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March 6, 2020

Dockets Management Staff (HFA–305)
Food and Drug Administration, 5630 Fishers Lane, Rm. 1061
Rockville, MD 20852
Attention: CMS-5528-ANPRM
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Docket No. FDA– 2019–N–5711: Proposed Rulemaking on Importation of Prescription Drugs.

Dear Sir or Madam:

Cardinal Health appreciates the opportunity to provide comments to the Proposed Rulemaking with Comment entitled "Importation of Prescription Drugs," 84 Fed. Reg. 70796 (December 23, 2019) ("Proposed Rule").

Cardinal Health shares FDA's concern about making medications affordable and accessible. Cardinal Health supports efforts to lower prescription drug costs for patients and is committed to engaging with the administration to promote reform efforts that improve the U.S. health system. Cardinal Health also supports improving patient convenience and access to local quality health care and would be concerned about any changes to the distribution of drugs in the United States that could result in unintended consequences on access to care or quality of services.

This comment provides information about the role of wholesale distributors in the pharmaceutical supply chain and offers our insight into the potential feasibility of achieving meaningful consumer savings by importing products and the possible impact that imported products could have on the security and safety of the drug supply.

The number and detailed nature of the steps addressed by the FDA in its proposed rule highlights the complexity and rigor of the processes that are in place in the United States to protect consumers from counterfeit, unsafe, adulterated or misbranded products. And yet, as the FDA notes, even with these processes and the advent of the Drug Supply Chain Security Act (Title II of Pub. L. 113–54; "DSCSA"), risks are still present. Cardinal Health is providing comments in the four areas that we see as incurring potentially significant effects if the Proposed Rule is implemented as envisioned. These are:

- Practical obstacles to the success of the Proposed Rule that are outside the sphere of FDA influence or authority;
- Complexity of process required to assure that imported products can meet U.S. standards and can be seamlessly utilized for prescribing and dispensing to U.S. consumers;
- Concern over the increased challenges posed by the Proposed Rule for supply chain safety and security; and

- Costs associated with assuring safe importation and significant hurdles to ensuring that any savings that might be achieved will be used to lower prices to consumers.

As a pharmaceutical distributor, Cardinal Health is concerned that establishing an alternative process with its own complexities solely in order to allow importation of drugs is unlikely to materially reduce the burden of drug costs and will prove difficult to integrate with existing prescription drug distribution systems.

I. Distributor's Role in the Supply Chain

Cardinal Health supplies an extensive and diversified range of pharmaceutical and related products and services in the complex U.S. health care supply chain. It has distribution agreements with thousands of health care providers and supplies products nationwide from its distribution centers.

As a wholesale distributor, Cardinal Health's role is primarily to serve as a conduit for pharmaceuticals to travel from manufacturer to patient along a supply chain that is as secure and efficient as possible. As a pharmaceutical distributor of both traditional and specialty pharmaceuticals, we do not set the wholesale acquisition cost (WAC) for brand name products, nor do we bill any payer.

Distributors play a key role in maintaining the efficiency of drug distribution by offering "just in time" delivery, greatly reducing the burden of provider inventory costs, and providing solutions to enable providers to improve patient care. Distributors also provide an array of supporting services that enable the pharmaceutical supply chain to function efficiently and safely.

II. Background

FDA is issuing the proposed rule under its rulemaking authority regarding importation of prescription drugs. As the Proposed Rule notes, Section 1121 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)[1] amended section 804 of the FD&C Act to its current version. That amendment authorizes the Secretary of HHS to issue regulations permitting pharmacists and wholesalers to import certain prescription drugs from Canada under certain conditions and limitations.

The FDA further notes that it has consistently considered the risk to safety of commercial importation hard to justify in light of its estimate that national savings from legalized commercial importation would be only "a small percentage of total drug spending and developing and implementing such a program would incur significant costs and require significant additional authorities."[2] FDA cites improvements in Canadian oversight, along with DSCSA requirements and limiting approval to proposals submitted by states that have reasonable plans to lower costs, as significant safeguards to protect consumers from being exposed to undue risks for uncertain benefit.[3]

III. Specific Comments on the Proposed Rule

The Proposed Rule provides a pathway solely for products approved by the Canadian Health Products and Food Branch (HPFB) that could have been approved for sale in U.S. but for labeling and packaging differences.[4] At the outset, Cardinal Health believes that there are

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[1] Pub. L. 108–173. *See* discussion at 84 Fed. Reg. 70799.

[2] *Id.*

[3] *See* 84 Fed. Reg. 70800-01

[4] Proposed 21 C.F.R. § 251.2 (definition of "eligible prescription drug").

significant practical obstacles to importation of products intended for marketing and distribution in Canada that are outside the scope of FDA regulatory jurisdiction. These constraints are relevant to whether the goal of the Proposed Rule is actually achievable, and thus whether potential increases in cost or decreases in supply chain security can be justified.

It is highly questionable that Section 804 products will be available in sufficient quantities to make a meaningful difference to U.S. pricing. The population of Canada is around 37 million, approximately 11% of the population of the United States.[5] The volume of drugs that are being marketed for distribution in Canada could not possibly meet the needs of United States consumers, and manufacturers are unlikely to distribute additional products in quantities that are sufficient to serve the United States as an export market. Moreover, Cardinal Health believes it likely that the Canadian government will act to discourage or even ban the exportation of products intended for distribution in Canada in order to protect the supply of drugs for its own citizens.

It is also likely that some manufacturers will at least consider increasing prices for drugs that are distributed to the Canadian market, in order to negate the price advantage of utilization of their products within the United States when those products were intended for distribution in Canada.

A. Complexity:

Cardinal Health believes that the Proposed Rule establishes a process that makes the drug distribution and tracking system in the United States more complex, less uniform, and ultimately less reliable. We highlight several areas in particular where we see increased complexity that may be unavoidable for the Proposed Rule to achieve its aims of lowering costs without compromising quality.

1. State Specific Importation Requests

The rule limits importation to "Section 804 Importation Programs" (SIPs) as defined by the regulation. There may be multiple sponsors, but at least one sponsor must be a state, territorial authority or other non-federal governmental authority.[6]

FDA puts a lot of emphasis on the fact that states and other non-federal governmental entities will act in a way that protects the interests of the public, noting that "a plan that has at least one sponsor that is a State, tribal, or territorial governmental entity under which pharmacists or wholesalers import drugs would offer enhanced accountability and protect the public health."[7] However, one effect of using SIPs as the focus of importation means that under the Proposed Rule, state specific "SIPs" will become the framework for consumer protection and drug safety, rather than the unified, national framework currently in place to regulate drug manufacturing and distribution. Even though SIPs must be approved by the FDA and importers will be subject to laboratory testing requirements and adherence to the DSCSA, this model could clearly result in individual SIP differences that will complicate the distribution and tracking of drugs.

For instance, if a SIP is intended to lower costs for a specific subset of consumers, will importers be required to track imported products to the point of consumer sales to ensure that the SIP is being carried out? What mechanisms will be required to avoid diversion solely to enable increased profitability of those administering or dispensing drugs?

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[5] *See* United Nations 2018 Demographic Yearbook at p.113. (Available here: https://unstats.un.org/unsd/demographic-social/products/dyb/dybsets/2018.pdf)

[6] Proposed 21 C.F.R. §§ 251.1 and 251.2 (definition of "Section 804 Importation Program" and "Section 804 Importation Program Sponsor").

[7] 84 Fed. Reg. 70801.

Moreover, it is not clear that requiring state sponsorship will result in states assuming close oversight of the importation process. As the FDA notes, SIP Sponsors can divide responsibilities for compliance, which means that the non-governmental co-sponsor could contractually assume responsibility for many if not most of the compliance plan requirements.[8] Cardinal Health assumes that states will in fact delegate compliance for laboratory testing, labeling, repackaging and other operational areas covered in the Proposed Rule to importers or other private entities.

2. Laboratory Testing of Imported Products:

The Proposed Rule establishes a laboratory testing process and requires importers to authenticate imported products.[9] While the Proposed Rule also establishes requirements that limit a SIP to utilizing a single foreign seller (with some exceptions) that purchases directly from the manufacturer, the FDA has no meaningful way to enforce that requirement.[10] Laboratory testing is being used to ensure that drugs imported from Canada are what they purport to be. In Cardinal Health's experience, however, testing the authenticity of products is rarely a straightforward undertaking. Such testing is clearly important where the FDA has no other way of assuring the authenticity of products, but it will create issues of interpretation over the validity of testing results that will complicate assuring the authenticity of products and raise significant delays, obstacles, and costs.

3. Identification, Labeling and Tracking of 804 Products:

The Proposed Rule also creates, essentially, a parallel process for each product that is imported, including the assignment of a new NDC number and a plan for "crosswalking" Canadian labeling information – and relabeling and if required repackaging – so that imported drugs can be seamlessly prescribed and dispensed for U.S. consumers.[11] This process includes designating specific products as Section 804 products so that they can be tracked and differentiated from their U.S. counterparts.[12] Each step in this process introduces additional costs, as well as an opportunity for error and potential risks to consumers.

B. Safety/Security

As a wholesaler, Cardinal Health takes its role in supply chain safety seriously, and has worked with the industry to refine and implement the DSCSA so that U.S. drug distribution is safe and secure.

Cardinal supports the application of supply chain security requirements to foreign sellers and importers, as well as imposing the additional proposed security requirements to account for the fact that the product was originally intended for the Canadian and not the U.S. market. However, the Proposed Rule will invariably increase the complexity of securing the safety of drugs distributed in the U.S.

As noted above, the FDA has no real way to police the supply chain that occurs in Canada. FDA notes itself that it does not possess information needed to trace drug products labeled for the Canadian market back to the original manufacturer, and for that reason has drafted the rule to limit the number of "supply chain" participants to the minimum necessary. The FDA cannot police whether, for instance, the foreign seller buys directly from a manufacturer, and

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[8] 84 Fed. Reg. 70811.

[9] Proposed 21 C.F.R. § 251.16.

[10] *See* 84 Fed. Reg. 70815.

[11] Proposed 21 C.F.R. § 251(c)(4).

[12] Proposed 21 C.F.R. § 251.13.

thus cannot really prevent the use of Canada as a transshipment point for drugs not intended for marketing or distribution in Canada.

In addition, because the FDA has built the process for ensuring authenticity around SIPs, rather than CGMP as it is in the U.S., identical products could be subject to different SIPs and different distribution requirements. Drugs that are for all intents and purposes identical are being subject to testing by different importers and different laboratories. Likewise, they are subject to different SIPs that could potentially require materially different "handling" in order to meet the terms of the SIP. This is antithetical to the efficient distribution of products that Cardinal Health strives to maintain, where products can be shipped expeditiously to where they are needed most, while still maintaining a high level of supply chain security.

C. Cost/Benefit

Cardinal Health agrees that SIPs should be required to demonstrate a reasonable likelihood of savings, and that without the possibility of savings there really is no justification for posing even a minimal elevated risk to the safety and security of the drug distribution system.

The process established by the FDA to guarantee the authenticity of drugs imported into the U.S. and their suitability for prescribing by physicians and dispensing by pharmacies in the U.S. will impose significant costs on importers (in particular) that will likely offset much of any projected savings. Even if importation does not completely offset cost savings, FDA is underestimating the extent to which those savings can be passed on to consumers, given the complexity of the distribution system from the point of manufacture (or importation) to the point of sale to the consumer.

There may be an opportunity for states to capture savings for state administered health care programs such as Medicaid, but Cardinal Health does not see any clear pathway for states, through SIPs, to ensure broad based savings to a significant number of consumers at the point of sale. In any event, a rule that would require the tracking of drugs all the way to the point of sale to guarantee that savings are passed on to individuals would be expensive to administer and highly inefficient.

The Proposed Rule does not address how imported products will be priced for sale in the U.S., for instance, how the wholesale acquisition cost will be established and by whom. The Proposed Rule also sidesteps how imported products might affect existing arrangements between purchasers or health plans and manufacturers of U.S. products, and matters as diverse as "Best Price" and intellectual property rights.[13] We realize that the FDA does not regulate these areas, but they are highly relevant to how drugs are priced and sold to consumers.

The dispensing of a drug to a consumer is one of the last steps in the distribution chain that takes place almost exclusively via agreements between private parties. Existing arrangements between PBMs, distributors, plans, pharmacies, or other purchasers and U.S. manufacturers could limit the extent to which any of these entities can rely on imported products to lower costs without raising costs on products that are purchased from U.S. manufacturers.

In addition, states have no authority to regulate Medicare program benefits (including Part C and D plans) and only limited authority to direct how ERISA plan benefits are administered, or to override reimbursement or other rules that apply to pharmacies or providers who participate in these plans. These barriers make it unlikely that any state will have the means to ensure that savings from imported products are passed on from purchasers to patients.

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[13] *See, e.g.,* 84 Fed. Reg. 70801 ("This notice of proposed rulemaking (NPRM) is not intended to address the applicability of the Medicaid drug rebate program for drugs under a SIP, which may be addressed in further guidance or rulemaking from HHS as appropriate.")

IV. Conclusion

Cardinal Health is skeptical that importation on the scale necessary to meaningfully reduce prices in the U.S. will be able to occur given likely resistance from the government of Canada to exporting drugs intended for distribution in Canada, in order to protect its own citizens.

We are also skeptical that manufacturers will prove willing to sell products intended for distribution in Canada to foreign sellers or provide data and methods to facilitate laboratory testing specifications that are necessary to ensure the safety of imported products.

While Cardinal Health agrees that laboratory testing and other measures to protect safety promulgated in the Proposed Rule are clearly warranted, it is unlikely such measures will duplicate the effectiveness of the U.S. framework for assuring the safety of drugs intended for distribution in the U.S. They will, however, make the distribution process much less efficient.

The costs of assuring the safety and security of drugs imported from Canada are still likely to offset many if not most of any potential cost savings, even as they are unlikely not to meet the same high standard that exists in the U.S.

Finally, Cardinal Health doubts that the costs and complexity of the Proposed Rule will result in savings that will be passed on to consumers, as opposed to purchasers or other entities in the distribution chain.

Sincerely,

Rebecca McGrath

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