The Honorable Jerrold Nadler
Chairman
U.S. House Committee on the Judiciary
2138 Rayburn House Office Building
Washington, D.C. 205105

The Honorable Doug Collins
Ranking Member
U.S. House Committee on the Judiciary
2138 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Karen Bass
Chairwoman
U.S. House Committee on the Judiciary
Subcommittee on Crime, Terrorism, and Homeland Security
2138 Rayburn House Office Building
Washington, D.C. 205105

The Honorable John Ratcliffe
Ranking Member
U.S. House Committee on the Judiciary
Subcommittee on Crime, Terrorism, and Homeland Security
2138 Rayburn House Office Building
Washington, D.C. 20515

January 27, 2020

Chairman Nadler and Ranking Member Collins,

The American Society for Pharmacology & Experimental Therapeutics (ASPET) is concerned about the impact to pharmacological research and human health of S. 3201, the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act. This bill extends the expiration of the Drug Enforcement Administration's (DEA) Temporary Emergency Scheduling Order of fentanyl-related substances until May 2021. ASPET strongly believes that classwide scheduling inhibits the very research that will help solve the abuse potential of fentanyl analogues and possibly result in new therapeutic treatments for overdose and addiction.

ASPET is a 5,000-member scientific society whose members conduct essential basic and clinical pharmacological research and are employed by academia, government, large pharmaceutical companies, small biotech companies, and non-profit organizations. ASPET members work in a variety of different fields and their efforts help to develop new medicines and therapeutic agents to fight existing and emerging diseases.

While ASPET understands that the proliferation of fentanyl analogues compelled the DEA to invoke its temporary scheduling authority, using that authority to schedule an entire class of substances creates arbitrary, scientifically unjustified decisions with potentially adverse consequences. Classwide scheduling operates under the presumption that all members of the same chemical class will share the same properties. However, very minor rearrangement of the exact same molecule can change its properties. For instance, naloxone could be considered an analogue of morphine; under classwide scheduling, naloxone might have been placed into Schedule I, yet it is the very antidote to opioid poisoning. To ensure that such unintended consequences do not occur, it is imperative

that the government rely on its scientific agencies (i.e., the Food and Drug Administration, the National Institute of Drug Abuse) to provide input on scheduling decisions.

A Schedule 1 classification—even a temporary classification—increases the regulatory burden on researchers significantly. The cost of licensing, the extended wait time to receive approval, the limitations on supply, the storage requirements, and mandatory inspections all contribute to making research on Schedule 1 drugs burdensome and potentially prohibitively difficult. The delays that researchers face mean they are unable to rapidly respond to the emergence of new drugs of abuse and assist law enforcement and health practitioners by providing information on a substance such as its dependence liability and the scope and duration of its effects. Complicating and further compounding these impediments is the requirement that even with the addition of the DEA code for all fentanyl analogues (DEA Code 9850) onto a researcher's DEA Schedule I registration, they still have to separately apply for approval to conduct research with any fentanyl analogue that has been individually scheduled in order to obtain and conduct research with such a compound. Placing all fentanyl analogues into Schedule I will foreclose research opportunities for all but the small number of investigators that possess a Schedule I license and make it more difficult for those that do. An extension of a Schedule I classification will eliminate an important avenue of research that has the potential to ameliorate the effects of the ongoing opioid crisis, and possibly lead to more effective treatments for pain.

ASPET believes science has a role to play in protecting individuals from the harms caused by drug abuse. To do that, however, researchers need access to those drugs so that they may study the benefits and risks associated with their use. ASPET urges the committee to consider alternative methods to classwide scheduling.

Respectfully,

Wayne L. Backes, PhD
President