ASPET
Transforming Discoveries into Therapies

The Honorable Roy Blunt
Chairman
U.S. Senate Appropriations Committee
Subcommittee on Labor, Health and Human Services, Education, and Related Agencies
Washington, D.C. 20510

The Honorable Patty Murray
Ranking Member
U.S. Senate Appropriations Committee
Subcommittee on Labor, Health and Human Services, Education, and Related Agencies
Washington, D.C. 20510

June 18th, 2019

Dear Chairman Blunt and Ranking Member Murray,

The American Society for Pharmacology & Experimental Therapeutics (ASPET) endorses the *Barriers to Research* section of the House's report accompanying H.R. 2740, and asks that the Senate Appropriations subcommittee on Labor, Health and Human Services, Education, and Related Agencies include the same language in its report. The report language would provide needed clarity on the burdens faced by researchers who work with Schedule I controlled substances.

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.

The *Barriers to Research* section includes the following language:

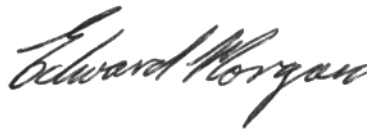
> *The Committee is concerned that restrictions associated with Schedule I of the Controlled Substance Act effectively limit the amount and type of research that can be conducted on certain Schedule I drugs, especially marijuana or its component chemicals and new synthetic drugs and analogs. At a time when we need as much information as possible about these drugs to find antidotes for their harmful effects, we should be lowering regulatory and other barriers to conducting this research. The Committee directs NIDA to provide a short report on the barriers to research that result from the classification of drugs and compounds as Schedule I substances.*

Research on Schedule I substances under the Controlled Substances Act is very heavily regulated, and in certain states handling of controlled substances is more regulated for researchers than the general public. Researchers and staff face stiff federal licensing requirements, in addition to any state-level licenses that must be maintained. Regulation is so strict that a researcher with a Schedule I license must maintain separate registrations for different lab locations, even if both facilities are located on the same grounds. Once in possession of a Schedule I substance, registrants are responsible for the safe and secure storage of the substance down to the milligram. There are also strict regulations regarding the disposal of the containers or bottles of drug after they have been emptied, and having even miniscule amounts left in the bottles during disposal can result in suspension of a researcher's license. In some cases, institutions have had to hire outside counsel to appeal suspensions. The costs attributable to burdensome regulation and enforcement make institutions wary of supporting Schedule I research.

The need for a report analyzing barriers to research is especially timely given recent regulatory efforts by congress. Last year, the House passed legislation that would have created a sixth scheduling classification—Schedule A—and placed synthetic, fentanyl-related substances within it. Last week, the Senate Judiciary Committee held a hearing on the DEA's expiring emergency scheduling action placing all fentanyl-related substances in Schedule 1, where the idea of codifying the order was floated. Actions like these would severely reduce access to synthetic, fentanyl-related substances for research purposes. Research on synthetic, fentanyl-related substances can produce outcomes that could mitigate the harmful effects of these drugs, much as research with opioids led to the development of buprenorphine and naloxone. A report from the National Institute on Drug Abuse that provides a better understanding of restrictions on Schedule I research will help Congress draft legislation that simultaneously addresses the opioid epidemic while encouraging and promoting scientific research that develops a deeper understanding of opioids.

ASPET encourages the Senate Labor-H committee to include the House's *Barriers to Research* language in its subcommittee report.

Respectfully,



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