Thank you Chairman Goodlatte, ranking member Nadler and members of the committee for the opportunity to testify, as well as for your leadership in fighting the opioid epidemic. I have worked for nearly two decades as an emergency physician battling the opioid epidemic and serve on the Wisconsin Medical Examining Board and Controlled Substance Board. I am the physician architect of the Wisconsin prescription opioid reform strategy and have become a subject matter expert on opioid scheduling. Following is a legislative solution now working in Wisconsin and which could be modeled and implemented federally.

But first, a brief story about a young man named Archie Badura. Every Sunday, we sat next to Archie and his family in church, where he was an altar server alongside my daughters. Archie got hooked on marijuana first, then prescription opioid pills, heroin next, and eventually fentanyl – a much too familiar slide. The last time I saw Archie alive, he was my patient in the ER. I had to resuscitate him with narcan after he overdosed on fentanyl. Before discharging him, we pulled out a body bag, un-zipped it, and pretended to fit him for it. It was a wake-up call. Archie became serious about getting clean and started following recovery principles. He told his family he was going to beat the odds and not end up in a body bag. He stayed drug free for 6 months. He eventually relapsed on fentanyl and died at the age of 19. His mom, Lauri, vividly remembers Archie being zipped into a body bag – identical to the one he had been shown months earlier. In his honor, Lauri founded SOFA -- Saving Others For Archie --and now helps others who are desperately trying to help their loved ones.

It is incontrovertible that the increased availability of prescription opioids has fueled the epidemic. As a medical regulator, I have spent countless hours working to identify and implement best practices. For starters, we need more judicious prescribing practices. We are doing this in Wisconsin -- not with top

down mandates, but through education and partnerships with the medical community. I refer to it as the “Wisconsin Strategy.” Simply put, it is a strategy based on education using evidence-based medicine. After close interaction with and guidance from leaders in the medical community, a series of specific and targeted bills were passed unanimously by the Wisconsin legislature as part of the HOPE (Heroin Opiate Prevention and Education) Agenda. Key components include: medical board promulgated opioid prescribing guidelines based on CDC guidelines; medical board mandated CME reinforcing the state guidelines; and targeted, required PDMP (Prescription Drug Monitoring Program) review prior to controlled substance prescription accompanied by cutting-edge PDMP design and reform.

The mandates for continuing opioid medical education and PDPM review are not permanent. While scheduled to sunset in a few years, the medical examining board could decide to continue them, if needed. The PDMP reforms started with a complete redesign based on the end-user experience and input. The result is an unbelievably useful tool, with cutting edge software design and functionality, with feedback and improvements ongoing. Whereas it would typically take 4 minutes to obtain data on the legacy PDMP software, the redesign with direct electronic medical record integration provides access in as short as 4 seconds. Because the system is now so easy to use and functional, one would be hard-pressed to think it would go away once the mandatory review expires.

Stakeholders have also created a state health system coalition in Wisconsin that connects all relevant entities, including professional associations, state government agencies, professional examining boards, the legislature, the Attorney General, insurance companies, and provider groups to name a few. The

idea was to imbed prescription opioid reforms into the fabric of the practice of medicine. It is reform at all levels and in a coordinated fashion.

Where Congress has – and can continue to be helpful – is in law enforcement and in providing flexible funding for states to invest in communities where the dollars are most needed. When government intervenes too much, for example, with the development of the pain scale and pain as the fifth vital sign, there is too much room for unintended consequences. Case in point: the governmental-endorsed mandate that pain was under treated and that chronic non-cancer pain should be treated with opioids. Dating back 20 years or so, this change in medical education and prescribing practices directly led to a 400 percent increase in opioid prescribing and has certainly contributed to the opioid epidemic we are facing today.

By far, the deadliest front in the opioid war is the danger posed by the creation of fentanyl-related substances. These deaths now surpass heroin deaths. The lethal dose of fentanyl is 2mg, which means there could be enough fentanyl in this 5 lb bag to kill more than 1 million people. In fact, fentanyl variants are so deadly, they can be used -- and are classified -- as chemical weapons.

The “bad guys” use loopholes in the existing scheduling laws to create new legal fentanyl variants. These untested chemicals are then produced -- mostly in China -- and introduced into the opioid supply. As our prescription opioid reforms take hold and the medical community returns to more judicious prescribing practices, resulting in a ratcheting down of prescription opioids, the market for counterfeit pills will continue to explode. Most illicit opioid users have no idea what they’re consuming. They would much rather take a pill they believe to be manufactured by a pharmaceutical company than resort to ingesting

powder from an unknown source. With the advent of counterfeit pill production, they believe they're taking a "safe" trade-name manufactured pill, when actually it's a fentanyl-related counterfeit substance. These pills can be alarmingly stronger than what they are purported to be, up to hundreds of times stronger.

Many in the new wave of fentanyl deaths are from these counterfeit pills and not from powder or IV use. The singer Prince died from counterfeit Vicodin pills that were actually fentanyl. And in 2016, during the span of one weekend in Milwaukee, there were 12 deaths from counterfeit pills containing cyclopropyl fentanyl. At the time, this was not controlled and could be bought legally on the internet.

The current way fentanyl-related substances are scheduled, the DEA and state-controlled substance authorities have to wait to schedule until bioactivity is proven, usually through multiple deaths occurring from the same fentanyl variant. The DEA then invests time and energy into an analysis to make the temporary schedule permanent, when, in fact, the agency is fully aware of how deadly it is. Until proven to constitute a danger to the public, the fentanyl variants are legal and can be manufactured and shipped legally (and purchased on the internet). It does not make sense to wait for countless more lives to be lost in order to control/schedule the fentanyl variants. In the US alone last year, 64,000 individuals died of drug overdoses; of this number, more deaths were caused by fentanyl- related substances than from heroin. It is why it is imperative that all methods to decrease the supply must be pursued.

As well, the penalties must provide adequate deterrent effects and mitigation of the imminent hazards to the public. Lack of strict criminal accountability may be problematic because very small amounts (milligrams and even micrograms) may

be re-distributed and cause overdose and death to others. Typically, larger amounts of drugs help prove possession with intent to distribute; but this is lost with fentanyl because a small amount goes a long way. One Kg of fentanyl can translate to one or two million doses of fentanyl. Manufacturing costs in the $5,000-$10,000 range for traffickers can generate upwards of $20 million in profit. A recent sentencing for a fentanyl trafficking case in New Jersey in which traffickers had over 45 Kg of fentanyl – an amount that can be carried in a suitcase -- is sufficient to kill 20 million people.

As we saw this tidal wave coming in Wisconsin, we worked closely with the DEA to get ahead of it. We created and enacted scheduling language now being modeled nationally. “Act 60” – or the SOFA Act (Stopping Overdoses of Fentanyl Analogs in homage to Saving Others For Archie) – controls, by structure, all likely and possible bioactive chemical fentanyl modifications. This novel, catch-all legislative language allows us to schedule proactively and not wait for loved ones to die before we can schedule each newly modified fentanyl variant. It unplugs the entire fentanyl machine.

Clear control of all possible fentanyl substances (other than ones with legal medical applications) will impact the development of new varieties around the globe. This is evidenced by what happened when China controlled specific analogs; they literally dried up the world supply of those specific analogs almost immediately. The hope is that SOFA Act’s catch-all language will be copied by foreign scheduling authorities as it gives law enforcement an urgently needed and powerful tool to fight the opioid epidemic. It will also save investigatory resources and manpower. But the language needs to be written into US code for the best permanent scheduling solution.

The week after Wisconsin enacted SOFA, the DEA published identical language in the federal register as the method of federal temporary scheduling. Chemists around the world, and in particular China, must be paying attention. Since the DEA announcement of intent to schedule using the SOFA language 6 months ago in Wisconsin and across the nation, no new fentanyl-related substances have been found by the DEA. In contrast, in the prior 2 years, DEA had scheduled 17 new fentanyls, representing hundreds of deaths.

Another reason for Congress to act is credibility when making requests to China, Mexico and others. If we desire other nations to take bold steps, we must demonstrate bold steps here at home. According to the 2017 DEA Threat Assessment, the majority of fentanyl-related substances coming into the US are manufactured legally in China, and then trafficked here. This reality demonstrates why the SOFA language is so critical: it controls the class of all possible fentanyl analogs in its entirety.

I would just add an important note: the SOFA language is clear with regard to the research community and its critical role. Research registrations for academic and scientific investigation will continue to be available for any Schedule I substance, including any new fentanyl-related substances. There would be no change in the ability of researchers to access and study Schedule 1 fentanyls. They do so currently with special use authorizations.

While there is a good version of controlled substance scheduling language in another bill that could be useful in addressing novel synthetic drugs as they first emerge like synthetic cannabinoids and club drugs like ecstasy, it is not the best response to fentanyl substances. Fentanyl substances are too dangerous and deadly and should be controlled as Schedule I and have strict penalties

attached to them. With regards to cutting off fentanyl-related substance supply, the catch-all language in the SOFA bill is the strongest and most direct path.

The DEA should be applauded for publishing the catch-all temporary scheduling of all fentanyl-related substances in the federal register, but it is not sufficient to address the very real threat this nation faces; it is temporary and a stop-gap. Congress must move to enact the catch-all language and make this critical change permanent. We have done so in Wisconsin and believe it should be modeled at the federal level. Many thanks to Congressman Sensenbrenner and Senator Ron Johnson for their leadership on this.

I want to leave you with the picture below -- lethal doses of heroin, fentanyl, and carfentanil (the most deadly and concentrated fentanyl variant).
This is why strict controls must be put in place – now. There is no time to waste