

VIA ELECTRONIC SUBMISSION

March 9, 2020

Division of Dockets Management (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Importation of Prescription Drugs (Docket No. FDA-2019-N-5711)

The Biotechnology Innovation Organization (“BIO”) would like to submit the following comments regarding FDA’s recent proposal to implement aspects of the Canadian importation provisions of Section 804 of the Food Drug & Cosmetics Act (“FD&C Act”).¹

BIO represents almost 1,000 biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, and environmental biotechnology products, thereby expanding the boundaries of science to benefit humanity by providing better healthcare, enhanced agriculture, and a cleaner and safer environment.

BIO and our members have long-standing concerns with the considerable public health and safety risk, and the purported cost effectiveness, of prescription medicine importation. We recognize that Congress, when enacting section 804 excluded biological products from the definition of “prescription drug” due to their more complex production and safety profiles. Even with this exclusion, however, we believe that implementing this rule will still pose considerable risks to the public health and safety and will not result in a significant reduction in cost of imported prescription drugs to the American consumer.

From a public policy perspective, as discussed more fully below, importation is unlikely to materially impact the ongoing debate over drug pricing. While importation sounds like a convenient and impactful tool in dealing with pricing concerns, in reality it is unlikely to yield any real savings to the American consumer. And, what is more, full implementation is likely to raise more safety concerns than cost savings. Moreover, the substance of the proposed rule is insufficient to meet the effectiveness provisions required by Section 804. As such, BIO respectfully urges FDA to withdraw this rule in recognition of the safety and cost hurdles

¹ 21 U.S.C. § 384.

outlined below. We would be happy to discuss this or any further issues with FDA or HHS at any time.

Importation of Canadian prescription drugs is not the solution to the U.S. drug pricing debate

As a threshold matter, we want to address the policy impetus for proposing this rule in the first place because it sets the stage for all of the regulatory rationale that follows. Specifically, FDA’s proposal to allow importation of certain prescription drugs from Canada is taking place during a significant national debate about the cost of prescription drugs. The Administration has released a slate of potential policy proposals, and both the House and Senate have considered legislation related to the pricing of prescription drugs and the pharmaceutical supply chain.

Unfortunately, this national conversation has become divorced from what the data actually show: that national spending on prescription drugs has been characterized by low, single-digit growth for most of the last decade.² In fact, real per capita spending on prescription drugs grew only \$44 from 2009 to 2018, despite the introduction of hundreds of new medicines – including cell and gene therapies, and curative therapies for Hepatitis C.³ The largest pharmacy benefit managers have all reported stable – or even negative – drug spending growth.⁴ And the Centers for Medicare & Medicaid Services recently reported that while spending on retail prescription drugs grew by 2.5% in 2018, this growth was due to “non-price” factors (e.g. utilization) – the prices of these medicines declined by 1% “reflecting a decline in generic drug prices and slower and relatively low growth in prices for brand-name drugs.”⁵

The concern around “prescription drug prices,” then, is less about prescription drug spending in the *aggregate*. To the extent that patients with health coverage face a “price” for a medicine, it is the cost-sharing imposed on that medicine by their health plan. Over the last decade patients have seen cost-sharing for all services soar, as health plans strive to keep premiums low. The average deductible for single coverage through an employer-sponsored plan now stands at \$1,655, more than double the average just a decade ago.⁶ Beneficiaries enrolled in stand-alone Medicare Part D plans face no limit on their out-of-pocket expenses for prescription medicines. And the pharmaceutical supply chain’s reliance on rebates significantly distorts

² Exhibit 15, “Medicine Use and Spending in the U.S.,” IQVIA. May 2019.

³ *Id.*

⁴ In their most recent trend reports for 2018, CVS Health reported prescription drug trend of 1.7% among their commercial clients, while Express Scripts reported trend of 2.1%. Prime Therapeutics reported a negative trend of 0.5%.

⁵ Hartman, Martin, Benson, et. al., “National Health Care Spending in 2018: Growth Driven By Accelerations in Medicare And Private Insurance Spending,” *Health Affairs*. January 2020.

⁶ 2019 Employer Health Benefits Survey, KFF. September 2019.

market incentives, as some commercial health plans and some government programs have come to favor higher list price drugs with greater rebates, with serious consequences for patients taking these medicines.⁷

These underlying issues would not be addressed by the importation of prescription drugs from Canada. In fact, coupled with the safety issues that can arise with new and separate system for drug delivery, Canadian imported drugs that are compliant with the obligations set forth in this rule may well be far more expensive for an American consumer than FDA-approved drugs obtained through insurance.

Implementation of Section 804 requires Secretarial certification

Turning to the regulations themselves, we are concerned that the proposed rule runs afoul of the basic commands of the statute involving the Secretary’s required certifications of no additional safety risks and significant cost savings to the consumer. Specifically, as set forth in the summary of the rule – and memorialized throughout – the rule “when finalized, would contain all requirements necessary for a State ... to demonstrate that their importation program will pose no additional risk to the public’s health and safety.” And further that the final rule will “require that the State ... explain why their program would be expected to result in a significant reduction in the cost of covered products to the American consumer.”⁸ The statute, however, does not operate this way.

Instead, Section 804(l) states explicitly that this “Section shall become effective only if the Secretary certifies to Congress that the implementation of this Section...” shall result in achieving both the required safety and cost savings.⁹ This certification, therefore, is not predicated on any plan submitted following rulemaking, but rather, on the Secretary’s own initial certification that *any* plan to implement Section 804 will result in both a safe system and significant cost savings. In other words, in our view, the Secretary must certify to a pattern and practice that, when implemented as outlined, *will necessarily* result in both a “significant reduction in the cost of covered products to the American consumer” and “pose no additional risk to the public’s health and safety.”¹⁰ The Secretary has not done this, nor does the proposed rule attempt to do so.

Further, Section 804 does not provide for delegation of the Secretary’s duties to the States or other non-federal governmental entities. Congress conditioned the force of section 804 on a

⁷ A recent analysis of claims data for enrollees across market segments found that Part D plans often preferred branded versions of treatments for Hepatitis C, despite the availability of lower-priced authorized generics (See “Why Part D Plans Prefer High List Price Drugs That Raise Costs for Seniors,” Drug Channels. January 2020).

⁸ 84 Fed. Reg. 70796 (December 23, 2019).

⁹ See 21 U.S.C. § 384(l).

¹⁰ *Id.*

determination to be made by the HHS Secretary. It is contrary to congressional intent for the HHS Secretary to subdelegate its duties to make the predicate factual determination to the States and other non-federal governmental entities when section 804(l) requires the executive branch to make that determination. If Congress had wanted the HHS Secretary to enter into third-party arrangements to implement section 804, it could have explicitly done so. Elsewhere in the FD&C Act, Congress has expressly provided for the HHS Secretary to enter into arrangements with the States to perform activities typically performed by FDA.¹¹ In stark contrast, states are not mentioned once in section 804. From a policy and practical perspective, this makes sense. Importation of goods from a foreign nation is primarily a federal function, which is why the HHS Secretary is required to consult with the heads of other federal entities (the U.S. Trade Representative and the Commissioner of Customs), prior to promulgating regulations implementing section 804. Section 804, as envisioned by Congress, is a federal program, and the HHS Secretary cannot delegate its core functions, including making the requisite safety and cost findings, to the States.

Moreover, Section 804 does not authorize partial certification. As the government itself has explained:

There is no language in section [804(l)] that authorizes or contemplates any waiver, partial certification, experiment, or other temporary, limited, or short-term program for importing prescription drugs from Canada; section [804(l)] is an explicit “all-or-nothing” provision that allows the Secretary to certify only whether the law is effective for all Americans, not just those in one particular state or county.¹²

The certification described in the proposed rule would apply to temporary, limited, short-term programs authorized by FDA, namely Section 804 Importation Programs (SIPs). In other words, implementation of section 804 will not result in a significant reduction for all Americans, just those in particular states. This partial certification would be inconsistent with section 804(l).

Additionally, even with this delegated approach, the draft rule explicitly recognizes that a submitted SIP might not attain the rigorous safety standards and/or result in the significant cost savings by outlining how a review process for a SIP will occur and discussing – although extremely vaguely – how HHS will assess a plan for cost savings and may reject a proposal on either or both grounds.¹³ More to the point, the proposed rule does not provide the required

¹¹ See, e.g., 21 U.S.C. § 360jj(1)(F) (authorizing “the Secretary to enter into arrangements with individual States or groups of States to define their respective functions and responsibilities to define their respective functions and responsibilities for the control of electronic product radiation and other ionizing radiation”).

¹² Gov’t Br., *Montgomery County v. Leavitt*, 2006 WL 1451757 at 11–12 (Apr. 26, 2006).

¹³ See 84 Fed. Reg. at 70802 (“FDA may nonetheless decide, in its discretion, not to authorize a SIP Proposal ... because of potential safety concerns ... [or] because of the relative likelihood the program would not result in significant enough cost savings.”)

safety and savings determinations and acknowledges that it will have to wait and see proposals in order to make those determinations.¹⁴

The statute, however, does not permit this *post hoc* appraisal. Instead, following the certifications, any resulting rulemaking should act to memorialize precisely how an entity will achieve the objectives of the statute -- basically setting forth a checklist that, if followed, will result in the satisfaction of both prongs of the statute. The proposed rule does not do this and, to the cost savings specifically, really pushes this question to a later analysis that would follow both a final rule and a SIP submission. This is why, as discussed more fully below, FDA's rulemaking authority, in our view, is really limited to the "safety" prong of the analysis unless reimbursement and coverage issues from the broader HHS contribute to a final analysis.

To that point, the proposed rule seeks to implement section 804 in a manner that lacks the factual basis and finding that section 804 implementation "will . . . result in a significant reduction in the cost of covered products to the American consumer" as required by section 804(l). FDA states "[a]s we lack information about the expected scale or scope of such programs, we are unable to estimate how they may affect U.S. markets for prescription drugs. In particular, we are unable to estimate the volume or value of drugs that may be imported under the Section 804 Importation Programs (SIPs) or the savings to U.S. consumers who may participate in such programs."¹⁵ A table that is supposed to summarize the costs and benefits of the proposed rule is left blank.¹⁶ FDA states that it lacks information to "estimate the present and annualized values of the costs and cost savings of the proposed rule over an infinite time horizon."¹⁷

The proposed rule also lacks the factual basis and finding necessary for the HHS Secretary to certify that section 804 implementation will "pose no additional risk to the public's health and safety." FDA indicates that it cannot show that implementation of section 804 in its entirety will not pose additional risk to the American consumer because of the significant safety risks associated with personal importation.¹⁸ It acknowledges that "[m]edications that are purchased online and imported through international mail, express couriers, and other means pose significant challenges for FDA and its ability to adequately safeguard the quality and safety of drugs taken by U.S. consumers."¹⁹ The "sophisticated criminal networks that knowingly and unlawfully cause the importation of adulterated, counterfeit, misbranded, and unapproved drugs into the United States" will use their "sophisticated technologies" to profit from commercial

¹⁴ In fact, the rule acknowledges itself that cost savings are not obvious at this point and that FDA currently lacks the information to even estimate savings. *See* 84 Fed. Reg. at 70798 ("

¹⁵ 84 Fed. Reg. 70796, 70798 (Dec. 23, 2019).

¹⁶ *Id.* at 70823.

¹⁷ *Id.* at 70823.

¹⁸ *Id.* at 70800.

¹⁹ *Id.*

importation of illegal drugs at the expense of American patients, just as they have for personal importation.²⁰ Excluding section 804(j) from the certification—which is another aspect of partial certification not permitted by section 804(l)—will not deter enterprising entities from distributing counterfeit drugs to the detriment of the American consumer.

For years, the closed US regulatory system has ensured the safety of the drug supply

Throughout the debate on drug importation, our first priority must be to maintain the protection of the U.S. drug supply in the interest of ensuring patient safety for all prescribed medicines. Under the FD&C Act, all drugs and biologics marketed in the United States must be approved by FDA based on demonstrated safety and efficacy. This “closed” regulatory system, which prohibits the distribution in the U.S. of drugs not approved by FDA (even if they have been approved by an ex-U.S. regulatory authority), is the reason that the U.S. has the safest drug supply in the world.

Importing non-FDA approved medicines from Canada and other countries, regardless of venue or import rules governing transport, invariably opens the U.S. drug supply chain and weakens our ability to provide safe drugs to patients. Canada imports 80% of its prescription medicines from other countries²¹, and while its regulators rightfully oversee the safety of the supply of medicines that are intended for and used by Canadians, they do not apply those standards to drugs intended only for export.

The overall quality of drug products in the United States is very high. However, recent episodes of contaminated foreign products that have entered the U.S. market illegally serve as a reminder that we need to remain vigilant in our efforts to ensure the safety, efficacy, purity, and potency of prescription drugs and biologics.

Regardless of the safeguards put in place for SIP operation, the fact remains that implementing a dual system of drug delivery in the United States injects uncertainty into the supply chain.

What is more, FDA has stated on multiple occasions that importation of products that have not been demonstrated to meet U.S. safety requirements would pose serious potential risk to consumers.²² Independent studies by the Department of Health and Human Services Task Force

²⁰ *Id.*

²¹ CRS Memorandum, *Drug Regulation in Canada* (January 24, 2017)

²² Imported Drugs Raise Safety Concerns (May 2016) <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143561.htm>

on Drug Importation²³ and the U.S. Department of Commerce have concluded that importing prescription drugs from foreign countries poses safety risks to American consumers and does not result in cost savings.

Given the illusory cost savings inherent in this program to begin with, we fail to see how this proposal's benefits outweigh its risks, particularly when programmatic costs are brought into consideration. For instance, Vermont's Agency of Human Services (VAHS) released a report²⁴ in response to that state's importation law acknowledging that any savings from importation would be minimal and that a compliant drug importation program would require substantial upfront investment and appropriations as well as inspection and auditing activities²⁵ -- none of which would ultimately serve the ultimate well-being of patients. The draft proposed rule at issue, to be sure, contains additional practical and technical considerations that will only add to the costs of any of these independent programs. Given the high bar set by the statute in demonstrating "significant reduction in the cost of covered products to the American consumer," it is increasingly difficult to reconcile how this program can be both demonstrate safety commensurate with the current US standard and save money.²⁶

Moreover, the complications presented by the supply chain security only add to this uncertainty surrounding safety and cost savings. In 2013, Congress passed the bipartisan Drug Quality and Security Act (DQSA)²⁷ to enhance the safety of the U.S. drug supply. Title II of DQSA (the Drug Supply Chain Security Act, DSCSA) created a national tracking system to secure the drug supply and protect patients from compromised or counterfeit drug products. DSCSA created a national system to track drug products from the manufacturer to the pharmacy. The roll-out, as FDA is well aware, has been phased to ensure robust compliance and minimize market disruption. The final provisions of the law, in fact, are yet to be finalized; the proposed rule ignores that DSCSA is in an implementation phase, and that certain provisions will sunset in 2023 when a second phase of statutory implementation will arrive.²⁸ Instead, the proposed rule implies that the "electronic, interoperable system" is already in place.²⁹ Even to the extent that FDA's description of the sophistication of the U.S. drug supply chain is correct, imported products would move through entities, like Foreign Sellers, that have not been subject to DSCSA

²³ Report on Prescription Drug Importation (December 2004). See: <http://archive.hhs.gov/importtaskforce/Report1220.pdf>

²⁴ <https://legislature.vermont.gov/assets/Legislative-Reports/AHS-12-31-2018-Wholesale-Importation-of-Drugs.pdf>

²⁵ Vermont Report Finds that the Costs of Prescription Drug Importation May Outweigh Savings <http://www.fdalawblog.net/2019/01/vermont-report-finds-that-the-costs-of-prescription-drug-importation-may-outweigh-savings/>

²⁶ 21 U.S.C. § 384(1)(1)(B).

²⁷ H.R. 3204 Drug Quality and Security Act <https://www.congress.gov/bill/113th-congress/house-bill/3204>

²⁸ See FDCA § 582(g).

²⁹ 84 Fed. Reg. at 70804.

requirements, and as mentioned above, SIP Sponsors with no role in the DSCSA would be ensuring compliance.

Shoehorning a modified requirement on top of the not-yet-final DQSA is asking for problems. The entire supply chain will need to re-focus efforts to ensure product tracing and troubleshooting can be assessed on this dual track. Issues like wholesaler chargebacks will need additional auditability to confirm product origin and compliance. Manufacturer adverse event reporting will require adjustment and long-term liability issues will be thrown into question. Again, all aspects of this reformulation of supply chain obligations will require investment – a fact FDA acknowledges in the rule, but which adds another element of analysis in the cost savings component required for statutory compliance.³⁰

US drug reimbursement must be considered

While outside the immediate scope of FDA’s regulatory authority, this proposal to disrupt the established supply chain for prescription medicines in the US is also likely to result in a myriad of reimbursement issues. BIO believes it is important to provide HHS with feedback on reimbursement since the proposal for importation is predicated on the idea of providing less expensive medicines to patients. Absent a fulsome regulatory analysis of reimbursement implications associated with Canadian importation, there appears to be no legal pathway forward under Section 804.

Specifically, the market for Federal and state reimbursement of prescription medicines is regulated by a host of laws and policies, varying significantly depending upon the government payor at issue (e.g. Medicare, Medicaid) Each system has requirements for selling through and being reimbursed by that individual program. This proposal does not consider the reimbursement implications of importation and does not assess at all whether cost savings would be achieved at the individual patient level.

For instance, the Medicaid program generally requires a manufacturer enter into a rebate agreement with HHS on behalf of the individually administered state programs.³¹ In exchange for access by Medicaid recipients to a manufacturer’s covered products, the manufacturer agrees to pay the program a statutory rebate on each prescription.³² Under the proposed SIPs outlined in the rule, assuming any individual sponsor wants to make imported product available to

³⁰ See, e.g., 84 Fed. Reg. at 70798 (“Costs of the proposed rule may accrue to the Federal Government, SIP Sponsors, importers, and manufacturers of imported drugs.”) We would also note that costs associated with re-labeling and/or updating labeling for compliant sale in the US, per the proposed rule, would add additional costs to the system in place. This will only compound the cost pressures inherent in the regulatory and statutory analysis discussed throughout this comment letter.

³¹ See 42 U.S.C. § 1396r-8(a)(1).

³² *Id.*

Medicaid recipients, then questions about savings versus traditional rebated drugs are relevant. Since the imported drugs are not approved by FDA, they are in a grey area regarding the rebate statute, but their cost to the end consumer nevertheless matters.

Medicaid is not the only federal program possibly implicated by the rule. It must be foreseeable that any individual SIP may involve Medicare beneficiaries, those in the VA, or any other of the number of private commercial insurance policies throughout the United States. The payment side matters as well. We believe this requires consideration of ancillary government reimbursement and coverage programs, like the 340B program, and their impact on a SIP's operation; all of this must be evaluated and presented for public comment. And this is only after a full analysis of the impact on actual costs savings is completed.

Turning back to the statute, the reimbursement aspects of this proposal require additional consideration. Specifically, there is significant discussion throughout the proposed rule that marginally attributes the proposed importation scheme to the cost savings requirements of the statute. But the majority of this discussion obfuscates the reality of drug delivery and pricing in the United States – focusing on comparing “acquisition cost per unit of the [imported] drug to the acquisition cost per unit of the FDA-approved drug.”³³ This ignores the practical reality that most patients are not paying acquisition cost at the pharmacy, most have out-of-pocket costs associated with their insurance - be it coinsurance or copayments. For the statutory cost savings analysis, this patient out of pocket cost matters.

The statute does not mandate a showing of cost savings to the “system” as a whole. Rather, the statute requires the Secretary to certify that an imported medicine program will “result in a significant reduction in the cost of covered products to the American consumer.”³⁴ It matters not, per the statute, that the imported product costs less to *someone*, nor does it matter that an aggregate purchase by an entity might lower costs for insurance and/or other system variables. The imported medicines must be cheaper for a patient at the pharmacy (or pharmacy stand-in depending on the program). That the majority of Americans have insurance must become a statistical factor in any cost savings analysis. The relevant analysis must be the out of pocket savings to the consumer; for those consumers with insurance, that means the difference in what they must pay as a copayment or coinsurance for the covered product versus what they would pay out-of-pocket for the imported product. The savings to the insurer, the PBM, or the pharmacy may not benefit consumers and is incidental to the statute until it does directly reduce costs. Thus far, the proposed rule ignores this reality. In fact, the proposed rule does not even mention insurance or other similar terms.

The topic of savings on covered products is complicated; one must assess the overall impact any given SIP may or may not have on the costs to the individual patients enrolled. The statute cannot be read to allow for this analysis after the fact. Instead, any proposal should assess

³³ 84 Fed. Reg. at 70807.

³⁴ 21 U.S.C. § 384(l)(1)(B)(emphasis added).

at the outset how a SIP program must be structured, how insurance issues and reimbursement hurdles must be addressed, and how patients will actually experience savings – including, as the circumstances merit, how an insured patient will tangibly benefit at the pharmacy counter. To date, this analysis is missing, and, as such, we urge FDA to withdraw this proposed rule in light of the concerns over safety and the lack of analysis on cost savings. No program, in our view, can operate lawfully until the required Secretarial certification is made. And, after considering all of the points made by FDA in the proposed rule, whether this could ever occur is of serious question.

Regards,



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