THE COLLEGE ON PROBLEMS OF DRUG DEPENDENCE, INC.

3420 N. Broad Street, Room 324, Philadelphia, PA 19140-5104
Telephone: 215-707-3242 • Fax: 215-707-1904 • Website: http://www.cpdd.org

Executive Officer:
Loretta P. Finnegan, MD
E-mail: finnegal337@aol.com

Director, Executive Office:
Ellen B. Geller, MA
215-707-5307
E-mail: gellerellen@gmail.com

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Representatives Robert Goodlatte and John Conyers
House Judiciary Committee
2138 Rayburn House Office Building
Washington, DC 20515

On behalf of the College on Problems of Drug Dependence (CPDD), we are writing to express our views on H.R. 2851, Stop the Importation and Trafficking of Synthetic Analogues (SITSA) Act of 2017. CPDD is the longest standing scholarly society in the United States that is devoted to issues surrounding substance use disorders. The College has over 1000 members, and serves as an interface among governmental, industry, and academic communities maintaining liaisons with regulatory and research agencies as well as educational, treatment, and prevention facilities in the drug abuse field.

We share the concerns of the Committee and sponsors of H.R. 2851 about the opioid epidemic and its devastating consequences for millions of Americans, their families, and their communities. According to a recent *New York Times* article, an estimated 59,000 Americans died in 2016 of drug overdoses, the largest annual jump in deaths ever recorded in the United States. One of the main reasons for that dramatic and disturbing increase is the spread of fentanyl, a synthetic opioid that is inexpensive and potent. The College supports robust, science-based efforts to curb the sale and use of synthetic analogues.

While CPDD agrees with the spirit of H.R. 2851, we believe that legislation to enhance the Justice Department's efforts to temporarily schedule new synthetic compounds must institutionalize a more enhanced role of the Department of Health and Human Services' science-based agencies, specifically the National Institute on Drug Abuse and the Food and Drug Administration. The current version of H.R. 2851 gives the Attorney General blanket authority to temporarily schedule a substance, and the AG is only required to provide a 30-day public notice of pending scheduling action and "take into consideration any comments" from HHS on proposed orders to temporarily schedule a compound. The temporary scheduling process for synthetic analogues bypasses the current process that requires the AG to conduct a three-factor analysis before temporary scheduling can proceed.

Moreover, to permanently schedule a compound, current law requires the AG to obtain an eight-factor analysis by FDA and a recommendation from HHS on a permanent scheduling action. For synthetic analogues, H.R. 2851 enables the Attorney General to bypass the current role of science-based agencies in reviewing what compounds should be scheduled.

We seek to ensure that science-based Federal agencies, including FDA and NIDA, are involved in decisions regarding temporary scheduling of synthetic analogues, rather than the current version of H.R. 2851, which merely requires that HHS be informed of the AG's intent to schedule such compounds.

If the intent of the legislation is to enable the “scientific and research communities to develop information on these newly-invented substances,” then the research exemption written into the current version of H.R. 2851 needs to be enhanced significantly. The bill provides that researchers who already have a Schedule I license will not need an additional one, except to review protocols for research on these targeted substances. This exemption applies to only a small subset of potential scientists who could and should research potential treatments to the targeted synthetic compounds but who will be discouraged from doing this research by the burdens and lengthy regulatory burdens and time required to gain approval of a Schedule I license. CPDD encourages the Committee to consider an expanded exemption that would enable researchers with Schedule I, II, III, IV and V licenses to conduct research on those synthetic analogues that will be temporarily scheduled under terms of this legislation.

Respectively

Alan Budney, PhD
President, The College on Problems of Drug Dependence