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Client Alert

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A Gimmick No More? HHS Moves to Authorize Prescription Drug Importation

Since its enactment in 2003, Section 804 of the Federal Food, Drug, and Cosmetic Act (FDCA) has been a dead letter in the law. The provision authorizes the importation of certain prescription drugs from Canada, but only if the Secretary of the Department of Health and Human Services (HHS) certifies that importation would "pose no additional risk" to U.S. consumers, and it would "result in a significant reduction in the cost" of those prescription drugs. Over the past sixteen years, no Secretary of HHS has been willing to make that certification. As a result, Section 804 has remained dormant. In the wake of President Trump's election, many consumer advocacy groups urged his administration to activate Section 804. However, last year HHS Secretary Alex Azar dismissed the idea as a "gimmick."[1] Now, it appears that Secretary Azar has reconsidered the issue.

On July 31, 2019, HHS released its "Safe Importation Action Plan," which is designed to pave the way for the importation of certain prescription drugs from foreign countries.[2] The plan provides for two pathways to facilitate drug importation. The first pathway would allow "demonstration projects" under Section 804 where States, wholesalers, or pharmacists could import Health Canada-approved drugs into the United States. The second pathway would allow manufacturers to import "versions of FDA-approved drug products that they sell in foreign countries" under a new National Drug Code (NDC) for those products, "potentially allowing them to offer a lower price than what their current distribution contracts require."[3]

This announcement marks a major shift in U.S. policy regarding prescription drug importation and will have a significant impact on regulated industry. In this Client Alert, we have outlined the new policies announced by HHS, along with our thoughts about the broader implications of the policy shift.

I. BACKGROUND ON SECTION 804

Section 804 was enacted as a part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.[4] The provision created a pathway for HHS to permit pharmacists and wholesalers to import specific categories of prescription drugs from Canada into the United States. Several categories of prescription drugs were excluded from Section 804, including controlled substances, biological products, and drugs meant to be infused or injected into patients.[5]

Section 804 also required "that safeguards be in place to ensure that each prescription drug imported under the regulations complies with [the New Drug Approval requirements under] section 505" and that the importer or manufacturer of the drug "meets all labeling requirements under this Act."[6] Those provisions have traditionally been viewed as formidable obstacles to achieving the "significant cost savings" required under the statute. After all, if wholesalers were required to relabel imported drugs with the NDA-approved labeling for each prescription drug, that would add significant costs to the imported drugs. Moreover, since FDA has repeatedly taken the position that foreign versions of FDA-approved drugs are considered unapproved new drugs that do not comply with Section 505 of the FDCA,[7] it has never been clear how compliance with Section 505 would even be possible.

Over the years, Secretaries of HHS and FDA Commissioners from both political parties have refused to support the implementation of Section 804.[8] In May 2018, Secretary Azar emphasized that prior FDA Commissioners had repeatedly refused to support drug importation from Canada:

> "Many people may be familiar with proposals to give our seniors access to cheaper drugs by importing drugs from other countries, such as Canada. This, too, is a gimmick. …[T]he last four FDA commissioners have said there is no effective way to ensure drugs coming from Canada really are coming from Canada rather than being routed from, say, a counterfeit factory in China. The United States has the safest regulatory system in the world. The last thing we need is open borders for unsafe drugs in search of savings that cannot be safely achieved."[9]

Secretary Azar also observed that the Canadian market cannot meet demand from U.S. consumers: "Canada simply doesn't have enough drugs to sell them to us for less money…."[10] That is one of the reasons that the purportedly "Canadian" internet pharmacy industry has evolved into an unregulated group of global wholesalers that source drugs from other parts of the world, such as the European Union, Turkey, and India.

That evolution has been a significant problem for global drug supply chain security. In 2018, subsidiaries of CanadaDrugs.com, then one of the largest Canadian internet pharmacies, pleaded guilty to distributing a counterfeit version of the cancer drug Avastin in the United States. CanadaDrugs.com was forced to shut down its operations.[11] The concerns voiced by HHS in recent years about the threat of counterfeit drugs were not hyperbole; they were based on concrete facts and disturbing breaches of the U.S. drug supply chain. Despite these legitimate concerns, Secretary Azar has now proposed two pathways to facilitate the importation of prescription drugs from outside the United States.

II. THE SAFE IMPORTATION ACTION PLAN

Pathway 1

According to the HHS announcement, the Agency will be submitting a Notice of Proposed Rulemaking (NPRM) that will rely on the authority established in Section 804 to authorize demonstration projects to allow importation of drugs from Canada. The NPRM will allow "States, wholesalers, or pharmacists" to "submit plans for demonstration projects for HHS to review outlining how they would import Health Canada-approved drugs that are in compliance with Section 505 of the FD&C Act."[12] The projects "would be time-limited and require regular reporting to ensure safety and cost conditions are being met."[13]

The HHS announcement states that the NPRM will provide additional details about an array of issues, including drug eligibility, safety requirements, and cost savings. With respect to drug eligibility, HHS clarified that eligible drugs "must be drugs authorized for sale in Canada that are versions of FDA-approved prescription drugs."[14] This would seemingly prohibit Canadian internet pharmacies from importing drugs meant for other markets, such as the European Union, Turkey, and India, which is a large part of their current business. In addition, controlled substances, biological products, infusion drugs, injectable drugs, certain parenteral drugs, and drugs subject to a Risk Evaluation and Mitigation Strategy (REMS) would be excluded from the demonstration projects.

Since concerns about supply chain integrity are at the center of the drug importation debate, HHS' approach to the safety requirements will be important to watch. The HHS announcement noted that the NPRM will require applicants to demonstrate how they will comply with various safety requirements, including "track and trace requirements to allow drug tracing from manufacture to pharmacy."[15] However, the announcement did not mention whether FDA intends to enforce the Drug Supply Chain Security Act in the context of drugs imported under Section 804, or how it would do so.

HHS also explained that the NPRM will address the factual basis for its decision to implement Section 804, including "past consideration of importation under section 804 and … what has changed since those previous reviews."[16] In the wake of the counterfeit Avastin incident, it will be interesting to see how HHS plans to justify its approach.

As noted in Section III below, this proposal raises many questions about HHS' legal authority under Section 804, supply chain integrity, and the basic logistics of trying to open the U.S. drug supply chain to Canadian drug importation.

Pathway 2

The second pathway does not focus on drug importation by States, wholesalers, and pharmacists. Instead, it would enable manufacturers to "import versions of FDA-approved drug products that they sell in foreign countries that are the same as the U.S. versions."[17] Under this pathway, which will be implemented through a guidance document, manufacturers would be required to establish that the foreign-market version of the drug is "the same as the U.S. version." If that condition is met, FDA "would allow the drug to be labeled for sale in the U.S." and sold "under the existing approval for the U.S. approved version."[18] The foreign version would be sold under a different NDC number than the U.S. version. Unlike the first pathway, this policy would not be restricted to Health Canada-approved drugs. It would apply to any "versions of FDA-approved drug products" that a manufacturer sells abroad.

HHS explained that, in the Agency's view, this would enable manufacturers to avoid contractual restrictions on drug pricing:

> "The Administration has reason to believe that manufacturers might use this pathway as an opportunity to offer Americans lower cost versions of their own drugs. In recent years, multiple manufacturers have stated (either publicly or in statements to the Administration) that they wanted to offer lower cost versions but could not readily do so because they were locked into contracts with other parties in the supply chain. This pathway would highlight an opportunity for manufacturers to use importation to offer lower-cost versions of their drugs."[19]

The plan also suggests that this is the Agency's preferred pathway, noting that "if costs can be lowered significantly through this pathway, there may be reduced need for the demonstration projects outlined in Pathway 1."[20]

III. KEY TAKEAWAYS FROM THE SAFE IMPORTATION ACTION PLAN

Many Unanswered Questions

It is not clear what these demonstration projects are actually going to look like and whether there are enough prescription drugs in the Canadian supply chain to make this work. In recent years, popular drug importation bills, such as Senator

Bernie Sanders' Affordable and Safe Prescription Drug Importation Act,[21] have been focused on legalizing the importation of drugs from an array of different countries because of supply limitations in Canada. The Safe Importation Action Plan does not go that far. It only applies to Health Canada-approved drugs. Right now, the wholesalers that are eager to facilitate importation are the Canadian internet pharmacies, and Health Canada-approved drugs constitute a very small subset of the drugs offered for sale by those companies. This plan is not consistent with their current business model, but we anticipate that they will work to secure additional sources of Health Canada-approved drugs to meet the coming demand.

This leads to the larger question of how HHS will treat the Canadian internet pharmacies. Until now, HHS and the U.S. Department of Justice have viewed Canadian internet pharmacies as smugglers that need to be prosecuted.[22] Section 804 would create a mechanism for "foreign sellers" to register with HHS.[23] What if a Canadian internet pharmacy that is currently importing prescription drugs from Canada and places like Turkey and India seeks to register? What will HHS do? It would be unusual (to say the least) for HHS to register such "foreign sellers" and effectively give them a free pass on their associated illegal imports. For those reasons, the Canadian internet pharmacies might try to spin off subsidiaries that specialize in HHS-compliant activities and maintain separate subsidiaries that continue illegal importation activities. How will HHS treat that kind of behavior?

There are also questions that arise from the involvement of States in the importation process. Florida's recent drug importation proposal would authorize the State of Florida to purchase prescription drugs in bulk from Canadian wholesalers.[24] Does Florida really know how to address the risks associated with the Canadian internet pharmacies and the global counterfeit drug trade? Moreover, even if HHS required Florida to adopt track-and-trace procedures, how can anyone trust the accuracy of that track-and-trace information when the Canadian internet pharmacies have been operating in open violation of U.S. law for years?[25]

Unfortunately, we fear that HHS is going to face a lot of pressure to ignore very serious safety concerns associated with Canadian internet pharmacies.

Legal Challenges Ahead

There are significant questions about the legality of the Secretary's actions under Pathway 1. First, as noted above, Section 804 can only become effective if the Secretary certifies that "the implementation of [Section 804] 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."[26] However, Secretary Azar is not planning to make that broad of a certification. Instead, the Secretary will "propose to condition certification on the ability to limit the program to demonstration projects under section 804(b)-(h) and would seek comments on that proposal."[27] In other words, the Secretary of HHS is not going to make the certification that is legally required to implement Section 804 and instead is choosing to make a narrower certification. It is not clear that the Secretary has the legal authority to make a "conditional" certification that is far short of the complete certification required by the statute.

Second, HHS is proposing to include "States" as sponsors of demonstration projects, along with wholesalers and pharmacists. Although HHS likely took that step to facilitate the submission of plans from Florida and other States that are attempting to spearhead importation, "States" are not authorized importers under the law. Section 804 provides that "[t]he Secretary, after consultation with the United States Trade Representative and the Commissioner of Customs, shall promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States."[28] HHS cannot authorize a demonstration project from Florida or any other State.

HHS is clearly preparing for legal challenges to its plan and appears to be taking an all-or-nothing approach to severability. The HHS announcement states that the "rulemaking would be clear that if any provision of Pathway 1 in a final rule is invalidated by a court, the entirety of Pathway 1 should be invalidated…."[29]

Laying the Groundwork for Broader Drug Importation?

If Secretary Azar is correct and there is not enough supply in Canada to meet demand in the United States, it would seem that implementing Section 804 could be one way to build public support for the legalization of importation from additional countries. Likewise, the second pathway seems like it is designed to apply additional pressure on drug manufacturers to reduce drug prices. If manufacturers do not avail themselves of this pathway, then public pressure for further action may grow, regardless of the logistical and contractual hurdles that must be addressed by manufacturers to facilitate importation.

Drug Reimbursement Issues

Finally, the announcement's focus on the details of how distinct new NDCs would be created for these products gives rise to a host of questions. First, there will be significant operational issues among wholesalers, distributors, health plans, and pharmacies in adopting these new NDCs, and practically distinguishing "American" drugs from "Canadian" drugs in pharmacy inventories. Second, the adoption of the NDC methodology suggests that, should the demonstration succeed, a legislative change to reimbursement rules would be enacted in which federal payors would reimburse on a blended average of the two NDCs for the products (similar to the way branded and generic drugs are reimbursed through the same "J-Code" in the Part B program today). Manufacturers will need to carefully watch how the new NDC provisions unfold and anticipate how they may be used for federal program reimbursement purposes in the future.

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[1] HHS Secretary Azar's Remarks on Drug Pricing Blueprint, 5.14.18, https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-drug-pricing-blueprint.html
[2] HHS Safe Importation Action Plan, https://www.hhs.gov/sites/default/files/safe-importation-action-plan.pdf
[3] HHS Safe Importation Action Plan, at 1.
[4] Medicare Prescription Drug, Improvement, and Modernization Act, Pub. L. No. 108-173; 117 Stat. 2257 (2003).
[5] 21 U.S.C. § 384(a)(3).
[6] 21 U.S.C. § 384(d)(1)(K).
[7] *See, e.g.,* FDA Q&A "Is it legal for me to personally import drugs?" (stating that "if a drug is approved by Health Canada…but has not been approved by FDA, it is an unapproved drug in the United States and, therefore, illegal to import.") https://www.fda.gov/about-fda/fda-basics/it-legal-me-personally-import-drugs
[8] For a compilation of quotes from various current and former officials at the Department of Health and Human Services, *see* https://www.safemedicines.org/2018/07/who-opposes-drug-importation-every-head-of-the-fda-and-hhs-since-2000.html
[9] HHS Secretary Azar's Remarks on Drug Pricing Blueprint, 5.14.18, https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-drug-pricing-blueprint.html
[10] *Id*.
[11] *See* DOJ Press Release Regarding CanadaDrugs.Com plea agreement, https://www.justice.gov/usao-mt/pr/canadian-drug-firm-admits-selling-counterfeit-and-misbranded-prescription-drugs
[12] HHS Safe Importation Action Plan, at 1.
[13] HHS Safe Importation Action Plan, at 1.
[14] *Id.* at 2.
[15] *Id*. at 2.
[16] HHS Safe Importation Action Plan, at 1.
[17] HHS Safe Importation Action Plan, at 3.
[18] *Id*.
[19] HHS Safe Importation Action Plan, at 3.
[20] *Id.* at 4.
[21] Affordable and Safe Prescription Drug Importation Act, S. 469, 115th Cong. (2017-2018).
[22] *See, e.g.,* DOJ Press Release Regarding CanadaDrugs.Com plea agreement, https://www.justice.gov/usao-mt/pr/canadian-drug-firm-admits-selling-counterfeit-and-misbranded-prescription-drugs; *see also* FDA's list of Internet Pharmacy Warning Letters, https://www.fda.gov/drugs/drug-supply-chain-integrity/internet-pharmacy-warning-letters.
[23] 21 U.S.C. § 384(f).
[24] *See* State of Florida Press Release Regarding Florida CS/HB 19, https://www.flgov.com/2019/06/11/governor-ron-desantis-signs-cs-hb-19-prescription-drug-importation-programs/
[25] It is also unclear how the HHS drug importation plan would impact state laws that have been passed to establish additional security measures governing the prescription drug supply, such as state drug stewardship laws.
[26] 21 U.S.C. § 384(l)(1).
[27] HHS Safe Importation Action Plan, at 2.
[28] 21 U.S.C. § 384(b) (emphasis added).
[29] HHS Safe Importation Action Plan, at 3.