



## PSM Legislative Agenda for the 117<sup>th</sup> Congress

### Protect Consumers

Stakeholders must work together to improve enforcement and regulations and increase penalties to combat online sales of counterfeit, misbranded and adulterated pharmaceuticals. In addition, PSM rejects proposals which call on HHS to allow foreign drug importation because they will open the U.S. drug supply to unsafe and counterfeit drugs. PSM supports policies such as increasing approvals of generics to help Americans receive safe U.S. medications at prices they can afford without sacrificing safety.

### We SUPPORT

#### **Requiring Registries/Registrars to Lock & Suspend Domain Names That Facilitate Illegal Online Drug Sales**

- PSM supports legislation that would amend the Federal Food, Drug, and Cosmetic Act (FDCA) to require credible parties (e.g., law enforcement, domain name registries and registrars) to immediately lock and suspend any domain name used to facilitate illegal medicine sales.
- The FDA should be given injunctive authority to seize and reassign domain names that facilitate the illegal online sales of medicines and illicit drugs.
- Failure to comply with such policies should be added to the FDCA's Prohibited Acts and Penalties.

#### **Requiring Online Search/Social Media/Marketplace Platforms to Report Illegal Online Drug Information to Federal/State Authorities ("duty to report")**

- PSM supports internet companies having a duty to report communications requisite to tackling illegal content.
- Oversight authorities should be able to assess whether additional measures are needed to ensure swift and proactive detection and removal of illicit drugs sales online.
- Search engines, social media platforms and online marketplaces should submit data including computer-mediated messages, posts, comments, interactions, and multimedia.

#### **Raising Awareness of the Prevalence of Counterfeit Pills and the Lethality of Fentanyl and Fentanyl-Related Substances, and Efforts to Permanently Schedule Fentanyl and Fentanyl-Related Substances**

- In February 2018, the DEA issued a temporary scheduling order to schedule fentanyl-related substances that has allowed federal law enforcement authorities to bring criminal actions against individuals who manufacture, distribute, or handle fentanyl-related substances. This scheduling order is set to expire on December 31, 2022.
- If permanent scheduling is not negotiated prior to the expiration date, Congress should extend the temporary emergency scheduling order for as long as possible.
- Multiple bills have been introduced to codify the DEA precedent to permanently schedule illicitly manufactured and deadly fentanyl-related substances, and several pieces of legislation have been introduced to extend the order, ranging from 2-, 5- and 14-month extensions.



## We OPPOSE

**117<sup>th</sup> Congress Legislation: H.R. 832/S. 259, the Safe and Affordable Drugs from Canada Act; and the HHS Safe Importation Action Plan; S. 920, the Affordable and Safe Prescription Drug Importation Act**

**117<sup>th</sup> Congress Legislation: S. 1898, the Affordable Medications Act**

**116<sup>th</sup> Congress Legislation: H.R. 1478, the Affordable Insulin Act**

- PSM opposes any legislation or administrative action that would legalize the importation of prescription drugs from other countries.
- Foreign drug importation would weaken our borders and open more loopholes for criminals trafficking dangerous drugs into the U.S.
- Importation will lead to the proliferation of counterfeit pharmaceuticals, including fentanyl-laced counterfeit drugs. This creates a significant interior enforcement issue and an unfunded mandate for law enforcement at the federal, state and local levels.
- Enforcement against illegal foreign actors is difficult because the FDA's and other U.S. law enforcement agencies' jurisdiction and powers of prosecution end at the border.
- Most drug importation legislation proposes to import drugs from Canada, a country with one-ninth the population of the U.S. Canada already experiences drug shortages. If just 20% of U.S. residents purchased their medications from the Canadian drug supply, we would exhaust their supply of prescription drugs in five months.

## Protect and Support Law Enforcement

PSM has partnered with law enforcement on the frontlines of interdicting counterfeit drugs to better understand their needs. We support giving law enforcement the tools to combat counterfeit drugs, enacting policies to curb the trafficking and sale of counterfeit drugs, and increasing penalties for the commission of the counterfeit pills laced with synthetic opioids that have become increasingly common in recent years.

## We SUPPORT

**117<sup>th</sup> Congress Legislation: S. 3399 / H.R. 6352 Domain Reform for Unlawful druG Sellers, or DRUGS Act**

- This bill would require registries and registrars to:
  - Stop profiting from licensing domain names used to illegally sell prescription medicine, controlled substances, and unapproved medical products.
  - Act on information from Trusted Notifiers including the Food and Drug Administration (FDA), the Department of Justice (DOJ), the Department of Homeland Security (DHS), State Attorneys General, State Boards of Pharmacy, an entity identified by the FDA as a trusted notifier, or any organization partnering with the FDA or the Drug Enforcement Agency to share such information.
  - Lock the domain within 24 hours of notification. This prevents the registrant from transferring the domain to another company but keeps the website otherwise operational.



- Suspend the domain name within 7 days of notification unless the domain name registrant successfully appeals the Trusted Notifier's findings. Suspension prevents the website from working, thus stopping the public health threat.
- Be accountable under the Federal Food, Drug & Cosmetic Act. Failure to comply has consequences: 1st time offense: one year imprisonment, \$1,000 fine, or both; 2nd offense: three-year imprisonment, \$10,000 fine, or both.

**117<sup>th</sup> Congress Legislation: H.R. 1303, the Criminalizing Abused Substance Templates Act, or the CAST Act**

- This bill would amend the Controlled Substances Act to prohibit the knowing possession of a counterfeit pill press mold for a controlled substance with intent to manufacture.
- Those found in possession of a Schedule I or II counterfeit substance in a capsule, tablet or other form intended for distribution, shall be fined and imprisoned for not more than 20 years.
- All sentencing guidelines would be in accordance with the Sentencing Commission.
- Enhancing statutory minimums and increasing fines and penalties will provide a stronger deterrence against criminals and criminal organizations seeking to make easy profits from counterfeit drugs.

**117<sup>th</sup> Congress Legislation: S. 4358, Bruce's Law**

- This bill would establish an awareness campaign related to the lethality of fentanyl and fentanyl-contaminated drugs and provides community-based coalition enhancement grants to mitigate the effects of drug misuse.
- Establishes a Federal Interagency Working Group on fentanyl contamination of illegal drugs

**117<sup>th</sup> Congress Legislation: S 4151, the Stop Pills That Kill Act**

- This bill would implement new penalties for counterfeit pill production and ensure existing penalties for possessing paraphernalia used to manufacture methamphetamine would also apply to possessing paraphernalia used to make counterfeit pills that contain methamphetamine, fentanyl and fentanyl analogues.
- The DEA would be required to develop a comprehensive plan to tackle the increasing spread of counterfeit pills containing fentanyl or methamphetamines, and report to Congress on the scope of seizures, investigations, prosecutions, and public awareness of the dangers of counterfeit pills laced with illicit substances.

**117<sup>th</sup> Congress Legislation: S. 339, the Federal Initiative to Guarantee Health by Targeting Fentanyl Act, or the FIGHT Fentanyl Act; S. 1006, the Stopping Overdoses of Fentanyl Analogues Act, or SOFA Act; S. 1216, the Temporary Extension of Fentanyl Scheduling Act; H.R. 2430, the Temporary Reauthorization of the Emergency Scheduling of Fentanyl Analogues Act**

- These bills add the entirety of fentanyl-related substances to schedule I of the Controlled Substances Act.



- Schedule I includes drugs, substances, or chemicals that have a high potential for abuse; have no currently accepted medical value; and are subject to regulatory controls and administrative, civil, and criminal penalties under the Controlled Substances Act.

**117<sup>th</sup> Congress Legislation: S. 2853 / H.R. 5382, the Providing Officers with Electronic Resources Act, or the POWER Act**

- This bill would provide grants for state, local, territorial and Tribal law enforcement agencies to purchase chemical screening devices and train personnel to use them.
- The devices would address the backlog of drugs awaiting laboratory identification. By alerting officers quickly to dangerous substances in the field, they will ensure officers can test substances like fentanyl safely.
- All law enforcement should have the necessary tools to protect themselves and quickly take bad actors off the street.

**117<sup>th</sup> Congress Legislation: H.R. 5274, the Prevent Exposure to Narcotics and Toxins Act, or the PREVENT Act**

- This bill aims to protect U.S. Custom and Border Protection (CBP) officers from accidental exposure to fentanyl and other potentially lethal substances they encounter while on the job.
- CBP would be required to make containment devices available to its officers and to provide mandatory annual training on the use of containment devices to prevent secondary exposure to fentanyl and other lethal substances.

**117<sup>th</sup> Congress Legislation: H.R. 8316, the Securing America's Borders Against Fentanyl Act; S. 3850, the Securing America's Ports of Entry Act**

- These bills will increase federal research & development into new technologies to identify, track, and interdict illicit fentanyl coming through America's borders and ports of entry.
- They also provide for additional resources for increased CBP officers and personnel, as well as analysis of current staffing, infrastructure and equipment needs to enhance ports of entry security.

## Past Bills We SUPPORTED that Became Law

PSM is committed to the safety of prescription drugs and protecting consumers against counterfeit, substandard or otherwise unsafe medicines. PSM's principles include unifying the fight against counterfeit drugs, securing and protecting the pharmaceutical supply chain, the education of public and government agencies of fraudulent and counterfeit products and ensuring online sellers operate in compliance with existing laws, regulations and platforms' terms of service.

Previously, PSM has supported proposals and worked with legislators to pass legislation that promote these principles. Examples of such efforts that successfully became law include:

**S. 400 / H.R. 1098, the Blocking Deadly Fentanyl Imports Act – incorporated into the FY22 NDAA and SIGNED INTO LAW December 27, 2021**



- This bill requires a study of the production of illicit fentanyl in foreign countries and determines which nations exporting illicit fentanyl without emergency scheduling of fentanyl would be ineligible for foreign aid or export-import bank loans.
- Closes the loophole for illicitly manufactured fentanyl, which is the primary driver of fatal fentanyl overdoses, and holds countries accountable for producing/manufacturing fentanyl into the U.S.

#### **H.R. 2630, the Extending Temporary Emergency Scheduling of Fentanyl Analogues Act**

#### **H.R.5663, the Safeguarding Therapeutics Act of the 116<sup>th</sup> Congress – SIGNED INTO LAW January 5, 2021**

- This bill bolsters our ability to keep dangerous counterfeit medical devices out of the country by granting the FDA and other U.S. customs authorities the power to seize and destroy them at international mail ports in the same way they have the authority to destroy counterfeit medicines.