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FDA Issues Final Rule Granting States Ability to Establish Canadian Drug Importation Programs

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On September 24, the U.S. Food and Drug Administration ("FDA") released a final rule enabling states to develop and seek FDA approval of programs for the importation of certain prescription drugs from Canada (the "Final Rule").[i] While the Trump administration expects the Final Rule to play an important role in its efforts to lower the cost of prescription drugs, multiple impediments reduce the likelihood that it will have a significant impact, including limited FDA oversight resources, the efforts states and other supply chain participants will have to take to establish and operate such programs, resistance likely to be encountered from Canada, and legal action likely to be brought by the pharmaceutical industry.

This Alert describes key features of the Final Rule and discusses some of the manifold impediments to its success in lowering prescription drug costs.

Background

As we previously described in an alert on this topic from January 2020, the Final Rule represents 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.[ii] In December 2019, acting at the direction of President Trump, FDA published (1) a proposed regulation to establish a program under which states could import certain prescription drugs approved by Health Canada's Health Products and Food Branch (HPFB) that, but for bearing HPFB-approved labeling when marketed in Canada, otherwise meet the conditions in an FDA-approved new drug application (NDA) or abbreviated new drug application (ANDA), and (2) a draft guidance document providing recommendations that would allow manufacturers of FDA-approved drugs sold abroad to import those drugs for U.S. sale.[iii] The Final Rule addresses the first proposed pathway.[iv]

Key Provisions

The Final Rule will go into effect on November 30, 2020, and relies on individual states to establish their own importation programs, defined under the Final Rule as Section 804 Importation Programs ("SIPs"), by submitting their proposals and obtaining the authorization of FDA.[v] The Final Rule requires, among other things, that SIP proposals specify the eligible prescription drugs that will be imported, identify a single Foreign Seller in Canada that will purchase the eligible drugs directly from their manufacturers and a single Importer in the United States that will buy the drugs directly from the Foreign Seller, designate a single port of entry for the imports, and provide a plan regarding supply chain security.[vi] There is no specified turnaround time by which FDA must accept or reject a state's SIP proposal, and FDA will have broad discretion to deny a proposed SIP, including because of "safety concerns with the SIP" due to "uncertainty that the SIP Proposal or supplemental proposal would adequately ensure the protection of public health," and to limit the number of authorized SIPs to ensure that FDA may effectively and efficiently carry out its responsibilities under Section 804 of the Food, Drug, and Cosmetic Act (the statutory basis for the Final Rule) "in light of the amount of resources allocated to carrying out such responsibilities."[vii]

A key aspect of the Final Rule is the "short supply chain" involving a single Importer that buys from a single Foreign Seller that buys directly from the drug manufacturer.[viii] FDA states, however, that in the future it may be willing to consider additional supply chain participants as part of a SIP, once a successful track record of importations under a SIP has been established.[ix] Similarly, FDA says that in the future it might be willing to consider SIPs sponsored by

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wholesalers or pharmacies rather than states, but that at the outset SIPs must originate from states or Indian Tribes, which wholesalers or pharmacies may "co-sponsor."[x]

Authorized SIPs will be valid for two years and will be subject to FDA renewal for successive two-year periods.[xi] Before importing a drug under an authorized SIP, the Importer will have to submit a Pre-Import Request to FDA at least 30 calendar days in advance, and such imports will be required to be filed as formal entries with U.S. Customs and Border Protection.[xii] The rule also sets forth detailed requirements relating to:

- Authenticity testing of the imported drugs to be conducted by the drug's manufacturer or the Importer,[xiii]
- Product identification labeling and recordkeeping by both the Foreign Seller (a Section 804 Serial Identifier or "SSI") and the Importer (a product identifier meeting the serialization requirements of the Drug Safety and Supply Chain Security Act and records linking that number to the Foreign Seller's SSI),[xiv] and
- Various post-importation requirements such as mandatory adverse event and field alert reporting by Importers, SIP Sponsor reports to FDA on cost savings, and product recalls.[xv]

Practical and Political Challenges to Implementation

Thus far, Maine,[xvi] Florida,[xvii] and Colorado[xviii] have submitted proposals in advance of the Final Rule's promulgation.[xix] Additional proposals may be likely soon, given that three other states, Vermont,[xx] New Mexico,[xxi] and New Hampshire,[xxii] have passed legislation to develop their own drug importation programs, however. These include:

As issued, the Final Rule stands to encounter a significant number of practical and political challenges to its efficacy.

Limitations on products. First, the Final Rule excludes entire categories of drugs from eligibility, including biologics, infused drugs, and intravenously injected drugs.[xxiii] By limiting the universe of drugs states may import through their SIPs, FDA limits the number of manufacturers whose drugs will be subject to importation and reduces the likelihood that the Final Rule will have a significant impact on prescription drug prices, especially given that many biologics and injected drugs are quite expensive.[xxiv]

Canadian resistance likely. Additionally, as we outlined in our earlier alert, the successful operation of the Final Rule requires significant tolerance by the Canadian government, and significant buy-in from Canadian businesses.[xxv] The Canadian government is incentivized to protect its own citizens' access to drugs by resisting diversion to the United States, as manufacturers are unlikely to sell more drugs to Canada to make up for what is diverted as part of the SIPs.[xxvi] In the event manufacturers are willing to sell more drugs to Canada, they may do so at a higher price, undoing Canada's own work to negotiate lower drug prices for its citizens.[xxvii] Canadian businesses, reluctant to incite the Canadian government and drug manufacturers, also appear reticent to participate in these programs.[xxviii] In fact, a Preliminary Regulatory Impact Analysis from December 2019, raised the possibility that, given the Canadian government's power to limit the supply of prescription drugs exported to the United States, the program might not yield any benefit.[xxix]

Significant state resources needed. Finally, in order to implement SIPs, states will be asked to invest a significant amount of time and resources into producing a proposal that may ultimately be denied not because of the application's merit, but because of FDA resource constraints. The resulting uncertainty may create a disincentive for states to develop such programs.

Legal Challenges to Implementation

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In addition to the practical and political challenges associated with implementation of the Final Rule, it is very likely the Final Rule will be held up in litigation under multiple theories, including allegations that it is unconstitutional. One comment discussed in the preamble to the Final Rule suggests that certain of the rule's required attestations on the part of drug manufacturers amount to compelled speech and violate the First Amendment.[xxx] Another comment suggests that information drug manufacturers are required to give to importers and qualifying laboratories under the Final Rule includes confidential commercial information and trade secrets, amounting to a Fifth Amendment taking for which just compensation is due.[xxxi] While FDA rejected the merits of each of these claims in its response to the comments, they are emblematic of legal challenges the Final Rule is likely to face once effective.

The Final Rule may also face challenges on administrative law grounds. Section 804 of the Federal Food, Drug, and Cosmetic Act, enacted in its current form in 2003, has long required that the U.S. Department of Health and Human Services ("HHS") Secretary certify to Congress that 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.[xxxii] Until now, no HHS Secretary has been willing to make that certification. In the preamble to the Final Rule, FDA states that the HHS Secretary is making that certification to Congress, concurrent with issuance of the Final Rule.[xxxiii] At the same time, however, the preamble to the Final Rule admits that it is not possible to estimate the cost savings from the Final Rule.[xxxiv] By simultaneously certifying that the rule will result in significant cost savings to the American people and admitting that cost savings cannot be estimated, HHS may be vulnerable to a legal challenge that its interpretation of the statute is arbitrary and capricious.

In the event litigation found portions of the Final Rule unenforceable, the Final Rule's severability clause would render the Final Rule void in its entirety.[xxxv]

Conclusion

While the effective date of the Final Rule is quickly approaching, any practical consequences are unlikely to be felt for some time. Given comments to the proposed version of the Final Rule and HHS' interpretation of Section 804, it is likely the Final Rule will be tied up in litigation for some period of time. However, even if the Final Rule survives myriad legal challenges, the numerous political challenges it faces, chief among them getting substantive buy-in from the Canadian government, could render the Final Rule functionally void, even if not legally so.

If you have any questions about this Alert, please contact your usual legal advisor at Ropes & Gray.

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i. 85 Fed. Reg. 62094 (Oct. 1, 2020), *available at* https://www.federalregister.gov/documents/2020/10/01/2020-21522/importation-of-prescription-drugs.
ii. *Drug Pricing: What Happened in 2019 and What to Watch in 2020* (Jan. 13, 2020), *available at* https://www.ropesgray.com/en/newsroom/alerts/2020/01/Drug-Pricing-What-Happened-in-2019-and-What-to-Watch-in-2020.
iii. *Id.*
iv. 85 Fed. Reg. at 62094.
v. *Id.*
vi. 85 Fed. Reg. at 62129.

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vii. 85 Fed. Reg. at 62130.
viii. 85 Fed. Reg. at 62100.
ix. 85 Fed. Reg. at 62132.
x. 85 Fed. Reg. at 62128, 62132.
xi. 85 Fed. Reg. at 62132.
xii. 85 Fed. Reg. at 62130.
xiii. 85 Fed. Reg. at 62136–62137.
xiv. 85 Fed. Reg. at 62134–62136.
xv. 85 Fed. Reg. at 62137–62139.
xvi. Maine Department of Health and Human Services, Application to Operate a Section 804 Prescription Drug Importation Program (May 1, 2020), *available at* https://www.maine.gov/dhhs/sites/maine.gov.dhhs/files/inline-files/Maine%20Section%20804%20Importation%20Program%20Application_0.pdf.
xvii. Florida's Canadian Prescription Drug Importation Concept Paper (Aug. 20, 2019), *available at* https://ahca.myflorida.com/executive/communications/requested_documents/Florida_Canadian_Prescription_Drug_Importation_Concept_Paper.pdf.
xviii. Colorado Department of Health Care Policy & Financing, Section 804 Importation Program: Colorado's Drug Importation Program – Draft Application (March 9, 2020), *available at* https://www.colorado.gov/pacific/sites/default/files/Colorado%20Draft%20SIP%20%20-%20Version%203-9-2020.pdf.
xix. *See* 85 Fed. Reg. at 62094.
xx. Vt. Stat. Ann. Tit. 18 § 4651 *et seq.*
xxi. N.M. Stat. Ann. § 26-4-4 *et seq.*
xxii. N.H. Rev. Stat. § 126-CC:1 *et seq.*
xxiii. 85 Fed. Reg. at 62126–62127.
xxiv. Jacquie Lee, Costly Drugs Left Out of Import Rule Blunt Projected Savings, Bloomberg Law (Sept. 25, 2020), *available at* https://news.bloomberglaw.com/health-law-and-life-sciences/costly-drugs-left-out-of-import-rule-blunt-projected-savings?usertype=External&bwid=00000174-c092-d632-a3fc-d6f3264b0001&qid=6984268&cti=LFVL&uc=1320000038&et=CURATED_HIGHLIGHTS&emc=hsnw_hlt%3A1&context=email&email=00000174-c6d8-d941-af7c-eed995290000&access-ticket=eyJjdHh0IjoiSFNOVyIsImlkIjoiMDAwMDAxNzQtYzA5Mi1kNjMyLWEzZmMtZDZmMzI2NGIwMDAxIiwic2lnIjoiSkFmNEx1b2pUbHZ1UVNRd2l3Wm5jTVJKNlhrPSIsInRpbWUiOiIxNjAxMDY0Mjk4IiwidXVpZCI6Ii90aGxhemlmZlFOS1UyWTR5MjBNSlE9PWkxa1ZNRmhVZFVNN0pLa011NXdGWlE9PSIsInYiOiIxIn0%3D.
xxv. *Drug Pricing*, *supra* note 2.
xxvi. *Id.*
xxvii. Rachel Sachs, Administration Finalizes Drug Importation Plans, But Legal and Practical Questions Remain, (Sept. 25, 2020), *available at* https://www.healthaffairs.org/do/10.1377/hblog20200925.874730/full/.
xxviii. *Drug Pricing*, *supra* note 2.
xxix. U.S. Department of Health and Human Services, Food and Drug Administration, Importation of Prescription Drugs: Preliminary Regulatory Impact Analysis (2019), *available at* https://www.fda.gov/media/133553/download.
xxx. 85 Fed. Reg. at 62115–62117.
xxxi. 85 Fed. Reg. at 62117–62119.
xxxii. 21 U.S.C § 384(l).
xxxiii. 85 Fed. Reg. at 62123.
xxxiv. *Id.*
xxxv. 85 Fed. Reg. at 62140.

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