

Senator Evan Vickers Utah State Senate 2166 N Cobble Creek Dr Cedar City, UT 84721

July 17, 2019

Dear Senator Evan Vickers,

The board and staff of the Partnership for Safe Medicines would like to thank you for doing the right thing by opposing foreign drug importation. Though popular, there are many reasons it's not a good policy idea. To name a few: There aren't enough medicines in Canada; Canadian criminals have already gotten caught selling wholesale counterfeit cancer drugs to Americans; We are already struggling to close the holes that are letting counterfeit opioids into our drug supply today.

Attached below is a letter of thanks from families of victims of counterfeit medications from around the country. Additionally I have included two important recent developments about the topic of importation of interest as you consider policy in this area.

- A recent study by the Healthcare Distribution Alliance, the national trade association for pharmaceutical wholesalers, on the topic of importation. They say that implementing importation, if even possible, will increase medical adverse events in America by 5% and a cost of implementation of US\$1bn-US\$2.9bn.
- Congressional testimony by the U.S. Food and Drug Administration that since the beginning of 2019, 99.1% of the medical products they have intercepted and examined coming into the U.S. via International Mail, which includes from Canada, are non-compliant.

Opposing drug importation is fiscally responsible, safe for patients, and backed up by independent data on imported drugs. Thank you for being a champion for patient safety.

Sincerely,

Shabbir Imber Safdar Executive Director, Partnership for Safe Medicines



The individuals who below also signed this thank you letter. They included some personal information about themselves to express why they feel strongly about the safety of the U.S. drug supply. I have added web links to websites where you can learn more about their story.

Carrie Luther, Mom, Aptos, CA

"My family and I have been devastated by the effects of counterfeit medications. My eldest son died as a result of taking 1/4 of what he thought was a Xanax tablet. I am so grateful for your courage in advocating against drug importation."

https://www.safemedicines.org/2017/09/young-californian-dies-after-accidentally-taking-counterf eit-xanax-made-with-fentanyl.html

Kristen DiVita, family member, Fairlawn, NJ

"I know the dangers firsthand." Kristen's sister Maggie was killed by a counterfeit pill. You can read Maggie's story here: https://www.safemedicines.org/2018/05/maggie-crowley.html

Lisa Hicks, Joe's Law: Their Lives Mattered, Atlanta, GA

"My family and myself have been profoundly affected by counterfeit medications which resulted in the death of my only son, killed by fake oxycodone pill that contained fentanyl. He was dead a few hours later and never had the chance to meet his son who was born a few weeks after his death."

https://www.safemedicines.org/2017/12/joe-patterson.html

Andrea Thomas, Executive Director of Voices for Awrareness Foundation, Grand Junction, CO

"I lost my 32 year old daughter to a counterfeit drug. I was not aware of the counterfeit drug problem until then."

https://www.safemedicines.org/2019/02/five-people-charged-over-the-death-of-ashley-romero-fr om-a-fake-fentanyl-pill.html

Nicole Hendrix, South Carolina

Nicole's brother Eric Griffin was killed in 2016 by a counterfeit Xanax made with a fatal amount of fentanyl.

Lisa McElhaney, Fort Lauderdale, FL, National President, National Association of Drug Diversion Investigators (NADDI) and Former Sworn Law Enforcement Officer

"With 25+ years of law enforcement experience in the pharmaceutical drug diversion field, we have seen counterfeit medications become an increasing threat. The integrity of the US drug



supply has been flooded with counterfeit medicines aimed to treat everything from colds to cancer, and while they inflict harm upon the patients that receive them, the counterfeit medicines made with fentanyl have killed tens of thousands. Individuals that believe the US can ensure the integrity of imported medications are not only fooling themselves, they are fooling the public. We shouldn't enact policies to increase an already existing threat to our communities." http://www.naddi.org



July 16, 2019 testimony in the House Energy and Commerce Committee, "Oversight of Federal Efforts to Combat the Spread of Illicit Fentanyl"

Carol Cave, Director, Office of Enforcement and Import Operations Office of Regulatory Affairs, Food and Drug Administration

"FDA's intelligence obtained through criminal investigations, data from import and regulatory inspections, and open source information shows that many Chinese-based manufacturing operations not only lack sufficient controls for drug products, but also produce and export a variety of synthetic opioids. Some of these manufacturers also synthesize new substances that produce effects similar to opioids with pre-market analytical reference names, such as Am-2201, Jwh-018, and U-47700. In addition, many counterfeit drugs sold online that appear to be FDA-approved medications, such as Oxycontin (oxycodone), Xanax (alprazolam), Vicodin (hydrocodone), or Percocet (oxycodone), may contain fentanyl or fentanyl analogs. OCI has investigated several such cases."

"It is our experience that legitimate commercial shipments of drug products enter the country via conventional means; air, rail, ship, and express consignment can all be part of a legitimate supply chain. However, FDA does not consider informal entry through international mail to be a method that sponsors of legitimate pharmaceutical products commonly use. So far in FY 2019, we have found 99.1% of the drug products entered the U.S. through international mail to be noncompliant.

FDA plays an important role related to the interdiction work that takes place in IMFs and has acted to enhance our operations there. When an illegal controlled substance is identified at an IMF, our partners at CBP will immediately seize it, and it will therefore not come to FDA investigators in these facilities. Instead, FDA is focused on inspecting, and sometimes testing, products that may be FDA-regulated drug products that violate the Food, Drug, and Cosmetic Act; for example, if they appear to be counterfeit or unapproved drug products.

While we examine what initially are believed to be non-opioid drug products, we still identify a large amount of controlled substances, in some cases because they are disguised as other types of drug products. From October 2018 through May 2019, FDA staff at the IMFs processed nearly 17,204 suspicious packages containing 28,356 products that FDA was tasked with inspecting because they were suspected of containing illegal prescription or counterfeit drugs or dietary supplements."