister of Health put out an interim order, intending to address and curtail an impending risk to public health and safety of a drug shortage. The order prohibits a person from distributing drugs for use outside of Canada unless that person has "reasonable grounds" to believe that the distribution of the drug will not cause or worsen a shortage of a drug. Interim Order Respecting Drug Shortages (Safeguarding the Drug Supply), HEALTH CANADA (Nov. 27, 2020) https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/importation-exportation/interim-order-drug-shortages-protecting-supply.html.

[3] Pub. L. 108-173 (2003).

[4] 85 Fed. Reg. 62094 (Oct. 1, 2020), *available at* https://www.federalregister.gov/documents/2020/10/01/2020-21522/importation-of-prescription-drugs.

[5] Safe Importation Action Plan, U.S. FOOD & DRUG ADMIN., *available at* https://www.hhs.gov/sites/default/files/safe-importation-action-plan.pdf. The plan references two "pathways" to provide lower-cost drugs to the U.S. public. Pathway 1 involves a Notice of Proposed Rulemaking that would rely on Section 804 to authorize programs to allow importation of Canadian drugs. Pathway 2 would allow manufacturers to import versions of FDA-approved drug products that they sell in foreign countries that are the same as the U.S. versions.

[6] Pharmaceutical Research & Manufacturers of America et al. v. Dept. of Health & Human Svcs., Complaint, Docket number 1:20-cv-03402, (D.D.C. Nov. 23, 2020), https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PhRMA-Commercial-Importation-Complaint.pdf; Pharmaceutical Research & Manufacturers of America et al. v. Dept. of Health & Human Svcs., Memorandum Opinion, Docket number 1:20-cv-03402, (D.D.C. Feb. 6, 2023).

[7] PhRMA et al. v. HHS Memorandum Opinion, *supra* note 6.

[8] Letter of Authorization, *supra* note 1.

[9] At the time of publication, Maine and New Mexico are awaiting response from FDA on their proposals, which were submitted in 2020. *See* Application to Operate a Section 804 Prescription Drug Importation Program, Maine Department of Health and Human Services (May 1, 2020), *available at* https://www1.maine.gov/dhhs/sites/maine.gov.dhhs/files/inline-files/Maine%20Section%20804%20Importation%20Program%20Application_0.pdf; Section 804 Drug Importation Program Application, New Mexico Department of Health, *available at* https://www.nmhealth.org/publication/view/meeting/6418/. FDA rejected New Hampshire's SIP proposal because it failed to identify the foreign seller in Canada that would buy the eligible prescription drug that would ultimately be imported from the relevant manufacturer as required by the Final Rule. *See* Letter, State of New Hampshire Department of Health and Human Services Section 804 Importation Program Proposal, U.S. Food & Drug Admin. (Nov. 16, 2022), https://khn.org/wp-content/uploads/sites/2/2022/12/New-Hampshire-Denial-Letter.pdf. FDA requested more information about Colorado's proposal, and the state indicated it would submit a revised proposal in early 2024 that would include a

new cost savings analysis and a significant update to the program's compliance plan. The plan was submitted on February 27, 2024 and identifies 24 drugs and dosages. Colorado's Drug Importation Program, Annual Report to the Colorado General Assembly, Colorado Department of Health Care Policy & Financing (Dec. 1, 2023) https://hcpf.colorado.gov/sites/hcpf/files/HCPF%20Drug%20Importation%20Annual%20Report%202023.pdf; Saving People Money on Healthcare: Polis-Primavera Administration Submits Updated Canadian Drug Importation Plan to the FDA, Colorado Department of Health Care Policy & Financing (Feb. 27, 2024), https://hcpf.colorado.gov/press-release/updated-canadian-importation-plan.

[10] *See, e.g.*, *In re Canadian Imp. Antitrust Litig.*, 470 F.3d 785, 790 (8th Cir. 2006) ("Because foreign labeling differs from domestic labeling, approval granted to a particular manufacturer for a particular product to be distributed in the United States does not constitute approval of another drug - even one with the same chemical composition - to be distributed in Canada with different labeling, and then imported into the United States.").

[11] 21 C.F.R. § 251.2.

[12] *Id.*

[13] *Id.* § 251.

[14] *Id.* § 251.3(d)(11).

[15] 85 Fed. Reg. at 62132; 21 C.F.R. § 251.6. FDA may also specify a shorter period of time in the authorization of the SIP.

[16] 21 C.F.R. § 251.5. Other information includes identification of the Importer, identification of the FDA-authorized SIP, and identification of the Foreign Seller.

[17] 85 Fed. Reg. at 62095.

[18] 21 C.F.R. § 251.2. Foreign Seller is defined to mean "an establishment within Canada engaged in the distribution of an eligible prescription drug that is imported or offered for importation into the United States…" Such a Foreign Seller must maintain certain Health Canada and provincial licenses, and "must not be licensed by a provincial regulatory authority with an international pharmacy license that allows it to distribute drugs that are approved by countries other than Canada and that are not HPFB-approved for distribution in Canada." The Foreign Seller must also register with FDA in accordance with Section 804 of the FDCA.

[19] *Id.*

[20] *Id.*

[21] *Id.* § 251.5(a).

[22] An entry for consumption refers to required documentation that must be filed with CBP related to foreign merchandise, including an "entry summary" in accordance with requirements in 19 C.F.R.§ 141.0a(f).

[23] *Id.* § 251.2. Statutory Testing is defined as "the testing of an eligible prescription drug as required by section 804(d)(1)(J) and (L) and section 804(e) of the Federal Food, Drug, and Cosmetic Act, including for authenticity, for degradation, and to ensure that the prescription drug is in compliance with established specifications and standards." *See also* §§ 251.16(d), (e) for clarifying language suggesting that the specifications and standards referred to are those that are established in the NDA or ANDA for the FDA-approved version of the eligible prescription drug. FDA also states in the preamble that "the final rule requires that drugs imported under section 804 meet the specifications of an FDA-approved NDA or ANDA." 85 Fed. Reg. at 62106, 62110.

[24] *Id.* § 251.13.

[25] *Id.*

[26] 21 C.F.R. § 251.5(c)(4)(xii).

[27] *Id.* § 251.13(a).

[28] *Id.* § 251.19.

[29] *Id.* § 251.18.

[30] *Id.*

[31] *See supra* note 2. Health Canada also issued a statement after Florida's SIP Proposal was accepted. *See* Press Release, Canada's regulations prevent drugs from being distributed outside the country if this could cause or worsen a shortage, HEALTH CANADA (last updated Feb. 8, 2024), https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-shortages/information-consumers/canada-regulations-prevent-distribute-drugs-outside-canada.html ("In line with this commitment, we have regulatory safeguards in place and continue to protect our country's drug supply. This includes protecting our supply from foreign bulk importation programs. The government's position is that importing large quantities of drugs intended for the Canadian market is not a solution to high drug prices in other countries.").

[32] *See, e.g.*, Kerry Dooley Young, *Canadians, Pharmacists Skeptical of Florida Drug-Import Plan,* MEDSCAPE (Feb. 1, 2024), https://www.medscape.com/viewarticle/canadians-pharmacists-skeptical-florida-drug-import-plan-2024a100027r. Canadian trade associations for pharmacists and pharmaceutical companies also expressed concerns about the new program. *See* Laura Osman, *Move to allow Canadian drugs to be imported by U.S. creates shortage fears,* CTV NEWS (Jan. 5, 2024), https://www.ctvnews.ca/canada/move-to-allow-canadian-drugs-to-be-imported-by-u-s-creates-shortage-fears-1.6713476.

[33] Marv Shepherd, *U.S. Drug Importation: Impact on Canada's Prescription Drug Supply,* HEALTH ECONOMICS & OUTCOME RESEARCH: OPEN ACCESS (2018), *available at* https://www.iomcworld.org/open-access/us-drug-importation-impact-on-canada8217s-prescription-drug-supply-47131.html.
[34] In the preamble to the final rule, FDA acknowledges the complexity of transactions between Foreign Sellers and manufacturers, stating that "[w]ith regard to the concern raised in some comments that a manufacturer could refuse to deal with participating Foreign Sellers, we do not intend to publicly disclose information from the SIP Proposal or authorization that is confidential business information where such disclosure is restricted by law, potentially including information about Foreign Sellers or the eligible prescription drugs that might be imported … the relationship between a manufacturer and a Foreign Seller will be subject to complex market dynamics, with many variables including relative market power, and it is difficult to predict what transactions might or might not occur." 85 Fed. Reg. at 62100.
[35] 21 C.F.R. § 251.5(d).
[36] Colorado's Department of Health Care Policy & Financing specifically noted in a 2022 annual report that certain manufacturers had contracts with Canadian wholesalers that barred exportation of drugs to the U.S. *See* Section 804 Importation Program Annual Report, *supra* note 9.
[37] PhRMA et al. v. HHS Memorandum Opinion, *supra* note 6.
[38] *Id.* at 31.
[39] Pharmaceutical Research & Manufacturers of America et al. v. Dept. of Health & Human Svcs., Amended Complaint, Docket number 1:20-cv-03402 (D.D.C. 2021) at 60-81. Among other things, the plaintiffs argued that Secretary Azar inadequately considered health risks and consumer savings in making the certification and that both the certification and Final Rule failed to acknowledge and explain the change in agency policy.
[40] *Id.* at ¶ 188 ("[T]he Final Rule would also restrict manufacturers' speech rights by depriving them of the opportunity to add to the labels of imported drugs any disclaimers or other language by which they could note that, for example, they disagree with claims that imported drugs are equivalent to approved drugs, or do not stand behind such products … Moreover, the blanket statement that the drugs were imported *without* authorization of the manufacturer also violates manufacturers' First Amendment rights, insofar as some manufacturers in some situations may approve of such importation.") (emphasis original).
[41] PhRMA et al. v. HHS Memorandum Opinion, *supra* note 6.
[42] *See, e.g.*, Nathaniel Weixel, *Florida scores drug import win — but many hurdles remain*, THE HILL (Jan. 6, 2024), https://thehill.com/policy/healthcare/4392301-florida-drug-import-win-hurdles/ ("Drug importation was a priority in the later days of the Trump administration, and in 2020 rules were issued allowing states to submit plans for approval. Florida was the first to apply. A 2021 executive order from Biden gave the policy new momentum and directed federal agencies to work with states on importation plans.").
[43] *See* Andrew W. Mulcahy et al., *International Prescription Drug Price Comparisons*, Rand Corp. (2021), https://www.rand.org/pubs/research_reports/RR2956.html (noting average prices in the United States are 218% those in Canada).
[44] Press Release, *Florida Becomes First in Nation to Have Canadian Drug Importation Program Approved by FDA,* GOVERNOR RON DESANTIS (Jan. 5, 2024), https://www.flgov.com/2024/01/05/florida-becomes-first-in-the-nation-to-have-canadian-drug-importation-program-approved-by-fda/.
[45] 21 C.F.R. § 251.2(2). Future evidence that cost savings have not materialized could be marshalled to challenge the Final Rule or authorized SIPs in the future.
[46] *Id.* § 251.14(d)(7).
[47] Any safety issues that emerge also could be used to challenge the Final Rule down the road.
[48] Participants in a SIP face potentially significant legal exposure under the FDCA if they fail to comply with the identified requirements. The importation of a prescription drug in violation of Section 804, falsification of any record required under Section 804, or any other violation of the regulations implementing Section 804 are prohibited acts under 21 U.S.C. § 331(aa). Additionally, Section 303(b)(6) of the FDCA (21 U.S.C. § 333(b)(6)) provides for a prison term of up 10 years and/or a fine of up to $250,000 for manufacturers or importers of prescription drugs under Section 804(b) that "knowingly fail[s] to comply with a requirement of section [804(e)] that is applicable to such manufacturer or importer." Violators are also subject to fines under 18 U.S.C. § 3571.
[49] For example, Senator Bernie Sanders has sponsored several sets of bills that would allow patients, pharmacists and wholesalers to import medicine from Canada and other major countries. As early as 2009, Senator Sanders argued that a Canadian importation proposal would save the federal government $19.4 billion and American consumers about $100 billion over the next decade. *See* Press Release, Senator Bernie Sanders, Safe Rx Drug Importation Needed in Health Reform (Dec. 8, 2009), https://www.sanders.senate.gov/press-releases/release-safe-rx-drug-importation-needed-in-health-reform/; *see also* Press Release, Senator Bernie Sanders, Sanders, Khanna Doggett, Welch, Bush Introduce Sweeping Legislation to Lower Drug Prices (Mar. 23, 2021), https://www.sanders.senate.gov/press-releases/news-sanders-khanna-doggett-welch-bush-introduce-sweeping-legislation-to-lower-drug-prices/.

[50] *See* Interim Order, *supra* note 2; *see* PhRMA v. HHS Amended Complaint, *supra* note 39, at 2.
[51] *See e.g.*, Christina Jewett and Sheryl Gay Stolberg, *F.D.A. Issues First Approval for Mass Drug Imports to States From Canada*, N.Y. TIMES (Jan 5. 2024), https://www.nytimes.com/2024/01/05/health/drug-imports-canada-florida.html (quoting Harvard Medical School professor of medicine Dr. Aaron Kesselheim as saying "I think it's going to be hard for states to import drugs like that in any kind of scale that would make a difference in terms of lowering prices for patients.").