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The Honorable Dr. Stephen M. Hahn
Commissioner of Food and Drugs
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993–0002

RE: Proposed Rule: Importation of Prescription Drugs, Dkt. No. FDA-2019-D-5711, [84 Fed. Reg. 70796 (Dec. 23, 2019)]

Dear Commissioner Hahn:

The McKesson Corporation ("McKesson") appreciates the opportunity to provide comments to the Food and Drug Administration (FDA) on the proposed rule "Importation of Prescription Drugs, Dkt. No. FDA-2019-D-5711, 84 Fed. Reg. 70796 (Dec. 23, 2019) (Proposed Rule or Rule).

About McKesson

McKesson is a mission driven company, focused on working with our customers and partners to create a sustainable future for healthcare. Together, we are charting a course to better health – not only in the US but also in Canada and Europe. McKesson is a global leader in healthcare supply chain management solutions, retail pharmacy, healthcare technology, community oncology and specialty care. McKesson partners with pharmaceutical manufacturers, providers, pharmacies, governments and other healthcare organizations to help provide the right medicines, medical products and healthcare services to the right patients at the right time, safely and cost-effectively. Our global footprint provides us a unique perspective on supply chain considerations and impacts to stakeholders and patients across the world.

In the US, McKesson delivers vital medicines, medical supplies, care management services and health information technology (IT) solutions that touch the lives of over 100 million patients in healthcare settings that include more than 50,000 retail pharmacies, 5,000 hospitals, 200,000 physician offices, nearly 12,000 long-term care facilities and 2,400 home care agencies. We are also a leader in pharmacy solutions. Our Health Mart franchise is the fourth largest pharmacy network in the U.S. with more than 5,000 independent pharmacies. Our RelayHealth Pharmacy Solutions manage the nation's most reliable pharmacy connectivity network, executing more than 18 billion pharmacy transactions annually and connecting more than 50,000 retail pharmacies with key healthcare stakeholders. In addition, our CoverMyMeds platform brings solutions, such as electronic prior authorization and real-time benefit tools, to more than 700,000 providers, 96% of pharmacies, more than 500 electronic health record systems and most health plans and pharmacy benefit managers.

In Canada, McKesson is the largest pharmaceutical distributor, delivering ~40% of all medications needed in the country daily. We deliver essential medications to more than 1,350 hospitals and more than 7,100 pharmacies daily across all provinces and territories. Our specialty infusion clinics and pharmacies support nearly 18,000 patients with 114,000 infusions and injectables annually. We own and operate six retail banner franchises and support over 2,300 independent community pharmacies. We are a leader in

pharmacy solutions, and our hospital technologies dispense over 200 million doses annually. We also operate well.ca, Canada's leading online destination for health and wellness products.

In Europe, McKesson supplies more than 50,000 pharmacies and hospitals every day with more than 100,000 pharmaceutical products in ten countries. We are also one of the largest pharmacy operators in Europe, serving more than 2 million customers daily. Through our pharmacies and network of logistic centers, we reach approximately 15 million patients daily.

Our company strives to ensure that our views on better healthcare prioritize what's best for the patient. Our public policy platform is driven by the core belief that the *Patient Comes First. In All Our Communities. Globally.*

General Comments

McKesson shares the Administration's commitment to foster an affordable, accessible heath system that seeks to reduce patient costs. Patients should have access to the medicines and treatments they need to make better health possible for themselves, their families, communities and the health system. We also share the Administration's commitment to ensuring the safety and integrity of the US pharmaceutical supply chain. McKesson is steadfast in its support of the Drug Supply Chain Security Act (DSCSA). We are a committed partner in implementing provisions of the law to improve the security of the pharmaceutical supply chain by reducing counterfeit, stolen, contaminated or otherwise harmful drugs from reaching patients and consumers.

We appreciate the FDA's importation proposal seeks to allow American patients to benefit from lower prices offered in other countries, such as Canada. However, commercial importation of drugs in order to drive lower costs in America may compromise patient access to safe medications, while not guaranteeing lower costs. Additionally, it is well recognized that Canada is not a sustainable source of lower cost drugs to meet the needs of American patients. Unrealistic efforts to support American patients will only compromise patient access in Canada and further disrupt the global marketplace.

McKesson cannot support any proposal, including commercial importation proposals, that:

- Undermine or threaten the safety and integrity of the US pharmaceutical supply chain in any way,
- Undercut the strict safety, quality and regulatory authority of the FDA,
- Do not clearly and transparently guarantee that patients will directly benefit from lower costs at the pharmacy counter,
- Lack operational clarity and sustainability, and
- Unnecessarily compromise patient access to medically necessary drugs and supplies in other countries.

We do not believe the FDA's current importation proposal addresses these concerns. We believe, that as well intentioned as this importation program is, it could create loopholes in the current DSCSA regulatory infrastructure, increasing patient exposure to counterfeit and harmful drugs. We are not alone in these concerns and note they are reflected in comments submitted by entities such as such as the Healthcare Distribution Alliance (HDA) and National Association of Chain Drug Stores (NACDS), whose members would be needed to facilitate the implementation of the proposed commercial importation programs.

Federal law states that the HHS Secretary may only certify commercial importation programs that pose "no additional risk to the public's health and safety [and would] result in a significant reduction in the

cost of covered products to the American consumer.[1]" We do not believe FDA's proposal could meet the threshold requirements of no additional public risk and significant cost savings.

We recommend the FDA and the Administration explore more reasonable measures to drive competition and lower costs. We continue to believe that accelerating FDA approvals, particularly for single source drugs will drive market competition. We continue to see the clinical and cost benefits when providers are incentivized to manage a patient's care holistically through total cost of care models, such as the Oncology Care Model.

DSCSA and Patient Safety Concerns

We cannot ignore the warnings of previous FDA commissioners who have noted time and time again that commercial importation is a "risky approach – one that the evidence shows will not achieve the aim, and that is likely to harm patients and consumers and compromise the carefully constructed system that guards the safety of our nation's medical products."[2] We also cannot ignore the safety and access concerns raised by our current HHS Secretary who recognized the limitations and potential negative consequences of importation just two short years ago:

> *"I want to raise a final point in the context of competition: 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. It has been assessed multiple times by the Congressional Budget Office, and CBO has said it would have no meaningful effect.*
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> *One of the main reasons is that Canada's drug market is simply too small to bring down prices here. They are a lovely neighbor to the north, but they're a small one. Canada simply doesn't have enough drugs to sell them to us for less money, and drug companies won't sell Canada or Europe more just to have them imported here.*
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> *On top of that, the 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."*[3]

As proposed, the FDA importation program risks undermining the DSCSA by decreasing uniformity and increasing the number of entities touching and impacting our distribution system and that attendant risk. A key aim of the DSCSA was to create an interoperable, electronic system for the exchange of data in accordance with widely recognized, international standards and federally mandated, preemptive, uniform national policy for the tracing of pharmaceuticals and the licensure of wholesale distributors[4]. Prior to the DSCSA, states were free to develop their own requirements for trading pharmaceutical and trading partner licensures that varied. This patchwork system created many 'weak' links and left the supply chain vulnerable. Allowing each state to implement its own Section 804 Importation Program (SIP) or multiple SIPs with varying DSCSA compliant business processes will essentially create 50-plus supply chains with varying level of safety controls. The FDA acknowledges in the rule that authorizing multiple foreign

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[1] 21 U.S.C. § 384(l)(1)
[2] https://healthpolicy.duke.edu/sites/default/files/atoms/files/2017_03_16_commissioners_letter_final_signed.pdf
[3] https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-drug-pricing-blueprint.html
[4] See, e.g., § 585, Uniform National Policy

sellers increases the number of entities outside the US impacting our supply chain and makes the supply chain "less transparent and more vulnerable to risk[5]".

The current proposal undermines the significant progress and investments made to bolster the safety and integrity of our supply chain. The FDA should not allow, within this program or others, any exceptions to the current DSCSA requirements. All drugs distributed in the US should meet the same standards. Even proposals to address DSCSA requirements may actually create new problems. For example, relabeling requirements seek to assure traceability and inform patients and other members of the supply chain of the provenance of the product. It will also make it far more difficult to identify suspect product in the U.S. supply chain.

We echo the same concerns of the previous FDA commissioners and caution the FDA against pursuing disruptive changes to the supply chain that may result in increased harm to patients.

Systems Costs and Patient Savings

We question whether the current proposal will result in meaningful savings for American consumers. In the proposed rule, the FDA states that it is unable to estimate the value or savings to consumers because they lack the information about the expected scale or scope of programs. They are also unable to estimate costs that may accrue to the various entities participating in the SIP. Additionally, the FDA recognizes that previous analysis expresses "concerns about public health and safety and the ability to achieve cost savings remain valid"[6]. We are concerned that the FDA will not be able to guarantee that the savings criteria is met per the statutory requirements to authorize commercial importation.

Former FDA Commissioner Dr. Gottlieb stated in March 2016 that, having studied the issue, safe regulation of foreign drugs "would have added so much cost to the imported drugs, they wouldn't be much cheaper than drugs sold inside our closed American system[7]." Though meeting the DSCSA's requirements is difficult and costly, wholesale distributors willingly shoulder their share of the critically important responsibility of supply chain safety and security. HDA estimates that its wholesale distributor members have spent in excess of $500 million, to date, to comply with the DSCSA and begin the migration to interoperable, electronic traceability. This cost is likely to increase over the next few years as progress towards full traceability in 2023 advances. To attempt to transplant these same DSCSA security protections onto unapproved Canadian drugs is costly. Research has recently estimated that the costs of protecting American patients from the risks posed by importation wholly subsume any intended cost savings. It is unclear how the SIP will account for the various expenses accrued across the supply chain for each entity that may have start-up and maintenance costs (i.e. pharmacies maintaining dual inventories).

Any program predicated on generating savings for the American consumer, must clearly outline how such savings are to be accrued, and how they will be conveyed to patients. **Safeguards to ensure patients benefit directly from lower costs at the point of dispensing or administration are critical.** Our healthcare system provides numerous avenues for savings to be absorbed by plans or pharmacy benefit managers, limiting the direct benefit to patients who are currently facing unsustainable out of pocket cost burdens.

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[5] 84 Fed Reg at 70813
[6] 84 Fed Reg at 70800
[7] https://www.forbes.com/sites/scottgottlieb/2016/03/04/why-trump-is-wrong-on-drug-prices/#79721f022e74

McKesson Canada Concerns

The recent COVID-19 outbreak has demonstrated how interconnected and delicate our global pharmaceutical supply chain is. Disruptions in one country can have far reaching impacts across global markets. We cannot compromise the Canadian supply chain or patient access, particularly when the Canadian government has expressed significant concerns about the FDA's importation proposal as it will threaten the country's drug supply[8]. How can a commercial importation program work if there is not sufficient drug supply in the exporting country?

Over the last 115 years, our McKesson Canada business has been dedicated to making better health possible for Canadian patients. This is the same mission we have for our American patients, and those patients we are dedicated to serve globally. We know first hand that the drug capacity in Canada is insufficient to meet the needs of the American market, even for a small-scale narrow state program. Canada is allocated certain quantities of pharmaceuticals, based on estimated national requirements, by manufactures with global supply chains. Canada's hospital and community pharmacies are therefore sourced to serve the Canadian public only. Canada's total population of 38 million is less than that of California.

As the largest pharmaceutical and wholesale distributor in Canada, we have first-hand experience navigating supply challenges as Canadian patients already face persistent drug shortage. While the US FDA drug shortage list reflects approximately ~100 drugs[9] as of this writing, there are about 1950 drugs currently in shortage with another 50 anticipated to be in short supply[10]. McKesson Canada, on average, manages about 65 drug shortages every week, and 2019 was one of the worst years for drug shortages in Canada, plagued by shortages of numerous high-profile cancer drugs (such as tamoxifen).

As the largest network of independent pharmacies in Canada, we also know first-hand the struggle patients face trying to find the medically necessary drugs at our pharmacy counters. We are proud that each and every one of our pharmacists puts patients first. This will not be sustainable if drugs are diverted from Canada to the US. It is clear that the Canadian health system cannot sustain external pressures to its supply chain. Further, Canadian pharmacies and global organizations, such as ASOP Global, are concerned that importation poses safety risks and may increase access to illegal or counterfeit medications.[11]

There are also operational considerations that challenge the feasibility of commercial importation programs from Canada. The proposed rule requires Canadian drug wholesalers to partner with SIPs. Canadian wholesalers, including McKesson Canada, have made it abundantly clear that they have no interest in partnering with SIPs for the export of drugs to the US. Agreements between manufacturers and distributors prevent the export of products made for the Canadian market, creating a commercial risk and deterrent to exporting.

As a company with a footprint in both countries, we recognize that each government has a duty to its own patients. American patients should not rely on Health Canada to assure that drugs used in the US meet the strict safety standards established by our own FDA, and vice versa. Canadian regulatory oversight becomes even more complicated if the FDA allows Canadian pharmacies to participate as SIP partners. Allowing alternative suppliers would shift regulatory oversight from federal to provincial authorities, making it more challenging to monitor and respond to non-compliant behavior.

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[8] https://nationalpost.com/news/pm-pledges-access-to-medication-as-pharmacists-patient-groups-fear-shortage
[9] https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm
[10] https://www.drugshortagescanada.ca/rws-search?perform=1
[11] https://www.regulations.gov/document?D=FDA-2019-N-5711-0927

McKesson, including our McKesson Canada business, discourages the FDA from moving forward with this proposal as presented to date. There are too many concerns for both countries and their patients. At McKesson, we believe we have a global responsibility to manage the supply chain ethically for all patients. Our recent experiences with supply disruptions in the US attendant to COVID-19[12][13] remind us that as global citizens we cannot disrupt supply flow to one customer or country to meet the needs of another. We have to work together to ensure we maintain a safe, and sustainable global supply chain.

Specific Policy Concerns

Should the FDA move forward notwithstanding the reservations articulated here, we have identified specific areas of concern outlined below:

- **DSCSA standards must be maintained and applied consistently to all drugs and all members of the supply chain.** This includes but is not limited to:
    - *All drugs distributed in the US must maintain the same labeling and serialization requirements.* Dispensers should not be exempt from affixing product identifiers to imported products that an importing pharmacist intends to dispense/administer directly to patients. We believe all drugs imported under this rule should be serialized, regardless of the U.S. importer's business status or dispensing intentions. Allowing pharmaceuticals to be transacted, sold, dispensed or otherwise change ownership without a product identifier could potentially make the supply chain vulnerable to suspect and illegitimate products. Serialization will also support other safety/security efforts, such as recall administration.
    - *Waivers to DSCSA requirements should face the same scrutiny as all drugs.* We do not support any further easing of DSCSA requirements for any products that would be imported pursuant to this rule under an approved SIP and caution against use of financial considerations or "undue economic hardship" as a means to circumvent DSCSA compliance.
    - *Identification of an illegitimate product in the SIP program should be grounds for automatic, temporary suspension and potential full revocation of the SIP.* The FDA must provide guidance and penalty to ensure SIPs are held accountable.
    - *Foreign sellers must be compliant with all DSCSA requirements applicable to US wholesalers*. Among them are requirements for notification of illegitimate products, compliance with all applicable federal standards for wholesale licensure once FDA promulgates them, undergoing the same inspections as U.S. wholesale distributors and be held to the same standards during those inspections.

- **Commercial importation cannot move forward without national standards for wholesale distribution licensure and State adoption of those standards.** The DSCSA expressly required FDA to issue "national standards" for the licensure of wholesale distributors by November 27, 2015 that would, in turn, be adopted by State licensing authorities. To date, FDA has not released the standards. It is deeply concerning that the importation of unapproved drugs from Canada

[12] https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-and-cdc-take-action-increase-access-respirators-including-n95s
[13] https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-supply-chain-update

relies upon the State oversight of wholesale distributors and dispensers when a key element of that oversight, mandated by law, has yet to materialize.

- **Minimum standards to protect patients and the supply chain from counterfeit and other dangerous drugs should not be eased in any way.** This includes but is not limited to:
    - *A SIP sponsor should be an entity that can perform the necessary regulatory oversight of the program and the US importer.* It is critical that the sponsor has a line of sight into and influence over the US importer, but also has authority to manage the Foreign Seller if needed.
    - *The SIP sponsor must show that its proposed importation plan will pose no additional risk to the public's health and safety and will result in significant cost savings to the American consumer*. 84 Fed. Reg. at 70802, 70821.
    - *The SIP co-sponsor must be an entity capable of performing and complying with the necessary regulatory oversight related to the distribution or dispensing of eligible drugs and demands of the SIP program.* A SIP sponsor must clearly define the role of the co-sponsor and oversight protocols. Per statute, co-sponsorship should be limited to those entities currently authorized to import drugs (i.e., wholesalers).
    - *Statutory Testing requirements should not be eased in any way*. See proposed 21 C.F.R. § 251.2 (definition of eligible prescription drug as a product that but for the fact that it deviates from the required U.S. labeling, meets the conditions of an FDA-approved drug application) (definition of statutory testing).
    - *SIPs should, as proposed, be limited to drugs that meet the definition of a DSCSA "product" so that they are subject to all DSCSA identification, tracing, and verification requirements once they move in U.S. commerce.* 84 Fed. Reg. 70804.

Conclusion

McKesson appreciates the opportunity to comment on this proposed rule. We are committed to ensuring the safety and integrity of the pharmaceutical supply chain is preserved at all times. We look forward to continuing our partnership with HHS and working with the Administration to promote a robust, patient-centered healthcare ecosystem that works for patients and reduces their financial burden more effectively. If you have questions or need further information, please contact Fauzea Hussain, Vice President of Public Policy, at Fauzea.Hussain@McKesson.com.

Sincerely,

Pete Slone