March 16, 2017

To Members of Congress:

As former Commissioners of the U.S. Food and Drug Administration, we have been following with concern the recently renewed debate about the importation of therapeutic drugs as a measure to reduce the cost of prescription medications. 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.

One of the FDA's most important responsibilities is to ensure that medications used by Americans are safe, secure, effective, and reliable. For nearly 80 years, the Federal Food, Drug and Cosmetic Act (FD&C) has granted the FDA the authority that allows it to take needed action to protect consumers. The "closed" distribution system undertaken by the FDA under the direction of broadly supported drug safety legislation, provides assurance that good manufacturing practices are used and that the increasingly complex supply chain, including shipment and storage, is carefully monitored to ensure the quality and security of approved medications.

The American public and members of Congress have expressed serious concerns about access to and costs of prescription drugs, particularly innovative therapies with major benefits for people with serious diseases. We share these concerns, and believe we need better systems that enable affordable access to life-saving medicines.

However, routine importation from foreign countries is not the right approach. Allowing importation of drugs purported to be manufactured overseas in FDA-inspected facilities and drugs purported to be manufactured domestically for export to other countries and re-imported from those countries to the United States cannot meet the requirements under the existing closed drug manufacturing and distribution system because the drugs could not be tracked and certified by the manufacturer..

Such a program would be very different from importation of consumer products like watches or clothing, where consumers can more easily discern quality and where there are no health consequences of fake products. It could lead to a host of unintended consequences and undesirable effects, including serious harm stemming from the use of adulterated, substandard, or counterfeit drugs. It could also undermine American confidence in what has proven to be a highly successful system for assuring drug safety. The major shortcomings of a broad-based importation scheme include:

- **Serious risks to patients and consumers.** Current law permits drug importation if the FDA determines it can be done safely. In unusual circumstances, such as a major

shortage of a generic drug for which there is urgent need, the agency has permitted importation in close cooperation with the manufacturer. However, none of us, acting in our roles as former FDA Commissioners, were able to conclude that a wider policy of routine importation would increase access to safe and effective drugs for the American public.

- **Drugs purchased from foreign countries may be substandard, unsafe, adulterated, or fake.** Americans who currently use the internet to purchase drugs from outside the U.S. are likely receiving medicines that are either of substandard quality, adulterated, or fake. Since 1999, the FDA has conducted investigations to curb online sales and distribution of such products. Through massive efforts that involve multiple regulatory and law enforcement agencies from 115 countries, these efforts continue to uncover websites illegally selling unapproved, potentially dangerous prescription drugs to U.S. consumers, including numerous sites claiming to sell Canadian drugs despite evidence that the drugs originated elsewhere.

  Given the enormous volume and complexity of imports to the U.S., obtaining sufficient resources and expertise to screen and verify the authenticity of every product destined for American consumers presents enormous challenges. Even if spot-checking discovered a dangerous or counterfeit product, in the absence of the closed system currently in use, there would be no way to trace that product to its origin or intervene to protect other consumers before irreparable harm occurs. This is not a trivial problem: global experience confirms that illicit, ineffective, or adulterated products are readily available on the open market and represent one of the most lucrative avenues for organized crime. And beyond the immediate safety threat to patients and consumers, such products also create economic harm, as patients wasted money on drugs that are either partly or wholly ineffective.

- **The FDA lacks the resources needed to oversee a major importation program.** It is conceivable that if extraordinary new resources were allocated to the FDA, it might oversee a major program of drug importation. But there are many far more urgent priorities for FDA reform that would have much greater benefits for Americans, including more effective ways to improve access to safe drugs. Further, we see no indication that Congress plans to commit the resources needed for this purpose.

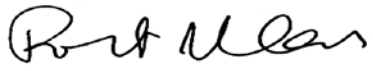
- **The global drug supply system will limit improvements in access.** Drugs are distributed to countries in allotments that are based on the needs of their respective populations, so only a limited supply of drugs would be available for importation, at best. For this reason, importation is unlikely to achieve real impact on the supply to the U.S. market, and could even exacerbate problems by increasing the likelihood of counterfeit or unsafe products.

- **Any improved access and cost savings resulting from importation are likely to be minimal.** Studies examining this issue have estimated that importation would likely have only a small, incremental effect on cost and access for drugs in the U.S. market; further, these small savings might not be passed on to patients, even if consumers are able to obtain a legitimate imported drug.

There are far better ways to improve access to safe and effective drugs. We believe Congress should consider other approaches to address problems with current drug pricing, and take steps to bring down drug costs and health care costs more generally. We all support drug payment reforms that align payments with results and development of improved guidance for industry to enable timely approval for complex generic drugs and "biosimilar" therapeutics.

The bipartisan Generic Drug User Fee Amendments Program, authorized by Congress in 2012, offers a successful model for such efforts. The program has promoted substitution of generic drugs, such that nearly 90% of prescriptions are now written for generic drugs that are safe, effective, and have yielded major savings for consumers. While we have some differing opinions about optimal approaches to the problem of high-priced drugs (such as government negotiation with manufacturers, or expanded use of competitive models of drug payment), we all strongly support attention to implementing effective solutions for drug costs and innovation.

We urge Congress and the many others concerned about the cost of drugs to deal directly with the issues driving the cost of medicines and not to place false hope in measures that will place patients who need treatment at risk and jeopardize public health.



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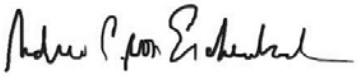

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