



# H.R. 2851 – Stop the Importation and Trafficking of Synthetic Analogues Act of 2017 (Rep. Katko, R-NY)

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### FLOOR SCHEDULE:

Scheduled for consideration on June 14, 2018, under a structured <u>rule</u>.

### **TOPLINE SUMMARY:**

<u>H.R. 2851</u> would amend the Controlled Substances Act to create a new prohibited schedule of certain synthetic drugs, allowing the Attorney General to make illegal certain unregulated substances on a temporary basis, and would establish criminal penalties for manufacturing, distributing, or importing such drugs

# **COST:**

The Congressional Budget Office (CBO) estimates that "DEA would collect (and spend) less than \$1 million per year from the additional fees; thus, the net budgetary effect would be negligible."

# **CONSERVATIVE CONCERNS:**

Some conservatives might be concerned that there is not an adequate *mens rea* "guilty mind" requirement for sentencing under the bill.

Some conservatives might be supportive of further increased penalties for drug offenses while conservative prison reform advocates might argue for reduced sentencing for non-violent drug offenders.

- **Expand the Size and Scope of the Federal Government?** Yes. It creates a new schedule of prohibited drugs and subsequent sentencing requirements.
- Encroach into State or Local Authority? Some conservatives might feel that addressing
  the opioid epidemic might be better accomplished at the state and local level, or by civil
  society at large.
- **Delegate Any Legislative Authority to the Executive Branch?** Yes, the bill would allow the Attorney General to schedule substances without Congressional Approval this bill would only provide for Congressional Disapproval.
- Contain Earmarks/Limited Tax Benefits/Limited Tariff Benefits? No.

### **DETAILED SUMMARY AND ANALYSIS:**

This legislation would address the synthetic drug epidemic in America. According to the Committee Report, over 52,000 Americans died from drug overdoses in 2015. Of those, nearly 1/5 were overdoses on synthetic opioids.

This legislation would establish a Schedule A drug category to include substances that "have a chemical structure that is substantially similar to an existing controlled substance in Schedules I through V, and it must have an actual or predicted physiological effect on the human body equal to or greater than an existing controlled substance in Schedules I through V." This definition is similar to the definition for controlled substance analogues. It would exclude new substances that the FDA has approved for investigational purposes.

Drug traffickers currently skirt the Controlled Substances Act (CSA) by making small variations to controlled substances, even though these changes can have deadly results. To address this, the legislation would provide for specific criteria that the Attorney General must find that a substance's effects on the central nervous system are largely similar or greater than those of existing substances found in Schedules I through V.

This legislation would add 13 variations of fentanyl to the newly created Schedule A. Drug traffickers sometimes modify the base molecules of fentanyl to create similar drugs, while circumventing the CSA. According to the Committee Report, these drugs have been confirmed as the cause of death in 162 cases in the United States. These drugs could still be classified as Schedule I through V drugs. This legislation institutes the ability to control them in the short term, to put a stop to trafficking.

Section 3 would permit the Attorney General to issue temporary or permanent scheduling orders. For temporary orders, the Attorney General must find that a substance meets the Schedule A criteria, and that listing the substance as Schedule A will help prevent the misuse or abuse of the substance. A temporary order would not be permitted to take effect until 30 days after the Attorney General publishes a notice in the Federal Register with grounds for inclusion as a Schedule A drug. Temporary orders would not be permitted to last longer than 5 years, though they may be extended for up to 180 days if the substance is in the process of being permanently declared a Schedule A substance.

Upon submitting notice in the Federal Register, the Attorney General would also be required to submit notice to Congress, who would have the power to disapprove and reverse a temporary scheduling order within 180 days following the federal register notice.

This legislation establishes penalties for manufacturing, distributing, or dispensing Schedule A substances. Simple possession is excluded and there are no mandatory minimum sentences. Penalties for a first offense of trafficking or distribution include imprisonment of not more than ten years, or not more than 15 years if death or bodily harm results and/or a fine of \$500,000 for individuals or \$2.5 million for those other than an individual. Subsequent offenses may be penalized by imprisonment of not more than 20 years, or 30 years for offenses involving death or serious bodily harm. The possible fine would increase to \$1 million for individuals or \$5 million for defendants other than an individual. This legislation would require a minimum of two years of supervised release for sentences involving imprisonment, with terms of at least four years for those with prior convictions.

For those found guilty of importing or exporting Schedule A substances, the person committing the violation would be sentenced to a maximum of 20 years. For those instances that result in death or serious bodily injury, they may be sentenced to life. Sentencing may also include a fine of \$1 million for individuals and \$5 million for others. For those with prior felony drug convictions, sentences must

include imprisonment of not more than 30 years, or life imprisonment for instances resulting in death or serious bodily injury, and/or a fine of \$2 million for individuals or \$10 million for others. Sentences of imprisonment would require supervised release of not less than three years for first convictions, or six years for those with prior convictions. This legislation would not permit the court to place someone sentenced under this provision on probation or have their sentence suspended for those with mandatory terms involving death or serious bodily injury.

This legislation would make it unlawful to import, export, manufacture, distribute, dispense, or possess with intent to manufacture, distribute, or dispense, a schedule A substance or product containing a schedule A substance, unless the substance is labeled using International Union of Pure and Applied Chemistry (IUPAC) nomenclature. It would provide an exemption for drugs or substances if they are labeled in the manner consistent with the Food, Drug, and Cosmetic Act. This legislation provides for civil remedies to fine or shut down those in violation. Drugs currently in clinical trials or undergoing FDA approval are exempt. This legislation provides for \$1,000 penalty.

Section 6 establishes requirements for handlers of Schedule A substances. The Attorney General would be permitted to register an applicant to manufacture a schedule A substance if: (1) the applicant demonstrates the substance would be used for research, analytical, or industrial purposes as approved by the Attorney General; and (2) the Attorney General determines the registration is consistent with US public interest and with treaty obligations. It would provide for certain considerations in determining whether the manufacture is in the public interest. Applicants that are already registered to manufacture controlled substances in Schedule I or II need not apply for a separate registration. All registrants would be required to comply with security and recordkeeping requirements. Quantities permitted for registrants would be limited, with procedures put in place for requests for increased amounts if there is scientific need.

Practitioners or researchers engaged in working with a substance that is subsequently placed on the list as a Schedule A substance would have 90 days to register.

The Attorney General would be required to grant, deny, or request additional information from applicants within 60 days. If supplemental information is requested, the Attorney General would then have 30 days to grant or deny an application. Scientific investigators and research institutions not already registered for Schedule I drugs will be referred to the Department of Health and Human Services to determine if the applicant is conducting bona fide research.

Section 7 would incorporate the new Schedule A into the Controlled Substances Import and Export Act, and incorporates requirements and penalties for Schedule A drugs into those already established for Schedules I and II. It also would provide for controls on importation, exportation, manufacturing and distribution, establishing production quotas, setting approved order forms, and the forfeiture of seized substances.

Section 8 would clarify the definition of a controlled substance analogue so that a substance must meet the first element in the definition, i.e. that a substance has a chemical structure that is substantially similar to that of a schedule I or II controlled substance, and then meet either of the remaining elements.

Section 9 would provide for equivalencies for substances not already listed in sentencing guidelines. Courts could first look to the U.S. Sentencing Guidelines, guidance provided by the Attorney General in the Federal Register, and the Drug Equivalency Table. Courts would then be permitted to follow steps in sentencing offenders.

If the Attorney General has provided guidance, courts would apply any sentencing equivalency or ratio. In the absence of guidance with respect to a substance or group of substances, courts would use equivalences for a list of structural classes of substances found in the Drug Equivalency Tables. If neither applies, the court would be required to determine an equivalency ratio based on factors in application note 6, which is already the practice for substances not referenced in guidelines.

Nothing in the legislation would affect the ability of the Attorney General to schedule, re-schedule, or decontrol substances under the CSA, or to prosecute under the Analogue Enforcement Act or the CSA.

Finally, this legislation would require the GAO to conduct a study on costs associated with the legislation.

### **AMENDMENTS:**

- 1. Rep. Griffith (R-VA), Rep Raskin (D-MD) This amendment would incorporate an interagency agreement transmitted to Congress by the Office of National Drug Control Policy (ONDCP), the U.S. Department of Health and Human Services (HHS) and the U.S. Department of Justice (DOJ). It would clarify when the Attorney General could temporarily or permanently schedule a substance. It would prevent the AG from scheduling a substance if HHS determines there isn't a sufficient likelihood for abuse. It provides further circumstances for applicants to conduct research while applications are pending.
- 2. Rep. Jackson Lee (D-TX) would strike section 9, providing for sentencing equivalencies.
- 3. Rep. Maloney (D-NY) This amendment would require the DEA to make a report on controlled substance analogues available on the internet for sale.
- 4. Rep. Thornberry (R-TX) This amendment would list factors allowing for the determination of whether a controlled substance is intended for human consumption, so law enforcement and health officials can swiftly take action against manufacturers, distributors or sellers.

## **GROUPS OPPOSED:**

<u>Friends Committee on National Legislation</u> **FreedomWorks** – Key Vote No

### **GROUPS IN SUPPORT:**

**VOW Foundation** 

### **COMMITTEE ACTION:**

H.R. 2851 was introduced on June 8, 2017, and was referred to the House Committee on the Judiciary, where it was reported, amended, by voice vote on July 12, 2017.

### **ADMINISTRATION POSITION:**

A Statement of Administration Policy is not available.

### **CONSTITUTIONAL AUTHORITY:**

"Congress has the power to enact this legislation pursuant to the following: Article I, Section 8."

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