

U.S. House of Representatives
Committee on Energy and Commerce
Subcommittee on Health

**An Epidemic Within a Pandemic: Understanding Substance
Use and Misuse in America**

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Testimony Submitted by:

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Chairwoman Eshoo, Ranking Member Guthrie, Chairman Pallone, Ranking Member McMorris Rodgers, and all members of the subcommittee -- thank you very much for inviting me here today. My name is Geoffrey Laredo. I am a substance use and addiction policy expert who retired from the federal civil service in 2018 after serving for 30 years in a variety of policy positions, mostly within the U.S. Department of Health and Human Services. Twenty-two of those years were at the National Institutes of Health, where I advocated as appropriate for science and scientists, research and researchers. I now have a small consulting practice where I continue to focus on those and related public health issues.

Thank you also for continuing your focus on the addiction crisis in the United States. Not just the “opioids crisis,” or “stimulant crisis,” or “overdose crisis,” but the broad addiction and health crisis. This committee has for several years written and advanced legislation aimed at a broad array of addiction research, prevention, treatment and recovery issues, and it was my honor to work with you and your staffs on those bills. I’m proud to have played a small role in helping you to help the nation, and am honored to be here today to continue our work together.

The addiction crisis, as you well know, is not new. We faced it for years prior to the COVID-19 pandemic, but things have only deteriorated over the past year. I know you have seen the data, especially the alarming increases in overdoses - most due to illicit fentanyl.

In this session of Congress, and at this hearing today, you are rightly considering a range of legislative proposals addressing the addiction crisis. As part of this very broad topic area, I know you are considering the issue of “classwide fentanyls scheduling.” Because of that issue’s timeliness and my experience working on it as legislative and policy staff at the National Institute on Drug Abuse (NIDA), that is where I choose to focus my testimony. I don’t want to get lost in too many details, but I do want to make clear the basis for my opinions.

How should we focus our work?

I think it is absolutely crucial to define what we care about -- what are our goals, and to the degree possible, how do we measure our success in attaining them? As a public policy professional especially focused on public health, what I care about is morbidity and mortality. I believe that every aspect of our nation’s drug policy must be laser-focused on decreasing disease and death. How do we decrease both, and how do we advance evidence-based practices to achieve both?

Is class-wide scheduling the answer?

To my knowledge, there isn't any evidence to show that class-wide scheduling of ANY compound reduces morbidity and mortality. Conversely, we can find ample evidence that properly funded and scaled research programs and evidence-based services will dramatically reduce morbidity and mortality.

Further, to my knowledge, proposals to increase the use of class-wide scheduling either completely or greatly eliminate the role of the health agencies -- most especially the FDA as a regulatory agency -- in this process. This is unacceptable. In my opinion, it should be the health agencies that have the primary, if not SOLE responsibility for deciding how or whether to schedule chemical compounds. I do not support including the DEA in this decision process, and would strongly support removing the agency from the process as it currently stands. Let health and medical authorities do the work of health and medicine - and let's provide them appropriate resources to do that work.

Let's back up and consider conducting research on any schedule 1 substance.

There is an argument in the substance use and addiction field around the difficulties many claim they face (or would face if they did this kind of work) in conducting research using schedule 1 substances. This issue dominated many policy discussions over the last several years of my federal career. The scientific community generally decries an overly burdensome system, and the regulators - the Drug Enforcement Administration (DEA) within the U.S. Department of Justice - generally rejects many of those claims. This argument is NOT focused on fentanyl or "fentanyl-like compounds;" it applies to ALL schedule 1 substances.

In brief: To obtain, handle and conduct research on schedule 1 substances, DEA requires a long list of security measures of any researcher and the institution to which they are attached. Strict researcher and institution licensing is required. They also require certain research protocol reviews to be conducted and approved by the Food and Drug Administration (FDA) before even the smallest addition or change to a research project is initiated. The scientific community has bristled at many of the restrictions and has cited numerous instances of licenses taking significant time and effort to obtain, research being slowed or thwarted, and many researchers choosing not to do this work at all, to avoid these difficulties.

In fact, NIDA Director Dr. Nora Volkow echoed these views in testimony to this very committee in January of last year. She testified: "Obtaining or modifying a schedule 1 registration involves significant administrative challenges, and researchers report that obtaining a new registration can take more than a year. Adding new substances to an

existing registration can also be time consuming.”

When I worked at NIDA, I also received these complaints on a regular basis. We reached out to DEA in an effort to help our field identify some common ground to streamline the process as much as possible. NIDA worked with DEA and FDA colleagues in an attempt to reach some level of compromise. We of course involved senior officials at NIH, HHS and DOJ, and did reach an agreement on ways to try to streamline the process. To my knowledge, these steps have not yet been implemented, and you have seen many of them articulated in documents such as Admiral Brett Giroir’s testimony to the House Judiciary Committee in January of last year (attached).

I am sorry to say that, despite the importance of the issue, my experience working on it was not at all positive. I will elaborate on this point later in my testimony.

How does this specifically relate to opioids?

From everything I have read and experienced, I am unaware of evidence showing us that class-wide scheduling of any schedule 1 substances reduced morbidity or mortality. Given that lack of evidence, I reject these proposals as possible avenues for success in addressing the addiction and overdose crisis in the United States.

Regarding opioids, researchers have clearly shown that similarities in the chemistry of certain compounds does not necessarily equate to similar abuse liability. This is a key point when discussing requirements for a schedule 1 designation, and I refer you to Dr. Sandra Comer and colleagues’ work - they describe things in stark detail (attached). Thus, we find ourselves in a situation where placing an entire class of compounds into schedule 1 would clearly delay and deter research on exactly what the Congress and all concerned with these issues have been begging for: additional and improved solutions for opioid addiction, overdose reversal medications, and other medications development results that we perhaps have not yet even considered. Why would we take a class-wide scheduling action at exactly the time that we need to be increasing and accelerating potentially life-saving work?

My negative experience working on this policy and why it matters.

As the opioid addiction and overdose crisis worsened several years ago, many fentanyl and “fentanyl-like” compounds were in fact placed into schedule 1. This action did not decrease morbidity or mortality. What it did do, as I understand it, was succeed in incentivizing “rogue chemists” to continually create new molecules that might or might not have been dangerous when added to fentanyl or other compounds known to be harmful to human health.

Legislation was also introduced by former congressman Charles Dent of Pennsylvania to administratively place into schedule 1 well over 300 compounds, the identifying information of which was provided to him by the DEA. This move concerned NIDA and FDA for the reasons I've outlined in this statement, and we hoped we could work with the DEA to look more closely at what the compounds actually were, what their abuse liability might be, and generally try to figure out if they were all truly harmful, held promise for some sort of therapeutic development, etc.

After significant discussion, we devised a process whereby scientific staff from NIDA, FDA and DEA spent some months developing a review protocol and actually worked through every substance Mr. Dent listed in his bill. It was difficult, detailed work, and those staff deserved and still deserve our thanks for their tenacity. At the end of the process, only two dozen of these identified compounds were "cleared" for scheduling action. The proposal in its initial form was an incredibly blunt instrument that had little if no chance of success; that is, of reducing morbidity and mortality. Scientific staff struggled to even identify what many of them actually were. This does not mean that over time we might have discovered some that should have been scheduled. However, this is exactly my point: identify what you think is a problem and rigorously do the work to figure out if it is or is not.

This episode was and remains personal for me. On one conference call involving all three agencies, the then Director of DEA's Diversion Control Division told me that I personally, and NIDA as an agency, was "aiding and abetting drug dealers." To say that I took affront to this charge would be a gross understatement. I was working with a large team of dedicated public servants, not to mention the entire scientific research community, trying to figure out what to do to alleviate a public health crisis. Then, as now, I was convinced that health and medicine experts should be making health and medicine policy. Period.

What Should We Do?

I am not naive, and I understand the difficult position the Committee is in as you consider policy and program issues aimed at addressing the nation's addiction crisis. Yes - that includes complicated political issues. I fully recognize that the "optics" of opposing class-wide scheduling of "fentanyls," at a time of high and increasing levels of disease and death, are difficult. I recognize that it is likely that compromises might be necessary. So, despite my strongly-held beliefs outlined in this statement, what might you focus on to make a notable difference right now?

I understand that there is a chance that you will choose to implement class-wide scheduling. Such implementation without addressing crucial research issues would be a setback for our field. IF you move in this direction, and understanding the strong disagreements among interested parties, I strongly recommend that you include in your decision provisions that:

1. For research purposes, treat all schedule 1 compounds as if they were in schedule 2. That change alone should help the research community a great deal;
2. More generally, streamline the process for obtaining a schedule 1 license. This could include, for example, mandated, relatively short approval times; eliminating or greatly reducing the “protocol change” review requirements; elimination of certain requirements within review teams or institutions regarding who has to hold what kind of license, etc;
3. Do not create separate licensing and process requirements for different classes of compounds. As I said, this is a schedule 1 issue broadly, NOT just a fentanyl issue. Through this process you can and should make changes that will facilitate research on ALL schedule 1 compounds; and
4. Facilitate the de- or rescheduling of compounds when scientists verify that this is justified.

Members of the Committee and Subcommittee, you have focused much time and effort on these issues over the past several years. So have other congressional committees. If we are serious about this HEALTH issue, then I think you deserve to take and have the lead on legislation guiding those efforts.

As I outlined earlier, I spent my entire federal career working in substance use and addiction policy. Twenty-two of those years were at the National Institutes of Health.

I believe in science.

I believe in evidence.

I believe our goal in advancing evidence-based drug policy is to reduce morbidity and mortality. We should measure everything we do through this lens.

We should listen to science and scientists, and help them do their jobs. We should be thoughtful, especially in the face of significant disease and death. We should make the wise choice and avoid the knee-jerk reaction of just trying to “ban” substances that might or might not be harmful, and might or might not be helpful. By doing so, we will help find answers that will improve conditions in the field.

Thank you so much for the honor of sharing my views with you. I would be glad to discuss any of these issues and answer any questions you have.

Attachments for the record:

1. Comer et al article: *Potential Unintended Consequences of Class-Wide Scheduling Based on Chemical Structure: A Cautionary Tale for Fentanyl-Related Compounds*
2. Dr. Charles France letter of 29 November 2019
3. Dr. Patrick Beardsley letter of 27 November, 2019
4. Testimony of Admiral Brett Giroir, January 2020