315 Montgomery, Suite 900 \* San Francisco, CA 94104 \* www.safemedicines.org

June 5, 2019

Dear members of the AMA House of Delegates,

As President and Director of the Partnership for Safe Medicines, a coalition of over 70 members of the pharmaceutical supply chain from manufacturers to wholesalers to pharmacists to patients. I write to you today to express my concern about Resolution: 129 submitted from the Texas State Medical Society. The resolution states that the AMA should "study the implications of prescription drug importation for personal use and whole prescription drug purchase across our southern and northern borders." With our collected decades of experience working to ensure that Americans have access to safe and effective medications, we can state definitively that should the United States allow drug importation from Mexico, our citizens will receive at best medicines that will have limited to no therapeutic value, and, at worst, medications that could kill them.

Just last year, the Mexican Association of Pharmaceutical Research Industries (<u>Asociación Mexicana de Industrias de Investigación Farmacéutica</u>) stated that 60 percent of all medications sold in Mexico are either stolen, expired, falsified, or produced without meeting minimum quality requirements.<sup>1</sup> Expensive drugs like antiretrovirals and cancer medications and fast-acting insulin are a favorite target of bad actors. These medications are some of the very same drugs that states want to import in the hope of lowering prescription costs for their residents.

Organized crime in Mexico is behind much of the manufacturing and selling of counterfeit medications that country.<sup>2</sup> However, Mexican drug cartels have also started manufacturing and distributing fake prescription pills containing fentanyl throughout the U.S. with devastating results. To date, PSM has documented counterfeit fentanyl pills being found in 48 states with deaths in 30. While it is unknown how many of those pills came from Mexico, we do know that Mexican cartels are a significant player. Not only are they making the pills, but they now can make fentanyl using precursor ingredients.<sup>3</sup>

Counterfeit and illicit medications from Mexico have already made their way into the United States. A multi-jurisdictional case in 2018 saw over 438,000 doses of illegal pharmaceuticals seized from 22 different locations in California and Arizona.<sup>4</sup> A Tijuana resident received a 30-month federal prison sentence for conspiring to smuggle and sell counterfeit and unapproved

<sup>&</sup>lt;sup>1</sup> https://www.excelsior.com.mx/nacional/mexico-sexto-en-venta-de-medicina-ilegal-victimas-8-millones-de-personas/1238537

<sup>&</sup>lt;sup>2</sup> https://translate.google.com/translate?hl=en&sl=es&u=https://www.milenio.com/policia/medicinas-robadas-en-tres-tianguis-de-cdmx&prev=search

<sup>&</sup>lt;sup>3</sup> https://www.safemedicines.org/2019/01/clandestine-fentanyl-producing-lab-found-in-mexico-city.html

<sup>&</sup>lt;sup>4</sup> https://www.lacityattorney.org/single-post/2018/05/09/City-Attorney-Mike-Feuer-and-Law-Enforcement-Partners-Disrupt-Alleged-Sales-of-Counterfeit-Misbranded-and-Illegal-Pharmaceuticals-Among-the-Largest-Multi-Agency-Investigations-Illegal-Pharmaceuticals-in-the-Nations-History



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drugs in the U.S. The man stored the drugs in various storage units near the border.<sup>5</sup> Multiple children in Texas needed to be hospitalized after they received counterfeit over-the-counter treatments that were falsely advertised as antibiotics.<sup>6</sup> DEA agents suspected Mexican cartels were behind the rash of string of overdoses from fake Percocet pills made with fentanyl.<sup>7</sup>

Stolen medicine is another major problem in Mexico and should never be trusted because storage at improper temperatures can dramatically affect a medication's potency. For example, insulin and thyroid hormones can lose effectiveness when exposed to heat. If concentrated epinephrine is exposed to repeated heating and cooling, it can lose 64 percent of its potency. Any aerosolized medication like an albuterol inhaler to treat asthma can explode if stored at a temperature over 120 degrees.<sup>8</sup>

Mexico found children treated at state-run hospitals in Veracruz with counterfeit cancer drugs that contained only distilled water in 2010.9 Four years later, doctors and nurses filed new complaints after continuing to find counterfeits in their hospitals. In February 2017, five additional vials were found.10 At that same time, investigators found 23 tons of expired medicine in state warehouses and multiple suppliers that did not have offices at the addresses listed on procurement forms.

This discovery of thousands of pounds of expired medicines is not an isolated incident. Just one month earlier, officials in Veracruz discovered 11 tons of expired medications. <sup>11</sup> In April 2017, authorities in Mexico City seized over 95,000 pieces of counterfeit medicines. <sup>12</sup> Sometimes, even prescription drugs produced at legal Mexican pharmaceutical manufacturing firms have had issues. In November 2013, authorities in Jalisco seized 166 tons of medicine due to bad manufacturing practices that meant the drugs could not have a guarantee of quality, safety, or efficacy.

<sup>&</sup>lt;sup>5</sup> https://www.justice.gov/usao-sdca/pr/seller-counterfeit-and-unapproved-pharmaceuticals-sentenced-prison

<sup>&</sup>lt;sup>6</sup> https://www.safemedicines.org/2011/05/texas-children-given-fake-antibiotics-234.html

<sup>&</sup>lt;sup>7</sup> https://www.safemedicines.org/2017/08/dea-suspects-deadly-fake-percocet-in-georgia-coming-from-mexican-cartels.html

<sup>&</sup>lt;sup>8</sup> https://www.theatlantic.com/health/archive/2011/09/why-you-should-never-store-medications-at-high-temperatures/245011/

<sup>&</sup>lt;sup>9</sup> https://www.safemedicines.org/2017/01/mexican-hospitals-treated-children-with-counterfeit-chemotherapy-drugs.html

<sup>&</sup>lt;sup>10</sup> https://globalnews.ca/news/3257918/mexican-authorities-find-vials-of-fake-anti-cancer-drug/

<sup>&</sup>lt;sup>11</sup> https://translate.google.com/translate?hl=en&sl=es&u=http://www.capitalmexico.com.mx/politica/las-11-toneladas-de-medicamentos-caducos-que-encontraron-en-desorden-en-veracruz/&prev=search

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While we all agree that something needs to give to help ease the burden of high costs for prescription drugs that Americans are paying at the pharmacy counter, the safety and security of our drug supply chain should not be the thing that we opt to sacrifice to achieve this goal. Since 2003, every single head of Health and Human Services and the Food and Drug Administration, appointed by both Democratic and Republican administrations have said that drug importation cannot be done safely.<sup>13</sup>

PSM's coalition sees, first hand, the problem with the cost of healthcare every day, and we believe that there is an urgent need to address it. However not all policy solutions are workable, safe, or cheap, and drug importation fails all three of those standards. We urge you to focus on one of the many other proposals that work within the existing regulatory structure.

Sincerely,

Marv Shepherd, Ph.D.

Professor Emeritus, College of Pharmacy, University of Texas at Austin President, Partnership for Safe Medicines

Kenneth L. McCall, BSPharm, PharmD, BCGP, FAPhA Director of Residency Programs & Professional Affairs Professor | College of Pharmacy University of New England

<sup>&</sup>lt;sup>13</sup> https://www.safemedicines.org/2018/07/who-opposes-drug-importation-every-head-of-the-fda-and-hhs-since-2000.html