H.R. 5228, "The Stop Counterfeit Drugs by Regulating and Enhancing Enforcement Now (SCREEN) Act"

Section by Section

Sec. 1. Short Title; Table of Contents

Sec. 2. Detention, Refusal, and Destruction of Drugs Offered for Importation

Provides FDA with the authority to refuse or destroy, or find to be misbranded, unlabeled or minimally labeled imported articles that are identified as containing an active ingredient that is contained within an approved drug or biologic, contains an active ingredient that is contained within a drug or biologic that is under investigation, or is chemical analog of a drug or analog. Grants FDA authority to refuse importation and destroy drugs on the basis that they have been identified to DEA as "articles of concern" (ie. unlabeled shipments of fentanyl analogs) for consideration for temporary or permanent scheduling. Allows the FDA Commissioner to increase the maximum dollar amount of drugs subject to destruction if the Commissioner finds that doing so would be in the interest of public health.

Sec. 3. Notification, Nondistribution, and Recall of Adulterated or Misbranded Drug Products

Gives FDA the authority to order any person who distributes a drug that may cause serious adverse health effects or death to immediately cease distribution. Any person subject to the order shall immediately cease distribution of such drug and provide the required notification. If there is credible evidence that a drug presents an imminent threat of serious adverse health consequences or death, FDA would be permitted to issue an emergency recall order. This order will require the distributor or person responsible to immediately recall the drug and provide notice to anyone who may be affected by adverse health effects of the drug product. FDA would be required to notify consumers and health officials when a drug has been recalled. If a drug is subject to an order to cease distribution or recall then the article shall be refused importation admission. For orders to cease distribution or recall, a person may appeal the order within 24 hours of issuance. An informal hearing shall be held as soon as possible, but no later than 5 calendar days, less if the Secretary determines the hearing should be held sooner or after if both parties jointly agree to an extension. If the Secretary determines following the hearing that there are inadequate grounds for the order, then the Secretary shall vacate the order.

Sec. 4. Seizure

Streamlines FDA's seizure authority and restricts the ability of importers to sell goods that are subject to a pending seizure complaint.

Sec. 5. Single Source Pattern of Shipments of Adulterated or Misbranded Drugs

Provides FDA with the authority to treat all drug products from a single manufacturer, distributor, or importer the same if that entity has a pattern of offering adulterated or misbranded drugs for import.

Sec. 6. Debarring Violative Individuals or Companies

Extends the authority to debar individuals or companies who exhibit recidivist illegal activity or who have been convicted of a FDA felony or other violations from importing any drug products under a different company name.

Sec. 7. Account to Strengthen FDA's Efforts to Combat the Opioid and Substance Use Epidemic

Establishes an account in the Treasury, the *FDA Opioid and Substance Use Epidemic Response Fund*, to be used for funding programs and activities to address the opioid epidemic and would authorize $110 million for fiscal years 2019 through 2023 to such fund. This fund shall support widespread innovation in non-opioid and non-addictive pain therapies, initiatives that increase access to opioid use disorder treatment, help to develop standards safe opioid use, and reduce illicit importation of opioids. FDA is required to submit an annual workplan identifying the activities the funding will support, as well as annual financial report to the House Committee on Energy and Commerce and Senate Committee on Health, Education, Labor, and Pensions and a report detailing the amount of money obligated out of the account for the prior fiscal year for each program and the activities of each program and use of the funds, as well as an explanation for how the programs and activities are advancing public health. This section sunsets on September 30, 2022.