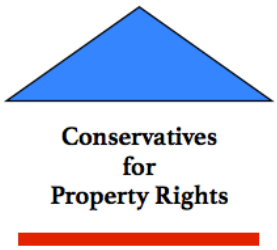

March 9, 2020

Stephen M. Hahn, M.D.
Commissioner
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Importation of Prescription Drugs Proposed Rule (Docket No. FDA-2019-N-5711)

Dear Commissioner Hahn:

Conservatives for Property Rights (CPR), a coalition of organizations representing millions of Americans from across the conservative and libertarian political spectrum, is pleased to comment on the Importation of Prescription Drugs Proposed Rule (Docket No. FDA-2019-N-5711).

CPR emphasizes the central importance of private property in all its forms — physical, personal, and intellectual. Our coalition is greatly concerned by the proposal to allow states and other entities to import certain prescription drugs. First, the proposed scheme will introduce tremendous risk and jeopardize the health and safety of millions of Americans and corrupt America's drug supply with counterfeits, while enabling bad actors to profit off of the scheme. Second, importation is unlikely to provide any out-of-pocket spending relief on pharmaceuticals for U.S. patients, failing to achieve the ostensible goal of this proposal. Third, the importation plan constitutes an assault on private property rights, thus disincentivizing American innovators and investors from pursuing research and investment into solving the knottiest, most challenging diseases with therapies and cures.

Heightened Risk to Health and Safety From a Corrupted Drug Supply

Importation of prescription drugs outside the regulatory controls of U.S. authorities introduces great risk to Americans' health and safety. Counterfeit and adulterated pharmaceuticals have been a major target to keep out of the U.S. drug supply for many years, while those trafficking in fake medicines have become more and more sophisticated. However, responsible U.S. government leaders of both parties have taken important steps to secure the safety of our pharmaceutical supply chain — this proposal runs in direct opposition to those efforts.

Most recently, the Drug Supply Chain Security Act (DSCSA) was enacted in 2013 and has introduced a track-and-trace system to help ensure that only bona fide pharmaceutical products enter the United States supply chain. The law already requires supply chain entities to track and trace products from manufacturer to dispenser, capturing and exchanging specific information at each change of ownership and engaging only with authorized trading partners. And beginning in November 2023, the law will require secure, interoperable, electronic product tracing at the package level, no matter where the product was manufactured, shipped, warehoused, or distributed. The United States drug supply already set the standard for ensuring quality, safety, and efficacy. The DSCSA provides U.S. authorities more tools for protecting the integrity of America's drug supply.

Government leaders have long warned of the dangers of importation schemes.[1] Previous Department of Health and Human Services (HHS) secretaries and Food and Drug Administration (FDA) heads, Republican and Democratic, have uniformly been unable to deem importation as safe for patients. Most recently, several including former FDA Commissioner Mark McClellan warned that importation "could lead to a host of unintended consequences and undesirable effects, including serious harm stemming from the use of adulterated, substandard or counterfeit drugs." This arises from the loss of the ability to confirm the provenance of a medicine imported under the proposed scheme.

"Foreign versions" of FDA-approved drugs may appear to be the same drug in packaging, labeling, and the pill or other form as the real drug. However, they often have been found to contain no active ingredient, poisonous or toxic components, or inert ingredients such as water. Former FBI Director Louis Freeh has concluded, "The potential [from importation] for lower drug prices for a small percentage of Americans would pale in comparison to the potential costs to the safety of American consumers and the integrity of the prescription drug supply chain, as well as the increased burden on U.S. law enforcement that would impact communities across the country."

The Freeh report discusses how importation would open an avenue for criminal enterprises and terrorist organizations, among others, to prey upon American consumers in states where importation becomes permitted. Among the "unintended consequences that would outweigh any potential benefits," the Freeh report specifies that importation would "worsen the opioid crisis – a crisis that has already grown substantially worse due to the powerful opioid fentanyl and fentanyl analogue-laced counterfeit pills being produced by illegal drug trafficking organizations, including in China, and reaching the United States through Canada and Mexico."

Former Trump FDA Commissioner Scott Gottlieb has recounted "the reason that we have the closed [pharmaceutical control] system in this country . . . [is] because of counterfeit drug problems that were originating in Florida. . . . We had concerns that the drugs weren't coming from brick-and-mortar places in Canada." Dr. Gottlieb highlights that medicines ostensibly sold in Canada do not necessarily originate in Canada, the United States, or legitimate pharmaceutical manufacturers subject to FDA or DEA controls. Nor do claimed "Canadian" pharmacies necessarily operate in Canada.

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[1] E.G., July 9, 2001, letter from Health and Human Services Secretary Tommy Thompson and his predecessor Donna Shalala to Senator James Jeffords regarding the Medicine Equity and Drug Safety Act of 2000 and William K. Hubbard's testimony at a hearing, "Buyer Beware: Public Health Concerns of Counterfeit Medicine," of the Senate Special Committee on Aging on July 9, 2001.

Indeed, HHS Secretary Alex Azar has derided drug importation, calling "Canadian" drug importation a dangerous "gimmick." Secretary Azar himself has noted that the imported medicines are often "routed from, say, a counterfeit factory in China or another country." Secretary Azar has warned that "the last thing we need is open borders for unsafe drugs in search of savings that cannot be safely achieved."

Therefore, the risks from allowing questionable drug products to enter the U.S. market, even in the name of lowering prescription prices, outweigh potential benefits. Counterfeit, adulterated, impotent, or dangerous packages of prescription medicines supposedly arriving from Canada to American homes unnecessarily turns filling a prescription into a form of Russian roulette. The "Canadian" purchase by an Arizonan lung cancer patient of what turned out to be fake Avastin illustrates why and how the proposed scheme would fail to protect American lives and health, and in fact place Americans in heightened jeopardy. All things considered, it is doubtful that the current secretary of Health and Human Services could reasonably certify pursuant to Section 804 that many proposed importation schemes meet the statutory requirements for safety and public health.

Ephemeral Cost Savings From Importation

In addition to exposing the American public to serious safety risks, this importation proposal would not likely result in reductions in the cost of covered products for the American consumer. The proposal gives false hope and unrealistic expectations because, simply put, the scheme would require those charged with carrying out the program — as well as all the private-sector entities affected by a program — to incur various implementation costs, the magnitude of which are challenging to estimate. Those costs, along with other considerations discussed below, could well render it difficult for HHS to certify that significant cost savings for patents will result.

Added costs of set-up and maintenance, regulatory compliance and more from a proposed Section 804 Importation Program (SIP) would be incurred by federal regulators, state government, law enforcement agencies, and those in the drug supply chain. Additional costs at each of these stages may actually translate into higher prices for patients. Importantly, one of the requirements of Section 804, under which this proposal is made, is that an importation scheme result in "significant reductions" in consumer spending.

In making its case to support certification of section 804, the FDA recently ran into insurmountable challenges to estimating the savings of such an importation program. FDA reported, "As 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 SIPs or the savings to U.S. consumers who may participate in such programs."

The nonpartisan Congressional Budget Office (CBO) also assessed importation's effect on U.S. drug spending, concluding that "permitting the importation of foreign-distributed prescription drugs would produce at most a modest reduction in prescription drug spending in the United States."

It would be short-sighted to assume that the status quo remains once a drug importation plan is adopted in the United States. The proposal in no way would simply import Canada's government-dictated, artificially low drug prices. Importation would likely prompt Canada to respond in any number of ways that would restrict access, raise prices, assess export fees, or otherwise change the picture. The costs of a given drug in Canada today would not be the price of that drug once importation is stood up.

In short, it is foolish to think importation is a silver bullet solution. It will neither import foreign price controls nor come cost- or consequence-free. The nearly guaranteed result will be less cost savings in the United States.

Attacks on Private Property Rights

The right to private property ranks among the unalienable rights the Founders referenced in the Declaration of Independence and secured by the U.S. Constitution and the Bill of Rights. Private property rights lie at the heart of research and development (R&D) and intellectual property (IP) intensive sectors of our economy. Such industry sectors lead our nation and often the world in innovation. The right of exclusivity IP, particularly patents, provide innovators is critical to developing and commercializing cutting-edge inventions in biopharma, medical device, 5G wireless, artificial intelligence, aeronautics, quantum computing, etc.

Importation disincentivizes the pursuit of the arduous path of R&D in biopharmaceuticals. R&D in a sector such as pharmaceuticals assumes great risk of failure on any given potential drug. About nine out of ten drug candidates fail to make it through clinical trials and to the market. The average cost to research and develop a medicine approved to market is conservatively $2.6 billion. Thus, failures along the way are the norm; successes are the exception. The vast majority of funds invested in drug discovery and development is private dollars.

These brand medicines must recoup billions and billions of sunk costs for themselves and the nine of ten failed tries. Importation effectively steals patent value from these inventions, erasing value just as much as a stock market plunge erases wealth that had been created. Misguided proposals such as drug importation are tantamount to eminent domain for intellectual property. Such bad policy has real-world consequences; in pharmaceuticals, the consequences involve government taking away private investments' rewards on successful products that would have paid a return as well as replenish the R&D pipeline for future breakthroughs. This causes a disincentive to invest.

Of special importance at a time that a novel coronavirus is gripping the globe, the United States government is marshaling our nation's private and public medical research and development resources to race to come up with therapeutics, vaccines, diagnostic tools, and cures. Ironic that the U.S. government is urging the very private sector it is targeting whose few but impactful commercial successes fuel the very R&D by which American pharmaceutical firms are able to come to the rescue during such emergencies.

As the Wall Street Journal observes, "a core U.S. strength is the breadth of its private medical resources. That's on display now as the government is calling on private actors to buttress the federal response." Further, the Journal warns, "By putting government in charge of every health care decision, Medicare for All [a proposed government-controlled health system] would eliminate the adaptability of private innovation, which is an American advantage. The Trump Administration is right to exploit it."

However, any of the panoply of IP-robbing proposals — importing foreign drugs, compulsory licensing, reference pricing to foreign government-set price controls, ex post facto inflationary penalties, march-in outside of Bayh-Dole's narrow conditions for such exceptional action, etc. — would weaken our nation's pharma sector, assault IP exclusivity in that renowned sector, rob Americans of the innovations our nation's patients enjoy the earliest access to, and diminish our patent system which has endured repeated assaults by Congress, courts, and administrative bodies for two decades now.

America's IP, including the right to exclude competitors during the limited duration of a patent term, is essential to our solving the current global medical crisis, continually introducing new

cures and better therapies, and sustaining the high-skill jobs in our nation's vibrant life sciences sector.

* * *

President Trump recently referred to Tesla CEO Elon Musk as "one of our great geniuses, and we have to protect our genius. You know, we have to protect Thomas Edison and we have to protect all of these people that came up with, originally, the light bulb and the wheel and all of these things." CPR heartily agrees with the President about preserving, protecting, and defending what empowers our inventors to lead the world in invention, in commercialization, and in IP.

All Americans want foreign freeloader countries to pay their fair share for American-made new medicines. But importation would put American patients' lives at risk, do little to reduce drug costs, and disincentivize pharmaceutical innovators by attacking their property rights. That would impose a high price to pay for "cheaper" medicine. Conservatives for Property Rights stands in good company, such as the long list of HHS and FDA officials who have wisely declined to approve any of a variety of pharmaceutical importation schemes, in opposing this drug importation proposal.

Respectfully,

James Edwards
Executive Director
Conservatives for Property Rights

Daniel Schneider
Executive Director
American Conservative Union

Jeffrey Mazzella
President
Center for Individual Freedom

Kevin L. Kearns
President
U.S. Business & Industry Council

James L. Martin
Founder/Chairman
60 Plus Association

Saulius "Saul" Anuzis
President
60 Plus Association

Tim Andrews
Executive Director
Taxpayers Protection Alliance

Matthew Kandrach
President
Consumer Action for a Strong Economy

George Landrith
President
Frontiers of Freedom