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Comment from Arkansas Pharmacists Association

The is a Comment on the **Food and Drug Administration** (FDA)
Proposed Rule: **Importation of Prescription Drugs**

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Comment

The Arkansas Pharmacists Association writes today to express our opposition to the proposed draft regulations to import Canadian medication into the United States. Our concerns are not with the legitimate Canadian drug supply, but with:
the unworkability of the proposal given the obvious size difference between Canada and U.S. populations, the current Canadian drug shortage problem, and the stated non-cooperation from Canadian stakeholders;
the unlikelihood it will save money for American patients because of the enormous cost and the lack of clear commitments to cost savings;
the unacceptable risks of relaxing Track and Trace standards; and
the history of and prevalence of counterfeits previously trafficked by Canadian operators and the difficulty of handing over our safety to uncooperative foreign entities.

Additionally, we are very concerned that the program as designed contemplates the inclusion of Pharmacy Benefit Managers (PBMs) in the importation supply chain. PBMs are not currently acting in the best interest of patients and are unfairly gaming the system and bankrupting pharmacies.

We believe that health care costs, of which pharmaceutical costs are a part, are a prime concern for Americans at nearly all income levels, even those with what many consider good insurance. However, implementing this policy is unlikely to bring down prices for most Americans, and very likely to create dangerous loopholes in the U.S. closed secure drug supply chain.

There are several ways these can be addressed that don't require taking risks with the safety of the American drug supply, including:
Reforming the role PBMs play in the supply chain: In West Virginia when most of the roles of traditional PBMs were removed from the state's Medicaid program they saved $54.4 million the very first year the program was in operation.
Stop the anticompetitive business practices of vertically integrated health plans where health insurance companies, pharmacy benefit managers (PBMs), retail pharmacy chains and mail order pharmacies are owned by the same company. Break these companies apart or at

the very least, implement common sense federal law that encourages competition and a fair market. Reform the current broken market and stop pharmacy benefit managers from paying themselves higher rates of pay compared to their competition and stop the anticompetitive unethical PBM practice of steering patients against their will to the pharmacies owned by the PBMs.

Provide transparency for patients to help them better understand their costs, including transparency for rebates and all payments received by PBMs and health insurance companies from the manufacturers. PBMs are not fiduciaries for the patient and therefore are perversely incentivized to support rising drug prices because the higher the list price for the drug, the higher the rebate for the middlemen and the higher the profits for these mega corporations. In Arkansas we continue to see this firsthand, including PBM generated formularies that exclude lower cost insulin and asthma inhalers, while requiring the use of brand name products that cost twice as much to the system with the only possible explanation being rebates to the PBM for profit.

Resource the FDA to allow them most efficiently review generics for small molecule drugs and biosimilars for biologics. Generics and biosimilars provide competition in the marketplace that will bring down prices.