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Regarding: S. 2701: Federal Initiative to Guarantee Health by Targeting Fentanyl Act

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S. 2701 "Federal Initiative to Guarantee Health by Targeting Fentanyl Act" proposes to amend the Controlled Substances Act (CSA) to list fentanyl-related substances as Schedule I controlled substances. Although laudatory in its intention to reduce the evils produced by the profiteering and health harms caused by the sale and abuse of fentanyl-related substances, it assumes the bill itself could not possibly create harm, and presupposes the current processes under the CSA for controlling abused substances are inadequate to respond to emerging fentanyl-like compounds promptly. Neither assumption may be correct.

Harm could be caused by this bill in that it will inevitably inhibit research with fentanyl-related substances. Research would be repressed because of the added requirements and delays involved with obtaining and maintaining a Schedule I registration by researchers, and of the likely unavailability there would be of fentanyl analogs for research. In this latter regard, legitimate chemical companies will not produce these drugs for researchers because of the strict requirements involved in producing and distributing Schedule I substances. The drugs just may not become available to conduct research with, and research will not get conducted.

Repressed research by this Act could prevent understanding why fentanyls can precipitously commandeer the life-choices of individuals. The reasons fentanyls have such power victimizing individuals regardless of genetic or socio-economic background is unclear and needs to be better understood. Additionally, this repressed research could prevent the development of medications that are themselves analogs of fentanyl, and that could actually be used to treat harms associated with fentanyl-abuse. For instance, naloxone is the antidote used to treat opioid overdose. Naloxone's molecular structure is very similar to that of morphine's; in fact, using an analogous logic for identifying a fentanyl-related substance described in S. 2701, naloxone could be considered an analog of morphine. If all morphine-related substances had been identified as Schedule I substances, would naloxone ever have been developed and to ultimately save so many lives? We do not know, but maybe it would not have been, and thousands would have died as a consequence. There are already examples in the scientific literature of fentanyl-related substances that have opioid-antagonist (antidote) effects, so this concern is very real. Although a compound classified as a Schedule I substance does not exclude it from possible development as a medication, legitimate pharmaceutical companies are not going to begin developing a drug that has such a stigma and carries so many associated legal burdens.

S. 2701 not only will unintentionally repress scientific research, but it is also actively anti-science in nature because it precludes any scientific and medical input from HHS or associated scientific agencies such as NIDA. This clearly bypasses current law (the CSA) for scheduling substances that requires such input. This not only maximizes the likelihood that potentially useful compounds will get overlooked and

not studied, but it becomes a statement to the world that the United States Government considers science irrelevant for making decisions on health-related matters.

The current processes under the CSA are adequate for promptly illegalizing fentanyl-related substances that emerge and become abused. When asked by Representative William Hollis Long II whether the current process for scheduling compounds was adequate, Susan A. Gibson, Deputy Assistant Administrator Office of Diversion Control of the DEA responded during the February 2018 hearing on "Combating the Opioid Crisis: Helping Communities Balance Enforcement and Patient Safety", *Sir, I appreciate your question. And I have to say, and I am just not saying this, since my time at Diversion Control Division, I am so impressed with the people that work there, primarily because we were able to do the class of fentanyls within 2 months. It may not sound quick to some people, but to get that done and get those substances scheduled in 2 months, a whole class, I think that was pretty darn good.* If it only takes the DEA to schedule an entire class of compounds in two months, it could likely take less time to bring singular compounds under control. This does not seem like an intolerable time lag, even if it only brings substances under temporary scheduling that then allows the DEA two more years (three years with an extension) to make a case for permanent scheduling.

S.2701 has noble intentions, but it could cause unexpected harms, and the processes under current law appear to be working. If S.2701 gets passed, research with fentanyl-related compounds will be inhibited, potential medications may not get developed, and scientific input from HHS that is now dictated by law during the scheduling process will be closed off.

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