



NATIONAL SHERIFFS' ASSOCIATION

TO: Department of Health and Human Services/Food and Drug Administration
FROM: Sheriff Keith Cain, Chairman, Drug Enforcement Committee, National Sheriffs' Association
RE: Comment on the Proposed Rule: Importation of Prescription Drugs, Docket ID: FDA-2019-N-5711-0001
DATE: March 6, 2020

The National Sheriffs' Association (NSA), founded in 1940, is a not-for-profit organization that represents the more than 3,000 elected Sheriffs across the United States. Sheriffs are the chief law enforcement officials in our counties, and Sheriffs' Offices have the public safety and public health responsibilities of operating most of the jails in this country, as well as providing court security and patrol duties in local communities.

Accordingly, NSA applauds the stated "purpose" of this proposed Rule on the importation of prescription drugs, i.e., "to lower costs and reduce out of pocket costs for American patients," whether these patients be the Sheriffs' citizenry out in the community or inmates in Sheriffs' jails. However, while supporting the purpose of the proposed Rule, NSA does, nevertheless, have serious concerns about the potential public health and safety consequences of this proposal to amend current Food and Drug Administration (FDA) regulations to "allow importation of certain prescription drugs shipped from Canada."

Thus, back in June of 2017, the NSA membership passed a resolution stating that "NSA Opposes Drug Importation Legislation Which Jeopardizes Law Enforcement's Ability to Protect the Public Health and Endangers the Safety of Law Enforcement and Other First Responders" (<https://www.sheriffs.org/government-affairs/resolutions>). And in January of this year, NSA reiterated its stance with the position statement that "NSA Urges Caution on the Food and Drug Administration's Proposed Rulemaking on the Importation of Prescription Drugs" (<https://www.sheriffs.org/Contact-Us/Press-Center>).

In short, NSA has serious concerns about any drug importation proposals — legislative, administrative, or regulatory — that could jeopardize local law enforcement's ability to protect the public health and safety of our citizenry, which we fear the proposed Rule could do. Accordingly, NSA appreciates that, per the FDA proposal, the Rule "shall become effective only if the [Health and Human Services (HHS)] Secretary certifies to the Congress that the implementation of this section will pose no additional risk to the public's health and safety." NSA cautions HHS/FDA, therefore, not to finalize this Rule, as proposed, without first inviting and hearing in-person the public health and safety perspectives and concerns of federal, state, and local law enforcement. If HHS/FDA has, indeed, already conducted such outreach to these law enforcement stakeholders, NSA was not included in that limited outreach! NSA's concerns about the proposed Rule include: (1) policing the importation of prescription drugs and (2) the challenges to law enforcement of preventing the infiltration of counterfeit and adulterated medications into the U.S. drug supply chain.

As elected officials, Sheriffs hear up close and personal about the impact of high medication prices on the incomes and healthcare of individuals and families in our communities. And as the administrators of most jails, Sheriffs are professionally well aware of the budgetary impact of those costs to counties for inmate care. That is to say, Sheriffs emphasize personally and professionally with the urgent need for affordable access to prescription medications for all American patients!

But, NSA contends that the “importation” of prescription drugs — instead of other Congressional approaches to ensure affordable pricing “domestically” — is hardly the most logical or safest option to lower costs and reduce out of pockets costs for American patients. And, how can federal policymakers not take pause when hearing a public safety warning like this one from a former FBI Director?

This is an extremely dangerous idea that requires a blind eye to a fundamental truth. For drug importation to be a reality, law enforcement entities must be able to protect against those who would see this policy as a promising new avenue to bring illegal and counterfeit drugs into the United States. And, despite what some might have you believe, that capability will never exist based on the magnitude of the law enforcement challenge created by drug importation initiatives.ⁱ

And how can HHS and the FDA not take pause when hearing a public health warning like this one from four previous FDA Commissioners?

Importation proposals seek to make lower-cost but genuine, safe and effective drugs available to U.S. consumers, however, this is not such a straightforward task. In fact, we believe that such importation represents a complex and 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.ⁱⁱ

In summary, NSA fears that the HHS/FDA Rule, as proposed, could:

(1) Open up the secure U.S. drug supply chain to adulterated and counterfeit prescription medications;

(2) Shift the actual cost of imported prescription drugs to federal, state, and local law enforcement — who may be underfunded, understaffed, and or untrained — to police this threat while HHS certifies that the importation “would be expected to result in a significant reduction in the cost of covered products to the American consumer,” and;

(3) Jeopardize Sheriffs’ ability to protect the public health and safety of our local citizenry.

Thus, to reiterate, the National Sheriffs’ Association asks that the U.S. Department of Health and Human Services and the Food and Drug Administration not finalize this Rule, as proposed, until hearing in-person the perspectives and concerns of all law enforcement, including Sheriffs. Only then can one fully understand the potential implications of prescription drug importation and whether or not it will pose no additional risk to the public’s health and safety!

ⁱ Freeh, L. “The rising threat of dangerous drugs.” The Washington Times (January 29, 2019). Retrieved at <https://www.washingtontimes.com/news/2019/jan/29/the-illicit-drug-crisis-is-getting-worse-each-day>.

ⁱⁱ Califf, R., McClellan, M., Hamburg, M., and Von Eschenbach, A. (March 16, 2017). Letter to Members of Congress (March 16, 2017). Retrieved at https://healthpolicy.duke.edu/sites/default/files/atoms/files/2017_03_16_commissioners_letter_final_signed.pdf.