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March 9, 2020

The Honorable Stephen M. Hahn, M.D., Commissioner  
Food and Drug Administration  
5630 Fishers Lane  
Rockville, MD 20852

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

Dear Commissioner Hahn:

AARP, on behalf of our 38 million members and all older Americans nationwide, appreciates the opportunity to comment on the proposed rule entitled “Importation of Prescription Drugs”. AARP has been at the forefront of enacting importation legislation at the state level and we welcome the opportunity to work with the Food and Drug Administration (FDA) to implement these important state laws.

Prescription drugs are only effective if patients can afford to use them, and Americans should not have to pay the highest drug prices in the world. Accordingly, AARP appreciates the Administration’s ongoing efforts to reduce prescription drug prices and costs and welcomes its proposal to allow states to begin safely importing prescription drugs from Canada. AARP has long believed that the safe, legal importation of less expensive but equally effective drugs is a critical step towards reducing drug prices and increasing competitive pressure on drug companies.

Older Americans use prescription drugs more than any other segment of the U.S. population. For older adults, prescription drugs are critical in managing their health, curing diseases, and improving quality of life. Unfortunately, three-quarters of Americans over age 50 worry about being able to afford prescription drugs, and forty-seven percent report that they have delayed or skipped filling a prescription because of cost.<sup>1</sup>

Meanwhile, drug companies’ pricing behaviors remain largely unchanged as the U.S. continues to struggle with high launch prices and subsequent price increases. In 2018, the average retail price for brand-name drugs widely used by older Americans reached over \$7,000 per year. For

<sup>1</sup> See <https://www.aarp.org/politics-society/advocacy/info-2019/prescription-drug-cost-survey.html>.

older Americans who take an average of 4-5 prescription drugs on a regular basis, this translates into an annual cost of therapy of more than \$32,000—almost 25 percent higher than the median annual income for Medicare beneficiaries.<sup>2</sup>

AARP and its members have been actively involved in bipartisan efforts to pass importation legislation at the state level. Those efforts have paid off in Colorado, Florida, Maine, Vermont, and New Mexico, all of which are now pursuing prescription drug importation programs, and additional states have similar efforts underway. These new programs have the potential to help states manage their ever-tightening budgets, save taxpayers' money, and help lower prescription drug costs for consumers.

As described in the rule, importation programs can also begin to address the unfair drug pricing system in the United States: international pricing comparisons consistently show that Americans pay the highest brand name drug prices in the world.<sup>3,4</sup> AARP strongly encourages the Administration to continue to pursue policies that will help reduce prescription drug prices and offers the following suggestions for consideration in finalizing this proposed rule.

### **Minimize Unnecessary Burden**

HHS should ensure that the process for states to apply for and establish Section 804 Importation Programs (SIPs) is as straightforward and administratively streamlined as possible. The final rule must ensure consumer safety but also avoid creating unnecessary and excessive requirements that effectively discourage participation. Unnecessary administrative requirements could also increase program costs, further reducing pricing benefits and the incentive for states to participate.

One particularly burdensome provision is the proposal to establish a two-year time limit on SIP approvals. While approved programs would have the ability to extend their approval for additional two-year periods, we believe such short timeframes could be problematic. For example, qualifying as a SIP will require developing and establishing new, complicated structures and processes that will undoubtedly consume a great deal of time and resources. States may decide that these initial costs cannot be offset by a two-year program with no guarantee of renewal and subsequently cause them to decline to participate—especially given the risk that the entire rule could be invalidated if a single provision is successfully challenged.

AARP is also concerned by potentially burdensome restrictions on SIP participants, such as the limitation that foreign sellers can only be licensed to distribute drugs that have been approved in Canada. Given the global nature of the pharmaceutical industry, it is unclear how many foreign

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<sup>2</sup> S. Schondelmeyer, L. Purvis, Rx Price Watch Report: Brand Name Drug Prices Increase More than Twice as Fast as Inflation in 2018, (AARP PPI, 2019) available at <https://www.aarp.org/rxpricewatch>.

<sup>3</sup> Patented Medicine Prices Review Board, 2017, “Annual Report 2017: Regulating Pricing of Patented Medicines: Continued Vigilance Necessary, Bilateral Price Comparisons, Average Foreign-to-Canadian Price Ratios, Bilateral Comparisons, <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1380&lang=en>

<sup>4</sup> U.S. House of Representatives, Ways and Means Committee, *A Painful Pill to Swallow: U.S. vs. International Prescription Drug Prices*, September 2019, [https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/U.S.%20vs.%20International%20Prescription%20Drug%20Prices\\_0.pdf](https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/U.S.%20vs.%20International%20Prescription%20Drug%20Prices_0.pdf)

sellers will be able to meet this requirement. Assuming there are relatively few acceptable foreign sellers, the number of SIPs that can operate effectively may be limited. In the absence of compelling evidence to support this new restriction, AARP urges FDA to return to the definition of foreign seller under section 804(f). Moreover, we also urge the FDA to consider allowing SIPs to import from more than one Canadian wholesaler, as the current proposal to limit it to a single wholesaler could be too restrictive.

### **Savings are Essential**

AARP believes that the one of the primary objectives of Section 804 is to create savings for consumers and that HHS is correct to focus on ensuring that SIPs achieve that goal. We also believe that SIPs should be required to clarify how they will share savings with both insured and uninsured consumers.

However, HHS should clarify and emphasize its instructions for how SIP applicants should describe expected savings. Under the proposed rule, SIP applications would need to provide statements describing how the SIP will result in “significant” savings. Little other guidance is provided as to what comprises significant savings; how a SIP could ensure significant savings are achieved; and how SIPs could ensure that any such savings ultimately reach consumers.

In addition, the full costs of operating a SIP, including the costs of labeling and safety testing as well as post-importation tracking and reporting requirements, should be included when estimating savings. Attestations of savings that don’t sufficiently incorporate all of the administrative and start-up costs could end up having unintended consequences for consumers and states – including potentially increasing their costs for obtaining needed pharmaceuticals.

Finally, HHS should ensure that Medicaid rebates will not be impacted by this proposal. HHS should issue guidance clarifying how SIPs will interact with state Medicaid programs, how the prices of products purchased via SIPs will be treated with respect to rebate calculations, and how HHS will track outcomes over time to ensure that Medicaid prices are not negatively impacted and Medicaid beneficiaries’ access to drugs is not reduced.

### **Safety is Paramount**

We applaud HHS’ strong emphasis on ensuring the safety of imported prescription drugs. While savings are important, safety should continue to be paramount to ensure that consumers are not exposed to misbranded or unapproved products.<sup>5</sup>

AARP supports efforts to educate providers and consumers about SIPs to the extent that such information is helpful and provides reassurance about the safety of imported products. However, the type and amount of information described in the proposed rule may not be necessary and could even be detrimental. For example, the rule includes a great deal of emphasis on ensuring that the pharmacist, prescriber, and patient are aware that a given drug is imported (e.g., labeling, letters to providers, websites). While AARP appreciates that some level of awareness is

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<sup>5</sup> R. Sachs, Trump Administration, In Shift, Announces Plan to Permit Drug Importation, *Health Affairs Blog*, July 31, 2019, <https://www.healthaffairs.org/doi/10.1377/hblog20190731.727552/full/>.

needed—particularly for pharmacists who are actually distributing the drugs—we are concerned that this level of differentiation between imported and non-imported drugs could inadvertently lead to the misperception that imported drugs are less safe even though they are effectively the same drugs.

Finally, as it continues to assess which drugs are eligible for importation, AARP urges FDA to be mindful that there is no evidence that a given country can only safely regulate certain types of prescription drugs. In addition, while there may be legitimate concerns about whether certain drugs will be handled appropriately during the importation process, it is notable that the majority of prescription drugs prescribed in the U.S. are not made in the U.S. or Canada and are therefore already safely moving across the globe.<sup>6</sup>

### **Ongoing Monitoring**

HHS should ensure that programs authorized under Section 804 are established, operated, and evaluated as transparently as possible. The appropriate agencies should carefully monitor SIPs for unintended consequences that may increase costs or create access barriers. There should also be a well-defined process for prompt corrective action should HHS become aware of problems through its monitoring efforts.

Ongoing monitoring of the SIPs and their impact on drug prices will also be important. HHS should ensure that there is careful consideration of the impact of importation programs on market prices, launch prices for new drugs, and the number and frequency of new product launches.

### **AARP Encourages Additional Efforts**

While AARP supports the current proposal to allow for the safe importation of less expensive prescription drugs, we believe more should be done to help reduce prescription drug prices for older Americans. We encourage the Administration to continue to pursue additional importation efforts, such as using its demonstration authorities to pilot projects that would allow importation from other countries besides Canada and importation of drugs products beyond those permitted under Section 804 (e.g., insulin and other expensive biologics).

AARP also notes that it would likely be considerably easier and far less costly to import drug prices rather than the actual products. One possible approach is the proposed International Pricing Index (IPI) model, which would base Medicare Part B reimbursement for selected drugs on the prices found in economically similar countries.<sup>7</sup> By HHS' own estimates, the IPI model is expected to lower Medicare reimbursements for those drugs by an average of 30 percent. Overall, savings of \$17.9 billion are expected for the Medicare program and an additional \$1.8 billion of savings for state Medicaid programs.

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<sup>6</sup> <https://www.fda.gov/news-events/congressional-testimony/safeguarding-pharmaceutical-supply-chains-global-economy-10302019>

<sup>7</sup> Medicare Program; International Pricing Index Model for Medicare Part B Drugs, Advance Notice of Proposed Rulemaking, 83 *Federal Register* 54546.

Moreover, we encourage the Administration to look for opportunities beyond Medicare Part B to implement an international reference price. According to a recent study, Medicare Part D could have saved approximately \$72.9 billion in 2018 if the price of certain brand-name drugs was equal to the average prices in Japan, the United Kingdom, and Canada.<sup>8</sup> We also urge the Administration to explore methods of using an international reference price to set or influence drug prices in the commercial insurance market. There is no reason why Americans should continue paying the highest drug prices in the world.

## **Conclusion**

AARP applauds the Administration for this important proposal to help make prescription drugs both more affordable and accessible for older Americans. We believe this proposed rule is a potentially effective tool to implement the laws that several states have now enacted to help make certain drug more affordable. The Administration should continue putting forward additional proposals that include other drugs, programs, and tools to help lower drug prices and ensure access to needed medications. Furthermore, we strongly urge you to continue working with Congress towards the enactment of meaningful prescription drug legislation that will lower drug prices and out of pocket costs.

Sincerely,



David Certner  
Legislative Counsel and Legislative Policy Director  
Government Affairs

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<sup>8</sup> <https://jhu.pure.elsevier.com/en/publications/using-external-reference-pricing-in-medicare-part-d-to-reduce-dru>