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The National Medical Association (“NMA”), the *Conscience of American Medicine*, is the America’s premier membership association for physicians of African descent. As such, the NMA represents over 25,000 medical practitioners, and the patients they serve. Many of our patients are from underrepresented and underserved minority groups, and are therefore representative of the most vulnerable populations seeking services from our nation’s healthcare system. These populations are also the victims of disparities in healthcare based on race and ethnicity in their everyday lives in communities all across our nation. Consequently, the outcomes of this inquiry process relating to drug reimportation is directly relevant to the practice of medicine for African Americans in particular, and for the US population as whole.

We are appreciative therefore for this forum, and we thank the Health and Human Services Task Force On Drug Importation for inviting us to participate. We are hopeful that our input, in addition to the input of all other stakeholders will bring us to a viable, commonsense strategy for dealing with this thorny issue. *Fundamentally, the NMA is of the opinion that the quality and safety of the drugs to be imported has to be our paramount concern.* If any doctor in America writes a prescription for a patient, and cannot be confident that the prescription will be correctly filled, then the patient may as well have written the prescription. It stands to reason then that the Food and Drug Administration (FDA)’s role in this process will be critical. Our comments will focus primarily on the FDA’s role in a prescription drug re-importation regime, with some peripheral comments about related matters.

I. Assess the scope, volume and safety of unapproved drugs, including controlled substances, entering the United States via mail shipment

The FDA should concern itself with determining which countries of the world have equivalent regulatory and approval processes for bringing pharmaceuticals to market. There is also a need for determining the safety of said pharmaceuticals if they are to be imported in to the US. If the drugs are safely produced, we need to be certain that they are safely shipped as well.

The FDA could develop standard protocols that can be enforced at our nation’s ports of entry. These protocols could be signed affidavits from the issuing pharmacist[s] that demonstrates that the products being inspected meet US quality and safety standards, and

therefore merit allowance into the US. The burden of proof would then be placed on the individual[s] seeking to do the importing, thus minimizing the administrative/regulatory burden placed on the resources of the FDA. Volume requirements should be reasonable. If an individual US citizen or resident attempts to bring drugs into the US, it should be up to them to demonstrate that the products are only for a specified period to treat a specific condition. This information may be included as a line item on the aforementioned affidavit, which should also be signed by the intended user or designee. If the affidavit is *barcoded*, it could be tracked for data collection, and for enforcement purposes if any questions of legality later arise. Any attempt to mislead the US Government in this process should be treated as a felony, with the appropriate penalties. Commercial shippers and mail carriers should be required to ask if packages contain prescription drugs, and if so require that customers present the aforementioned affidavits.

II. Assess the pharmaceutical distribution chain and the need for, and feasibility of, modifications in order to assure the safety of imported products

If a prescription drug shipment goes through an intermediary(ies) before it gets to the intended consumer, they should also be required to certify that the shipment is delivered to the intended recipient in the safest and timeliest possible fashion. This would include relevant information such as meeting refrigeration and packaging requirements, for example. This certification should be numerically linked to the aforementioned affidavit (probably as an addendum or a Part 'B' of the document).

Intermediaries in the supply chain should be restricted to certain categories of persons. It is probably safest if each category of intermediaries has a pharmacist designated for this purpose, in order to improve the probability the integrity of the product is maintained pending delivery to the consumer.

III. Determine the extent to which foreign health agencies are willing and able to ensure the safety of drugs being imported from their countries to the US

This determination requires the collaboration of other US government entities, such as the Department of Commerce. To the extent that international trade agreements affect these arrangements, the FDA should be given the prerogative in setting the pharmaceutical requirements necessary to protect the interests of the American consumer. The attitude or protocols of foreign health agencies with regard to exporting their pharmaceuticals to the US should be considered in light of what works best for our nation's taxpayers.

IV. Identify the limitations, including limitations in resources and in current legal authorities that may inhibit the Secretary's ability to certify the safety of imported drugs

The NMA has no specific input on this question at this time, but the current relationship between FDA and US Customs is worth investigating. It is probably worth the time and resources necessary to develop compatible documentation mechanisms for these two entities, for the purpose of regulating drug importation.

V. Estimate agency resources, including additional field personnel, needed to adequately inspect the current amount of pharmaceuticals entering the country

No specific comments from the NMA on this question at this time.

VI. Identify ways in which importation could violate US and international intellectual property and describe the additional legal protections and agency resources that would be needed to protect those rights

Foreign pharmacies should be prohibited from exporting pharmaceuticals that do not pass US safety and quality standards, to the extent that the FDA can ensure compliance. All American manufacturers should be held to the same standard, whether or not they manufacture generics. The NMA is strongly committed to the principle that the best therapy should be sought for each patient, irrespective of whether the drug is generic or brand name, or for that matter whether the patent was issued in the US or elsewhere.

VII. Estimate the costs borne by entities within the distribution chain to utilize anti-counterfeiting technologies that may be required to provide import security

No comments from the NMA on this question.

VIII. Assess the potential short- and long-term impacts on drug prices and prices for consumers associated with importing drugs from other countries

An HHS entity such as the Agency for Healthcare Research and Quality (AHRQ) or the National Center for Health Statistics (NCHS) should be definitively involved in answering this vital question. The findings would be particularly useful to the Centers for Medicare and Medicaid Services (CMS), which, as we all know, is America's most significant purchaser of pharmaceutical services. The populations served by CMS happen to significantly overlap with the NMA's key constituencies, so we would be very interested in the answer to this question. If, as a nation, we decide we can successfully import safe, top quality drugs, then it means viable competition for America's drug manufacturers, and therefore greater bargaining power for purchasers such as CMS. This should translate into lower out-of-pocket costs for the most vulnerable consumers, who are currently forced to choose between medications and other essential goods and services. HHS should commission a study on this question, as soon as possible.

IX. Assess the impact on drug research and development, and the associated impact on consumers and patients, if importation were permitted

The pharmaceutical industry would be the more expert resource on this question. If the impact is increased research and development activity in the US market, we can probably expect more effective and efficacious therapies. Depending on how this impacts price, it could be a great value to vulnerable populations that are most susceptible to healthcare disparities.

X. Identify the liability protections, if any, that should be in place if importation is permitted for entities within the pharmaceutical distribution chain

No specific comments from the NMA on this question at this time.

XI. Analyze whether anti-counterfeiting technologies could improve the safety of products in the domestic market as well as those products that may be imported

Are there any data on currently existing anti-counterfeiting technologies? If not, the data need to be collected in order to inform the proposed analysis. It would stand that the pharmaceutical industry's input be solicited in devising a solution to this problem, provided it is significant enough to warrant the expenditure of precious government resources.

The NMA is hopeful that these concise comments prove useful as this discussion proceeds. If there are any other thoughts from our membership, we will forward those to the appropriate forum in a timely manner.

Again, we thank the Task Force for the opportunity to contribute.