Catherine M. Davis, Ph.D.
Assistant Professor

Department of Psychiatry and Behavioral Sciences
Division of Behavioral Biology
Hopkins Bayview Medical Center
5510 Nathan Shock Drive / BBRC 3000
Baltimore, MD 21224-6823
410-550-2775 T
410-550-2780 F
cdavis91@jhmi.edu

Comments of Catherine M. Davis, PhD

Health Subcommittee of the Committee on Energy & Commerce

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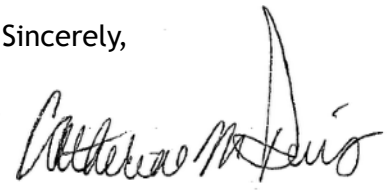
Combating the Opioid Crisis: Helping Communities Balance Enforcement and Patient Safety

Performing research with compounds on Schedules I-V creates hurdles for researchers that must be met before state and federal licenses will be issued, including how they store the compounds, in addition to how the compounds are distributed, tracked, and wasted within the laboratory. These are not trivial concerns and require specialized equipment (e.g., certain type of safe) and inspections (from the DEA, but also from each researcher's institution - which can be more variable and restrictive in their requirements than the DEA). A researcher who has completed and received his/her Schedule I and/or II-V licenses has shown the state and federal governments that they have the necessary facilities and personnel in place to safely use this compounds with minimal risk of diversion. Adding another schedule to this structure would increase the burden already placed on these researchers, slow the progress made in researching these substances, and possibly turn away new (and more senior) investigators from researching these substances due to the regulatory and financial burdens of maintaining these various state and federal licenses.

Given that the DEA's emergency scheduling ability, it is not clear exactly what schedule A will do that emergency scheduling to schedule I would be unable to achieve. The creation of Schedule A creates another regulatory burden for researchers, such that they may need to apply for an additional license in the future or have this sub-schedule added to their current licenses, even though they already have both Schedule I and/or II-V licenses and thus have the appropriate facilities in place to receive, store, handle, and dispose of Schedule I-V substances. Further, this bill could limit the research completed on these compounds by making them harder to acquire at a time when it is imperative that we understand the abuse liability of various opioids and their analogues. It is unclear how the creation of this new schedule or sub-schedule will actually decrease abuse of these compounds. As written, this legislation does not differ substantially from Schedule I or II, such that without this legislation, these compounds would go unscheduled.

Finally, this new legislation removes scientific input from the discussion regarding the scheduling associated with a specific compound or class of compounds. With no input from scientists and pubic health officials this legislation would provide the Justice Department a method to put almost any substance in the Schedule A category, even if the scientific evidence for such a classification is limited or lacking. This fact could potentially place many compounds on Schedule A due to their similarities in chemical structure without sufficient evidence from the scientific community to support their possible abuse.

Sincerely,



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