Attachment 1
Additional Questions for the Record, The Honorable Frank Pallone, Jr.

1. How will passage of the MAT Act affects efforts to treat opioid addiction in the Emergency Room? How important is it to intervene at that point of care?

Intervening in the emergency department (ED) in substance use disorder (SUD) is critical. The quicker you can get someone to start MAT and get them into treatment or closer to treatment, you've kept them alive and away from playing Russian roulette with the fentanyl polluted drug supply. Improving and maximizing access to treatment is critical in treating opioid use disorder, anything that does that should be embraced. SUD intervention needs to happen at any and every point of contact.

However, it is important to note that the MAT Act removes the burden that was put in place in the first place by the federal medical regulatory community (NIDA/HHS/DEA/FDA) on physicians to prescribe buprenorphine. That requirement for a special certification to prescribe buprenorphine had the opposite effect of what the medical regulators intended, instead of increasing knowledge around and increasing the prescribing of buprenorphine, it stigmatized it and put in place a significant regulatory burden that has gone on to cause it to be massively underutilized. This underscores the difficulty in being able to predict the unintended consequences of well intended legislation and regulation.

Buprenorphine especially when given with naloxone in its formulation (as suboxone) is effectively the safest opioid medication that could be prescribed. There is little to no euphoria from it and with naloxone ingested in combination with it, there is almost no chance of overdosing and dying from respiratory suppression.

It never made sense to me that the federal government decided to put heavy restrictions on prescribing the safest opioid while allowing anyone and everyone to prescribe as much oxycodone, oxycontin and almost every other opioid (except methadone) as we cared to. The FDA even changed the indication for opioids from only short acting to ok for long term use without any research to back it up (by a guy that went from his job at the Center for Drug Evaluation and Research at the FDA to a job at Purdu Pharma which then went on to make tens of billions off that simple indication change.)

Starting in 2014, I was the physician architect of the Wisconsin prescription opioid reform strategy and designed. I worked with State government and the medical community to reverse the tide of opioid overprescribing that had started in the 1990's from big Pharma fully endorsed by the federal medical regulatory community (chiefly HHS, the Joint Commission for Hospital Accreditation and the Federation of State Medical Examining Boards) that urged physicians to prescribe as many narcotics as the patients asked for (and at times threatened those who didn't.) They asserted that patients pain was being under treated, pain was the fifth vital sign and patients had a right to have narcotics for their pain - (which all unbelievably were uncovered to have started as Purdu marketing strategem.)

The policies, laws and regulations I put in place in Wisconsin in 2016 gave physicians back the tools and empowered them to go back to prescribing opioids as they saw fit clinically, which has happened. There has been a cultural awakening amongst physicians who are getting back to prescribing opioids judiciously-the way we used to- as little as is humanely possible. Equally or more importantly there has grown an awareness of society in general that opioids are not harmless and potentially very dangerous. Deaths are now driven by illicit fentanyl pouring into the country poisoning our kids, not from overprescribing by physicians.

The problem with centralized federal medical regulation is that it always seems to be a one size fits all answer. It is usually well intentioned, and meant to solve a problem that's real. But there are almost always unintended outcomes, many times that happen to be the opposite of what the original intended outcome was. Medical regulation and oversight needs to happen at the state and local level as it is already set up to be. I hate to say it, but the federal government just needs to get out of the way and not fix what isn't broken.

2. As a doctor of Emergency Medicine, can you tell me what education on addiction you received in medical school? Residency?

The training to become a physician is the most rigorous of any profession in our society, as it should be. I started preschool at age 4 and finished my residency at age 30 with no time off. Physicians have a culture of constant re-education, staying up to date with the most current treatment options and therapies. We are self directed learners, constantly looking at our knowledge gaps and learning what we need to to give the best care to our patients.

My training in medical school included many hours of pre-clinical academic study of psychiatry and addiction medicine, then a month or more of clinical psychiatry with addiction medicine.

Emergency medicine training is full of lectures on substance abuse and addiction, along with the actual work of caring for innumerable hundreds of patients who present to the academic training institutions with diseases that are either directly or indirectly related to substance abuse. I'd make a guess that that number is at least 10% of the patients I saw.

3. Do you agree that more physicians, especially new physicians entering the workforce, should have access to continuing education and training to identify and treat substance use disorders?

But we do, there is a large and growing body of education on SUD. It seems to me the more relevant question to ask is whether the legislature/federal government or it's agencies should mandate more continuing education around such training? Because as I've stated, physicians are amongst the most educated members of society (looking at years of and time spent in preparation of independently practicing medicine) and are in a much better position to know their educational and training shortcomings, and to know the path to rectify any knowledge gaps or deficits than anyone else, especially the government. The opportunity cost for time we spend on mandated education that we really don't need is less time for the education and trading we really need.

My daughter is a med student who just finished her academic pre-clinical work and she's already had significant substance use disorder (SUD) education and training, way more than I had when I was in her shoes 30 years ago. Medical education is set up to adapt quickly to new treatments, best practices, and knowledge deficits.

The government needs to be very cautious when trying to impose it's own idea as a solution to an incredibly complex problem. The main problem that surrounds SUD is tied into the very nature of the disease itself. A significant problem is getting those unfortunate patients who suffer from it to accept the treatment that is available. The old adage of how you can lead a horse to water but not make him drink certainly applies.

To be quite clear, I'm certain that the main issue with SUD treatment is not that physicians haven't been taught or don't have access to continuing education and training to identify and treat SUDs.

The other important factor to consider is the way any federal educational mandates would be rolled out. Again as with any legislatively mandated medical reform, it would almost invariably be a one size fits all solution that would attempt to modify the behavior of a tiny percentage of physicians who do have a lack of knowledge of SUD treatment. The majority of physicians do practice above the minimum level of competence, and if they don't, then the solution best comes from the system that is already in place to provide medical oversight and regulation. This is the state medical boards, specialty licensing boards, and hospital system credentialing and quality boards, not legislators and government agencies.

4. What evidence is there that FRS scheduling has led to a decrease in the appearance of new FRS substances? Please give us specific numbers.

The main evidence and source of information comes from In the 2021 GAO report on FRS page 23 of 98 it says this :

"Our analysis of DEA data on these reports show that encounters with fentanyl analogues that were not individually scheduled by name—which is what class-wide scheduling was intended to target—decreased from 7,058 reports in 2016 and 2017 to 787 reports in 2018 and 2019."

https://www.gao.gov/assets/gao-21-499.pdf

5. In response to a question from Chairman Guthrie at the January 11 roundtable, you mentioned rapid descheduling of substances that are inert and not biologically active. Do you agree that FRS found to have a lower risk or no risk to public health should be rescheduled or descheduled, respectively?

I do agree that the ability to rapidly de-schedule an inert FRS should be included in FRS legislation that moves in Congress. The reason rapid de-scheduling wasn't included initially in the Wisconsin FRS language is that the language was so specifically targeted to include only known bioactive modifications that any trafficked FRS would certainly be bioactive. Which turned out to be true. The data from research done of FRSs in the 5 years since have borne out and validated this. The fact is that there are no inert FRSs. All FRSs encountered to date by DEA are potent opioid stimulators. One of them is 7,000 times more powerful than morphine, making it the 3rd deadliest chemical weapon, behind carfentanil, tetanus toxin, and botulinum toxin.

So the idea that there could be a prosecution, conviction and incarceration for trafficking an inert FRS is purely theoretical and doesn't seem possible, except the theoretically. This theoretical argument is however being used by the major groups opposing FRS scheduling who are in fact mainly criminal justice reform and drug reform legalization based activist organizations.

The power of FRS scheduling and what makes it proactive and preventative is in the fact that it removes the existing incentives for Chinese chemists and translational criminal organizations

from creating new FRSs and stops them from existing in the first place. I've heard it argued that FRSs shouldn't be subject to the same penalties as other schedule 1 substances and this concerns me. That would re-incentivize the chemists and cartels to create and traffic new FRSs because the penalty would be less than for illicit fentanyl and other schedule I controlled substances. The effect would be to significantly degrade the powerful proactive and preventative effects.

Thank you for your questions. I'm happy to discuss further as needed.

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