United States Senate
COMMITTEE ON THE JUDICIARY
WASHINGTON, DC 20510–6275

July 10, 2019

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Secretary Azar:

We are concerned that the Drug Enforcement Administration (DEA) and Department of Justice (DOJ) have not adequately consulted with public health agencies in connection with the DEA/DOJ's recent request that Congress legislatively place all "fentanyl-related" substances into Schedule 1 of the Controlled Substances Act (CSA).[1] We request that, consistent with longstanding practice and the requirements of the law,[2] the Department of Health and Human Services conduct a scientific and medical evaluation of this scheduling request, and that you notify the Senate Judiciary Committee regarding the results of this evaluation.

We are concerned that the failure to engage necessary health experts vests far too much authority to a law-enforcement agency and may result in action that will deter valid, critical medical research aimed at responses to the opioid crisis, including efforts to identify antidotes to fentanyl-analogue overdoses and improved treatment options. We are also concerned that by sweeping a broad set of substances onto Schedule 1, with no scientific consultation, we risk erecting unnecessary research barriers to drugs that may have great potential to society, and criminalizing substances that have no psychotropic effects.

On June 4, 2019, representatives from the DEA, DOJ, and the Office of National Drug Control Policy testified before the Senate Judiciary Committee about legislation to place fentanyl-related substances on Schedule I as a class. At the hearing, Senator Durbin noted concerns that there was no testimony from the Department of Health and Human Services (HHS), including the Food and Drug Administration (FDA), and the National Institute on Drug Abuse (NIDA).

On June 20, 2019, representatives from the FDA, DEA and NIDA provided a briefing to Senate Judiciary Committee staff on "Schedule I Research," but the briefing raised more questions than answers.

First, the briefing made plain that DEA has made no meaningful effort to solicit the views of HHS, FDA, or NIDA. Indeed, a panelist inaccurately stated that "FDA has a minimal role in

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[1] *See* Amanda Liskamm & Greg Cherundolo, *Statement of the Department of Justice and Drug Enforcement Administration for a Hearing Entitled* The Countdown: Fentanyl Analogues & the Emergency Scheduling Order (June 4, 2019) (hereinafter DOJ/DEA Hearing Statement).
[2] *See* 21 U.S.C. §§ 811, *et seq.*

drugs becoming Schedule I." In fact, DEA typically asks FDA to evaluate the medical and scientific validity of drugs placed on Schedule I in order to make permanent a scheduling made under DEA's emergency authority. DEA indicated that it has *always* made such a request in the past; yet the agency did not do so here.

Second, the briefing confirmed the critical need for medical and scientific research of fentanyl-analogues. NIDA stressed that "[t]he research community believes it to be very important for this research to go forward," and that studies must "be done to find medicines, antidotes. . . ." Despite this need, NIDA described "confusion and delays" in the research community about how to perform research into Schedule I drugs, and a "lack of transparency" into how DEA regulates this type of research. Plainly, these barriers should not be erected on an arbitrary basis, without adequate consultation with experts about whether it is appropriate to place the entire class of fentanyl-analogues onto Schedule I in the first place.

Finally, the briefing raised serious concerns about the scope of this request. During the briefing, a panelist said the covered class encompassed "an infinite number of compounds, millions of compounds." Moreover, DEA could not identify any meaningful effort to exclude benign or beneficial substances from its request.

Yet if the class-wide scheduling is enacted, a person found in possession of one of these substances—even one with no demonstrated negative psychoactive effects—could now be subject to harsh criminal penalties established by the Controlled Substances Act and the United States Sentencing Guidelines.[3] Even more alarming, that person would have no opportunity to challenge her charge or sentence even if she is able to prove that the substance in question was completely benign.[4]

Given the urgency of this issue, please respond to the following questions as soon as possible and no later than August 1:

1. Please identify and produce any documents prepared by any public health agency that:

    a. Review, discuss, or evaluate the proposal to schedule all fentanyl-related substances as a class; or

    b. Discuss the impediments to medical and scientific research that may result from the class-wide scheduling of Fentanyl analogues, and any recommendations that may alleviate such barriers.

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[3] *See* 21 U.S.C. §§ 841(b)(1)(A)(iv) (establishing a 10-year mandatory minimum for cases involving "100 grams or more of a mixture or a substance containing a detectable amount of any analogue of N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide"); 841(b)(1)(B)(iv) (establishing a 5-year mandatory minimum for cases involving 10 grams or more of same); 841(C) (establishing a statutory maximum of 20 years "in the case of a controlled substance in schedule I or II); *see also* United States Sentencing Guidelines, §2D1.1, *et. seq.*).

[4] *See* DOJ/DEA Hearing Statement at 5 (noting that class-wide scheduling would eliminate the current requirement that prosecutors must prove that an alleged controlled substance analogue have not only a substantially similar chemical structure as a Schedule I or II drug, but also "has a substantially similar effect on the central nervous system," or that it was intended to have such effect).

c. If no such documents exist, please explain why.

2. Please describe, in detail, the process by which a researcher or researching entity would be able to research fentanyl-related substances if the class-wide scheduling is enacted.

3. Please produce any documents related to NIDA's, FDA's or HHS's review of the substances listed in the original version of H.R. 3537 (114th Congress).

Thank you for your time and consideration. We look forward to your prompt response.

Sincerely,

RICHARD J. DURBIN
United States Senator

MICHAEL S. LEE
United States Senator

SHELDON WHITEHOUSE
United States Senator

AMY KLOBUCHAR
United States Senator

CHRISTOPHER A. COONS
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MAZIE K. HIRONO
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KAMALA D. HARRIS
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