



March 6, 2020

Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

RE: Docket No. FDA-2019-N-5711, "Importation of Prescription Drugs"

Introduction

On behalf of National Taxpayers Union (NTU), I write in response to the Food and Drug Administration (FDA)'s Proposed Rule, "Importation of Prescription Drugs." Although NTU shares the FDA's goal of lowering prices and reducing out of pocket costs for American patients, we urge the FDA to withdraw the Proposed Rule. The FDA (or "the Administration") has not clearly defined the potential benefits of importation to patients and taxpayers, nor has it provided an explicit estimate of the potential costs to taxpayers at the federal and non-federal levels. NTU is also concerned with the Administration's willingness to import drugs at artificially controlled prices. The Council of Economic Advisers (CEA) recently issued a report that acknowledged these foreign price controls enable "products to be sold below fair market value" while "Americans [pick] up the tab for making their availability feasible in the first place."¹ We believe that drug importation will neither meaningfully reduce prices paid by U.S. patients nor reduce the prevalence of foreign price controls, and urge the Administration to consider alternative proposals we will outline below.

NTU's Stake in Prescription Drug Policy

NTU is the nation's oldest taxpayer advocacy organization, and our advocates and experts have been stakeholders in prescription drug policy for decades. Policymakers in Washington, D.C. and in the states exercise significant leverage over whether a drug is approved or not, how it may be marketed, and (in the case of Medicare and Medicaid) how that approved and marketed drug is priced. While we seek limited government interference in the development, approval, marketing, and pricing of prescription drugs, NTU also acknowledges that the generic drug competition ushered in by the Hatch-Waxman law has made the United States the only country in the world that:

¹ The Council of Economic Advisers. (February 2020). "Funding the Global Benefits to Biopharmaceutical Innovation." Retrieved from: https://www.whitehouse.gov/wp-content/uploads/2020/02/Funding-the-Global-Benefits-to-Biopharmaceutical-Innovation.pdf?mod=article_inline

“...can boast of such a successful policy environment that both encourages discoveries to reach patients (nearly 90 percent of newly launched drugs worldwide are available here) and controls costs (over 90 percent of prescriptions written in the U.S. are for generics).”²

To that end, we work actively with Congress, federal agencies, and state capitals to craft pro-taxpayer, pro-consumer, and market-oriented prescription drug policy.³ However, NTU believes that allowing for prescription drug importation from Canada meets none of these criteria, and we will outline why below.

NTU Believes the FDA Should Withdraw the Proposed Rule

There are three primary reasons we believe the FDA should withdraw this proposed rule, rather than simply revise it or pause their efforts:

1. The Administration has failed to define the potential benefits of importation to both patients and taxpayers, and robust analysis from independent sources suggest that federal savings from allowing prescription drug importation from Canada would be negligible.
2. The Administration has failed to adequately estimate the potential costs of importation to both federal and state taxpayers. The FDA acknowledges that it will assume both upfront, one-time costs for setting up an importation regime, and additional costs for each Section 804 Importation Program (SIP) Proposal it receives and approves. The Administration also acknowledges that SIP Proposal sponsors, which will include states, will assume set-up and reporting costs. However, the FDA does not provide any estimate of these costs to federal and state taxpayers, making it impossible to conduct a cost-benefit analysis of the Proposed Rule.
3. The Administration’s proposal to allow the importation of prescription drugs from Canada, where the government plays a significant role in setting drug prices, will not reduce the global utilization of price controls, as recommended by the White House Council of Economic Advisers (CEA) in a report published in February 2020, “Funding the Global Benefits to Biopharmaceutical Innovation.” The CEA concludes that “[r]educing foreign price controls would increase profits and innovation, thereby leading to greater competition and lower prices for U.S. patients.”⁴ Allowing for importation of drugs from Canada will neither significantly reduce prices paid by U.S. patients nor effectively combat foreign price controls, and the Administration should instead consider a number of alternatives.

² Sepp, Pete. “Hatch-Waxman Drug Patent Law Meets Middle Age – and Taxpayers Can Celebrate.” National Taxpayers Union, April 1, 2019. Retrieved from:

<https://www.ntu.org/publications/detail/hatch-waxman-drug-patent-law-meets-middle-age-and-taxpayers-can-celebrate>

³ See: Sepp, Pete, “Prescription Drug Costs: Better Ways to Help Patients and Taxpayers.” National Taxpayers Union, December 6, 2018. Retrieved from: <https://www.ntu.org/publications/detail/prescription-drug-costs-better-ways-to-help-patients-and-taxpayers>; and Lautz, Andrew, “Pro-Taxpayer Ways to Increase the Availability and Use of Biosimilars.” National Taxpayers Union, September 16, 2019. Retrieved from: <https://www.ntu.org/publications/detail/pro-taxpayer-ways-to-increase-the-availability-and-use-of-biosimilars>

⁴ The Council of Economic Advisers. (February 2020). “Funding the Global Benefits to Biopharmaceutical Innovation.” Retrieved from:

https://www.whitehouse.gov/wp-content/uploads/2020/02/Funding-the-Global-Benefits-to-Biopharmaceutical-Innovation.pdf?mod=article_inline

Since the FDA determined the Proposed Rule is “a significant regulatory action as defined by Executive Order 12866,” the Administration conducted a preliminary economic analysis of the Proposed Rule’s impacts.⁵ Unfortunately, the analysis lacks almost any specifics on the potential benefits of the Proposed Rule to patients and taxpayers.

For example:

- The FDA states SIPs “may result in cost savings for U.S. consumers,” but adds “[w]e are unable to estimate the cost savings from this proposed rule, as we lack information about the likely size and scope of SIP programs, the specific drug products that may become eligible for importation, the degree to which imported drugs would be less expensive than non-imported drugs available in the U.S., and which SIP eligible products are produced by U.S. drug manufacturers.”⁶ NTU is concerned the Administration went forward with the Proposed Rule given how little information it appears to have on the size, scale, and scope of future SIPs.
- The FDA acknowledges that “importers and private intermediaries would face costs to implement SIPs and use markups to cover these costs and profit. Existing prices may provide a limited basis for forecasting savings to consumers without information on the likely markups applied at each stage in the supply chain.”⁷ However, because the Administration did not conduct a detailed supply chain analysis, it is unclear how markups and supply chain costs would impact the potential savings to consumers and taxpayers.
- The FDA deserves credit for considering several factors that could influence the potential (but undefined) benefits of the Proposed Rule. However, it is troubling that the Administration acknowledges, when considering the Canadian drug supply and the potential Canadian regulatory response to SIPs, that “there is question as to whether this proposed rule could yield non-zero benefits.”⁸

The Administration also fails to recognize that prior work from CBO suggests “[p]ermitting importation only from Canada would produce a negligible reduction in drug spending.”⁹ In the same report, CBO claimed that allowing importation “from a broad set of industrialized countries” would “reduce total drug spending by \$40 billion over 10 years,” or just one percent. Though this report is dated, a more recent CBO report from 2017 (which the FDA references in its analysis) tried to estimate the savings from a Senate bill (S. 469) that would allow for importation from several countries. CBO estimated the bill would reduce deficits by just \$6.8 billion over 10 years.¹⁰ While reductions in deficits are not the same as reductions in drug spending, the relatively paltry deficit savings of an expansive S. 469 leads NTU to believe the savings from the Proposed Rule would be extremely minimal (if, indeed, the Proposed Rule even produces savings).

⁵ FDA Office of Economics and Analysis; FDA Office of Policy, Legislation, and International Affairs; and FDA Office of the Commissioner. (December 23, 2019). “Importation of Prescription Drugs.” Retrieved from: <https://www.fda.gov/media/133553/download> (Accessed February 14, 2020.)

⁶ *Ibid.*

⁷ *Ibid.*

⁸ *Ibid.*

⁹ Baker, Colin. “Would Prescription Drug Importation Reduce U.S. Drug Spending?” Congressional Budget Office, April 29, 2004. Retrieved from: <https://www.cbo.gov/sites/default/files/108th-congress-2003-2004/reports/04-29-prescriptiondrugs.pdf>

¹⁰ Congressional Budget Office (July 31, 2017). “PRELIMINARY ESTIMATE - S. 469, the Affordable and Safe Prescription Drug Importation Act (as introduced).” Retrieved from: <https://www.cbo.gov/system/files/115th-congress-2017-2018/costestimate/s469preliminary.pdf>

The FDA Has Failed to Estimate the Potential Costs of Drug Importation

In its economic analysis of the Proposed Rule, the Administration lays out expected costs of importation for a variety of stakeholders, including the federal government, SIP sponsors, and drug manufacturers. The FDA notes in part:

“The Federal Government would incur one-time fixed costs as well as ongoing costs to implement the rule, if finalized, and to review SIP Proposals and reports. SIP Sponsors would face costs to prepare proposals, implement approved SIPs, and produce SIP reports and records.”

However, the FDA makes no attempt to estimate the costs the federal government will incur in setting up an importation regime. While there are certainly dynamic costs to the Proposed Rule, depending in part on how many SIP Proposals the FDA receives and approves, the Administration could have at least made a good-faith estimate of the one-time, fixed costs the federal government will incur if the Proposed Rule takes effect. The Administration could have also offered a sample cost to federal and state taxpayers if a state government sponsors an importation regime, with the necessary caveat that costs will vary from state to state for a number of reasons.

While the FDA did a thorough job of anticipating the types of costs that federal and state governments may incur under the Proposed Rule (pre-importation set-up, proposal management and review, and import compliance, monitoring, and enforcement for the federal government; set-up costs, extension and annual reporting, consumer education, and legislative costs for state governments), they give stakeholders no working estimate of whether those costs are in the millions of dollars, nor tens of millions, hundreds of millions, billions, and beyond. Given the minimal savings that CBO expects taxpayers to reap from allowing importation from Canada, it is critical to know if prescription drug importation may, in fact, cost taxpayers more than it saves.

This is especially relevant given the Canadian government’s resistance to drug importation proposals from the U.S. federal government and state governments. *The Hill* reported in December 2019:

“But it’s not clear if the U.S. will find a willing partner in Canada, whose support of drug importation would be crucial for the proposal to take off. ‘It is important to recognize that Canada’s market for pharmaceuticals is too small to have any real impact on U.S. drug prices,’ Canada’s acting Ambassador to the U.S. Kirsten Hillman said in a statement following her meeting earlier this month with Joe Grogan, Trump’s domestic policy chief. ‘Canada’s priority is to ensure a steady and solid supply of medications at affordable prices for Canadians,’ she added.”¹¹

This resistance extends to Canadian drug suppliers. From a December 2019 *Reuters* report:

“Many of Canada’s drug suppliers cannot, or will not, agree to ship cheaper prescription medicines into the United States, a new challenge to the Trump administration’s push to reduce drug prices, companies and industry officials told Reuters. ... Two drug distributors and two Canadian industry groups that

¹¹ Hellmann, Jessie. “Trump’s drug importation plan faces resistance in US, Canada.” *The Hill*, December 1, 2019. Retrieved from: <https://thehill.com/policy/healthcare/471963-trumps-drug-importation-plan-faces-resistance-in-us-canada> (Accessed February 19, 2020.)

between them represent all of the potential suppliers named in a proposal published by Florida in August said they are not interested in participating.”¹²

Regardless of one’s position on the Proposed Rule, stakeholders across the spectrum would agree that one of the worst results of an importation regime would be if governments spent millions or billions of taxpayer dollars to set up and monitor importation programs, only to have Canadian stakeholders block or resist participation.

There Are Less Costly Ways to Achieve the CEA’s Goal of Reducing Foreign Price Controls

In February 2020, the White House Council of Economic Advisers (CEA) released a report titled, “Funding the Global Benefits to Biopharmaceutical Innovation.”¹³ In the report, the CEA finds:

“...that foreign ‘free-riding’ on U.S. investments and innovation in drug development has increased over the past 15 years. The prices of many high sales volume pharmaceutical drugs in European countries have decreased from costing on average 51 percent of U.S. prices in 2003 to about 32 percent of U.S. prices in 2017. Many other developed nations with monopoly government insurance plans can push prices down below the value of the treatment as reflected by U.S. prices paid by private insurers in a free market.”¹⁴

The CEA also considers Canadian drug prices at length in its report, noting first and foremost that only a portion of the 200 top-selling drugs available in the U.S. are also available in Canada:

“The first thing to note is that according to the IQVIA-MIDAS data, many of the 200 top-selling drugs examined here show no quantities sold in the countries of comparison, suggesting that those drugs are not available for sale in that country. For example, in Australia, only 97 of the 200 drugs show evidence of significant sales. Similarly, Canada has only 120 of the drugs, France 109, and Germany 133. The absence of significant sales volume for these drug products might be the result of delayed regulatory approval, a decision by a public insurance program not to cover a drug based on health technology assessment criteria, or other factors.”¹⁵

The CEA goes on to state that if Canada paid drug prices consistent with their GDP per capita, relative to the prices Americans pay, “total revenues for innovative drugs in Canada would have been \$27.2 billion instead of the actual \$12.2 billion.”¹⁶

The CEA concludes, “[r]educing foreign price controls would increase profits and innovation, thereby leading to greater competition and lower prices for U.S. patients.”¹⁷

¹² Martell, Allison. “Canadian drug distributors say no to Trump import plan.” *Reuters*, December 20, 2019. Retrieved from: <https://www.reuters.com/article/us-usa-healthcare-canada/canadian-drug-distributors-say-no-to-trump-import-plan-idUSKBN1YO24O> (Accessed February 19, 2020.)

¹³ The Council of Economic Advisers. (February 2020). “Funding the Global Benefits to Biopharmaceutical Innovation.” Retrieved from: https://www.whitehouse.gov/wp-content/uploads/2020/02/Funding-the-Global-Benefits-to-Biopharmaceutical-Innovation.pdf?mod=article_inline

¹⁴ *Ibid.*

¹⁵ *Ibid.*

¹⁶ *Ibid.*

¹⁷ *Ibid.*

While NTU agrees with the conclusions reached by the CEA in its report, we do not believe that allowing prescription drug importation from Canada would meaningfully reduce prices for U.S. patients or reduce the prevalence of foreign price controls in Canada.

Importantly, the CEA does not place the blame for high U.S. drug prices on American taxpayers, patients, or pharmaceutical companies. The Council explicitly states that foreign government price controls have led to drugs being sold for “below the value they generate” in those countries, leaving Americans to foot the bill for those innovations.

The FDA should follow the CEA’s guidance to reduce foreign price controls, and NTU has endorsed several policies (outlined below) that would help lower drug costs for patients and taxpayers without utilizing heavy-handed government tactics that only create scarcity and deadweight costs to society.

If FDA Does Not Withdraw the Proposed Rule, FDA Should Significantly Revise the Proposed Rule

Absent a withdrawal, NTU’s only preferred course of action with this Proposed Rule, FDA should significantly revise the rule and limit its scope. We respond below to several requests for comment from the Administration.

- *The FDA should remove or significantly limit the co-sponsorship provisions of the Proposed Rule.* The FDA seeks comment on its co-sponsorship approach. NTU believes the FDA should remove the co-sponsorship provisions of the Proposed Rule, or otherwise significantly limit the ability for pharmacists, wholesalers, and non-governmental entities to co-sponsor SIP Proposals. The FDA acknowledges the potential conflicts of interest in allowing pharmacists and wholesalers to co-sponsor SIP Proposals by seeking comment on “whether there are certain arrangements that should not be permitted,” for example, “whether [or not] a pharmacist or wholesaler should be able to be both a SIP co-sponsor and an Importer within the same SIP.” This is an inherent conflict of interest, and demonstrates the potential for importation programs to be abused by non-patient stakeholders who stand to gain financially from importation regimes.
- *The FDA should not allow group purchasing organizations, PBMs, or union health and welfare benefit plans to co-sponsor SIPs.* The FDA seeks comment on whether non-governmental entities other than pharmacists and wholesalers should be permitted to co-sponsor SIPs. NTU believes the FDA should not allow additional types of co-sponsors, for many of the same reasons we believe FDA should curtail or remove the current co-sponsorship provisions.
- *The FDA should require SIP Proposals to include disciplinary actions imposed against the Foreign Seller or the Importer beyond just U.S. and Canadian borders.* The FDA seeks comments on whether the rule should require additional background information in SIP Proposals. The Proposed Rule requires plans to include “list of all disciplinary actions, to include the date of, and parties to, any action imposed against the Foreign Seller or the Importer by State, Federal, or Canadian regulatory bodies.” This notably leaves out disciplinary actions imposed against the Foreign Seller or Importer outside of the U.S. and Canada. The FDA should require that SIP Proposals include disciplinary actions imposed against the Foreign Seller or Importer anywhere, not just in two countries.
- *The FDA should ensure that a demonstration of expected cost savings includes the costs an SIP Sponsor incurs for set-up, reporting, renewal, consumer education, and any other activities involved in building and sustaining an importation regime.* The FDA seeks comments on what “factors should be considered in determining whether a reduction in the cost of covered products is significant.” One factor the FDA

must include is the one-time and dynamic costs to SIP Sponsors, especially non-federal governments, in setting and standing up importation regimes. Currently, the FDA only offers that an SIP Sponsor “could compare anticipated acquisition costs or consumer prices per unit of each drug that the SIP Sponsor is seeking to import.” Acquisition costs or consumer prices per unit are not sufficient to compare the costs and benefits of importation to a non-federal government entity, and the cost to state taxpayers of any importation program must be included in the demonstration of expected cost savings.

- *The FDA should consider the cost of importation to federal taxpayers as it determines whether an SIP Sponsor’s expected cost savings are significant.* Another factor the FDA should consider in determining the significance of an SIP Sponsor’s expected cost savings is the one-time and running costs of importation to federal taxpayers. The FDA has acknowledged they will incur both types of costs. For example, if the net expected cost savings from an SIP Sponsor’s importation plan are \$100 million a year, and the FDA does not consider the past, present, and future importation costs to federal taxpayers, then the expected cost savings could be considered significant. However, if the annual cost to federal taxpayers for importation is, say, \$1 billion a year, and the one-time fixed costs were \$10 billion, then the \$100 million a year in an SIP Sponsor’s expected cost savings are much less significant.

NTU stands ready to work with the FDA on these changes, and the broader reforms we suggest below.

NTU Supports Several Pro-Taxpayer, Pro-Consumer Initiatives to Lower Drug Costs

While not all of the reforms outlined here fall under the FDA’s jurisdiction, we share them as part of NTU’s continuing efforts to be a constructive partner in lowering drug costs for American patients and taxpayers:

- *Congress and the FDA should work together to reduce barriers in the drug approval process.* As NTU President Pete Sepp noted in a December 2018 Issue Brief, “Congress and the administration should engage in a comprehensive overhaul of the FDA to streamline efficiencies and cut down on red tape. Faster approval of safe drugs can increase innovation, and by approving drugs more quickly, it can decrease costs associated with research and development. This will allow research companies to put more resources into developing new life saving medications and restrain drug costs on consumers.”¹⁸
- *The FDA should continue its efforts to streamline its review and approval of complex biosimilars.* Biosimilar development, approval, and utilization promise significant savings to patients and taxpayers, given biosimilars compete with complex, expensive biological products that make up a significant portion of spending Medicare Parts B and D. As NTU noted in a September 2019 Issue Brief, “the [FDA] itself has noted it can improve and streamline its review and approval process for biosimilars. ... These moves offer promise to biological product manufacturers, taxpayers, and patients, so long as FDA’s guidance and tools make applying and receiving approval for a biosimilar easier, faster, more clear, and more efficient.”¹⁹
- *Pass the Reciprocity Ensures Streamlined Use of Lifesaving Treatments (RESULT) Act of 2019.* This legislation (S. 2161) would provide an expedited, reciprocal approval process for drugs, biologics, or medical devices that have been authorized to be lawfully marketed in a limited set of other countries.

¹⁸ Sepp, Pete, “Prescription Drug Costs: Better Ways to Help Patients and Taxpayers.” National Taxpayers Union, December 6, 2018. Retrieved from: <https://www.ntu.org/publications/detail/prescription-drug-costs-better-ways-to-help-patients-and-taxpayers>

¹⁹ Lautz, Andrew, “Pro-Taxpayer Ways to Increase the Availability and Use of Biosimilars.” National Taxpayers Union, September 16, 2019. Retrieved from: <https://www.ntu.org/publications/detail/pro-taxpayer-ways-to-increase-the-availability-and-use-of-biosimilars>

NTU has endorsed this legislation and believe it would help remove some of the regulatory barriers put in place by Congress and prior administrations.²⁰

- *Reform Medicare Part D.* One of the most promising, bipartisan proposals Congress can pass this year is Medicare Part D reform. NTU has regularly called for Congress to redesign the Part D benefit, and has pointed to the American Action Forum (AAF) proposal as a strong step in the right direction. AAF’s proposal would eliminate Part D beneficiary costs beyond a catastrophic threshold (currently, beneficiaries are on the hook for five percent) and shift the Medicare/taxpayer liability beyond this threshold from 80 percent (under current law) to 20 percent.²¹ Aspects of the AAF proposal are reflected in both the Prescription Drug Pricing Reduction Act (PDPRA; S. 2543) and Lower Costs, More Cures Act (H.R. 19). Most versions of this proposal feature the first ever out-of-pocket cap for seniors in Medicare Part D while also promising tens of billions of dollars in savings to taxpayers over a decade.²²

While some of these proposals involve regulatory reform at the FDA and some require acts of Congress, NTU stands ready to work with both lawmakers and regulators on deregulatory, market-based reforms that lower the cost of drugs for patients and taxpayers.

Conclusion

The FDA’s stated purpose of their Proposed Rule is to lower prices and reduce out of pocket costs for American patients. NTU shares those broad goals with the FDA. However, we strongly believe that allowing for prescription drug importation will not ultimately lower prices and reduce out of pocket costs for patients. In fact, the proposal may increase costs for taxpayers without having a meaningful impact on prices. The Proposed Rule suffers from a lack of thorough economic analysis of importation’s potential costs and benefits, though, so NTU must rely on prior, independent estimates from entities like the CBO. The FDA should withdraw its Proposed Rule, and pursue policies that combat the foreign price controls that have Americans unfairly picking up the tab for other countries’ access to prescription drugs.

Thank you for your time and consideration of NTU’s comments, and should you have any questions I am at your service.

Sincerely,

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²⁰ Lautz, Andrew. “NTU Thanks Senator Cruz for Introducing the RESULT Act.” National Taxpayers Union, July 26, 2019. Retrieved from: <https://www.ntu.org/publications/detail/ntu-thanks-senator-cruz-for-introducing-the-result-act> (Accessed February 19, 2020.)

²¹ O’Neill Hayes, Tara. “Redesigning Medicare Part D to Realign Incentives.” American Action Forum, August 14, 2018. Retrieved from: <https://www.americanactionforum.org/research/redesigning-medicare-part-d-realign-incentives-1/> (Accessed February 19, 2020.)

²² Lautz, Andrew. “Why a Contract-Based Solution to Surprise Billing Is Best for Taxpayers and Patients.” National Taxpayers Union, January 24, 2020. Retrieved from: <https://www.ntu.org/publications/detail/why-a-contract-based-solution-to-surprise-billing-is-best-for-taxpayers-and-patients> (Accessed February 19, 2020.)