



PSM Legislative Agenda for the 117th 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.

We OPPOSE

117th 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

116th Congress Legislation: S. 1801, The Affordable Medications Act; 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

117th 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.

117th 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. 2630, the Extending Temporary Emergency Scheduling of Fentanyl Analogues Act; H.R. 2430, the Temporary Reauthorization of the Emergency Scheduling of Fentanyl Analogues Act

- 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 May 6, 2021, and these bills codify the DEA precedent to permanently schedule illicitly manufactured and deadly fentanyl-related substances.
- Adds 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.



- If permanent scheduling is not negotiated prior to the May 6, 2021 expiration date, Congress should extend the temporary emergency scheduling order for as long as possible. Several pieces of legislation have been introduced to extend the order, ranging from 2-, 5- and 14-month extensions.

116th Congress Legislation: S. 954, 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.

116th Congress Legislation: S. 400 / H.R. 1098, the Blocking Deadly Fentanyl Imports Act

- This bill would require a study of the production of illicit fentanyl in foreign countries.
- Nations exporting illicit fentanyl without emergency scheduling of fentanyl would be ineligible for foreign aid or export-import bank loans.
- The bill would close the loophole for illicitly manufactured fentanyl, which is the primary driver of fatal fentanyl overdoses.
- These conditions already apply to countries which are major producers or traffickers of illicit heroin, marijuana, cocaine and methamphetamine and their precursor chemicals.
- It will also hold countries accountable for producing/manufacturing fentanyl into the U.S.

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:

H.R.5663, the Safeguarding Therapeutics Act of the 116th 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.