TESTIMONY

OF

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BEFORE THE
UNITED STATES SENATE
COMMITTEE ON HOMELAND SECURITY AND GOVERNMENT AFFAIRS
FIELD HEARING

"BORDER SECURITY AND AMERICA'S HEROIN EPIDEMIC: THE IMPACT OF THE TRAFFICKING AND ABUSE OF HEROIN AND PRESCRIPTION OPIOIDS IN WISCONSIN"

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Chairman Johnson, Ranking Member Carper, Senator Baldwin and other distinguished Members of the Committee:

It is an honor and privilege to testify, and I thank you for the opportunity to address you today on behalf of the patients and doctors in the State of Wisconsin.

I serve as Vice Chairman of the State Medical Examining Board, where I am also the Controlled Substance Committee Chairman. I work as a full-time Emergency Physician, and have over 15 years of practice in the suburban Milwaukee area. I am also EMS medical director for many of the EMS agencies in the communities surrounding my hospital. In these roles, I have been both in the trenches intimately involved in the treatment of heroin and prescription drug abuse, as well as helping lead the State's response on a regulatory and policy level. I would like to share some of my experiences on this complex issue, what we are doing in Wisconsin in the battle, and finally propose a few small changes to federal code that you as federal legislators could do to help support our communities in battling this scourge.

As is now becoming common knowledge, there is an epidemic occurring from the use of prescription opioids almost invariably followed by heroin in this country. Across the United States you are statistically more likely to die of an accidental prescription drug or heroin overdose than from a motor vehicle crash. In my practice as an emergency physician in a small suburban hospital in it is not uncommon for me to see one or more opioid overdoses per week, and of the 20 or so patients I see per day, usually 3-4 are on chronic opioid medications. The diagnosis of opioid use disorder has a mortality and long term survival prognosis similar to a diagnosis of cancer. Over 80% of the heroin use in general and nearly all of the teenage and young adult use starts with prescription drugs. The direct and indirect costs to our society is astronomical, but is easily dwarfed by the the impact of the pain and suffering experienced by the users and their families. On average across America, someone dies from an opioid overdose every 24 minutes. Quite simply, It is the public health crisis of our times.

To speak frankly, there can be no doubt that the sources of the supply of opioids stem from the ease of availability of prescription opioids due to over-prescription by doctors themselves. We physicians need to own our part in the problem. It is incontrovertible that over 80% of heroin users start first with prescription opioids. Almost inevitably, when the pills are too expensive and the person is opioid-dependent, the next step is to move into heroin use. With the relatively cheap cost of heroin trafficked over the southern border and with synthetic opioids such as fentanyl and other synthetic opioids coming by mail order, Wisconsin is awash in opioids.

As an emergency physician, I unfortunately see the carnage up close and intimately, and on a far too frequent basis. I have been witness to heartbreak beyond comprehension and have had to tell innumerable families that their beloved family member will never come home. I will never forget sitting next to and telling a good friend and nurse colleague from my very emergency department that the patient in room 3 was dead. I could not save her own son from a prescription drug overdose. My friend Carolyn's son Josh had started on prescription opioids, then moved to heroin, and went back and forth based on what he could beg, borrow or steal. Eventually one morning Josh was found dead in his underwear in the front yard of a drug house and brought to the ER at which his mom and I worked. The paramedic that was called to the scene and tried to resuscitate him and was a close family friend and knew Josh from when he was a baby. What can be said to a mom who just lost her child? Sometimes all I can do as an

emergency doctor is to bear witness to the pain and suffering in my community. As far too many reading this are aware, there are almost no families untouched by the scourge of addiction.

It is very important when looking for the cure of a disease, to understand the causative factors that led to the development of the disease in the first place. To be honest, as long as healers have been using opioids to relieve pain, there has been abuse. As physicians, it is a fine balance we walk while attempting to alleviate the suffering of our patients while at the same time being responsible prescribers and not enable the devastation and destruction of addiction. The surge in abuse was and is made possible by the increased availability of prescription drugs directly related to regulatory changes that occurred in the late 1990's. The origins come from the idea that pain was under-treated and physicians should be more generous with opiate prescriptions. You will all recognize one outcome as the pain scale that is incessantly asked of you when you visit your doctor. As with many regulatory mandates in healthcare, it started as a well intentioned idea, but has had devastating unintended consequences.

Traditionally, and up until the early 2000's, opiates had not been used in cases of chronic non-cancer pain. But then the "Pain as the fifth vital sign" initiative was released federally (coincidentally first by JCAHO, CMS and at the VA), which artificially alters literally all patient encounters and keeps patients focused on their pain. It is well established that patients can be comfortable while having moderate pain, and the pain scale itself has never been proven scientifically to be an empirically sound tool for guiding pain treatment and management. At the same time the pain scale was federally mandated, there was also a very effective legislative push by pain advocacy groups, pain specialists, and drug companies to alter state statutes that prohibited the use of opiates for chronic non-cancer pain. Also occurring concurrently new extremely potent and potentially addictive long acting pain medications like Oxycontin and MS-Contin were released to market. All of these lobbying effects were extremely successful, and by 2003 there were only 5 States that had not changed their regulations and/or statutes to allow more permissive use of opiates in cases of chronic non-cancer pain. The effect was to open the flood gates and the amount of prescribed opiates has increased explosively since. The scourge of the prescription drug epidemic is a direct unintended consequence of these changes.

I cannot state strongly enough that the urge to try to do something and address this crisis by federal legislative solutions needs to be resisted. The lions share of healthcare regulation occurs at the State and local level, and as such, most of the responsibility for addressing the prescription drug epidemic will come from the States, hospital systems, and physicians themselves. It is very important to remember that in the first place, most agree that the spark that ignited and continues to fuel the epidemic was born out of federal regulatory effort.

In Wisconsin, we are blessed to have the insightful leadership of State Rep. John Nygren and Attorney General Brad Schimel. They understand that the most useful role of government is to provide and encourage the best environment where the healthcare providers and systems themselves can find the solutions that work in their own communities-for both the prescription opioid as well as other problems. We have been involved in the NGA Best Practice Policy Academy for Reducing Prescription Drug Abuse, and have extensively studied what other states have done and looked at what legislative and regulatory reform has worked and what has not, in order to come up with the best possible regulatory reform for our state. State Rep. Nygren has led the state with phenomenal innovation and insight in crafting and shepherding the passage of wise legislation that really addresses the root of the problem while remaining as least-invasive as possible. Rep. Nygren has real skin in the game with a daughter who’s battled opioid

addiction, and he's committed to finding and implementing the best possible solutions. He has sought out stakeholders from all areas of what his legislation touches and asked real questions and listened and adjusted his legislation accordingly. Attorney General Schimel has been visionary in attempting to find real solutions to this crisis, not just lay on the heavy hand of law enforcement. I remember when he was the Waukesha County District Attorney almost 7 years ago and came to my hospital and was educating the doctors and staff about the crisis that was occurring in prescription opioid and subsequent heroin abuse, a proverbial canary in a coal mine. He has always said we can't arrest our way out of the epidemic, a comprehensive approach was needed. He made impacting the opioid crisis a plank of his campaign for election to the Attorney Generals office and it is a cornerstone of his work to this day.

At the State policy level, under the leadership of AG Schimel, Rep. Nygren and me, we have established the Wisconsin State Coalition for Prescription Drug Abuse Reduction. This is a collaborative impact practice model that leverages the strengths of the members of the coalition to position the state's resources in a way to best address the prescription drug abuse issue and any intended and unintended consequences from the regulatory and legislative changes. Members of the coalition represent all the stakeholders in healthcare: Legislature, Attorney Generals office, Medical/Nursing/Dental Exam Boards, Wisconsin Medical/Nursing/Dental/ Pharmacy Societies, Hospital Association, addiction community, treatment community, public health community, Department of Human Services/Medicaid, insurance providers, rural hospital cooperatives, and most importantly representatives from almost all the health systems across the state large and small. We are looking at what can be done to provide support to the doctors in the trenches and the patients to whom they are giving care. We are looking at ways to find and share best practices system to system and implement the reform from within the systems and medical community ourselves with the least collateral damage to those already addicted. We understand that the true solutions will come from within the communities and health systems themselves and have worked to engage stakeholders from every level.

In looking at causes of over-prescription we have seen that we are dealing with 2 main types of prescriptive behavior. The first and by far most common is the 99% of prescribers that are meaning well, but whose arguably "overly generous/loose" prescriptive practices have helped lead to patient addiction directly and also indirectly by "leftovers" that are then abused. On the other hand, there are the prescribers that know what they are doing and intentionally profit from the prescribing--I see them as the "doctor dealers". Both groups are completely different and require different measures to address them effectively. The "doctor dealers" will and should be addressed by law enforcement and state medical examining boards. State legislative and regulatory reforms are being instituted across the country at the state and local level which are significant improvements.

We have come up with 2 areas that could significantly help in fighting the scourge of prescription drug abuse, that would require a change to US statutory code. I will go into detail below.

1)The biggest "bang for the buck" federal legislative solution that would likely have the largest impact in curbing excessive prescriptive behavior would be for some type of legislative change that would restrict federal agencies/entities from being able to fiscally mandate use of the pain scale. It has been my privilege to work with Senator Johnson's staff in helping determine what federal legislative changes would be most effective in this battle. We are extremely excited to hear that Senator Johnson has just released a bill last week that does exactly that! The bill

already has broad bipartisan Senate support and is the PROP act (Act to Reduce Pressure to Overprescribe Painkillers). Sen. Ron Johnson was joined by his colleagues Sens. Joe Manchin (D-W.Va.), John Barrasso (R-Wyo.) and Richard Blumenthal (D-Conn.) in introducing the bill. Johnson's bill is the Senate companion to H.R. 4499, a bipartisan measure introduced by Rep. Alex Mooney (R-W.Va.) that has been endorsed by the American Medical Association, American Hospital Association, American Society of Addiction Medicine, American Academy of Neurology, American Osteopathic Association, Physicians for Responsible Opioid Prescribing, Hazelden Betty Ford Foundation, Friends of NIDA, and American Association of Orthopedic Surgeons.

Let me explain how the use of "the pain scale", "pain as a fifth vital sign", and the use of pain-related quality metrics in medical/hospital system reimbursement has significantly altered the physician patient relationship and led to over prescription. It has literally altered every single doctor patient interaction. As it stands, CMS is responsible for the 2 main parameters that are used to measure "Quality" but also have the unintended consequence of increasing the amount of opiates prescribed overall. The main item is the PQRS (Patient Quality Reporting System) item 0420- Pain Assessment and Followup. It looks at the percentage of patients aged 18 years and older with documentation of a pain assessment through discussion with the patient including the use of a standardized pain tool(s) on each visit and documentation of a follow-up plan when pain is present. The second CMS parameter is from the HCAHPS (Hospital Consumer Assessment of Healthcare Providers and Systems) --item 0166-Question on Pain Control. These have very significant downstream impact on prescriptive practices.

The effect of these financial reimbursement based mandates has been the unintended consequence that pain is brought up again and again in every single patient encounter in the country. Pain is a completely subjective symptom, and is highly variable. When a provider is artificially forced to ask all patients again and again to rate their pain, this causes the patients to focus on their pain unnecessarily increasing the subjective experience of it. When you add in making the provider responsible for formulating a plan to address this elevated non-scientific pain measure, this completely changes the encounter. It is invariably skewed to the almost inevitable outcome that more narcotics will be prescribed. Having to use the pain scale introduces questions in a way they would not normally be asked. It is not useful to me, nor is it my natural practice, to be forced to always ask patients repetitively what their pain level is. It is much more natural to instead ask about pain without making focusing completely on it. I prefer to ask about how comfortable the patient is, and if they need/want anything else done to be more comfortable. Many patients when asked if they want anything more for their pain will respond "No", even with a pain rating of 7. The current federal reimbursement pain measures mandate that we address the patients pain and establish a plan to bring it down if it hasn't numerically changed after treatment, even if the patient is comfortable enough with the treatment and doesn't ask for further pain treatment.

Having to use the pain scale is like having a federal regulator in the room of every single patient encounter asking the patient over and over what their pain level is. I have given the example of 6 research studies that back up the idea that not only does the pain scale not symptomatically improve pain control, it is actually responsible for significant problems with over medication and over-prescription. Again, another example of unintended consequences to a well-intentioned idea. Now that we know how ineffective and potentially damaging it actually is, it is time to do away with the pain scale. Below I point to several evidence-based research with some interesting titles:(1)"Increased Adolescent Opioid Use and Complications Reported to a Poison Control Center Following the 2000 JCAHO Pain Initiative", (2) "Kindness Kills:The Negative

Impact of Pain as the Fifth Vital Sign", (3)"Measuring Pain as the Fifth Vital Sign Does Not Improve Quality of Pain Management", (4)"Government Regulatory Influences on Opioid Prescribing and Their Impact on the Treatment of Pain of Nonmalignant Origin", (5)"Has The Pendulum Swung Too Far in Postoperative Pain Control?" ....These articles are eye opening and give credence to what almost every provider instinctively knows. I can provide links to the articles as needed. Just ask any doctor, nurse or medical assistant--It is well past time to do away with the pain scale! Thank you Senator Johnson for starting the process! We have had more than enough of the harmful consequences of over-regulation.

That being said, it will also be very important to address the role and effects that JCAHO has played and continues to play in this epidemic. JCAHO is an abbreviation for Joint Commission on Accreditation of Healthcare Organizations. Only hospitals that have been accredited by JCAHO can receive payments from government plans like Medicare and Medicaid, making the group's standards highly influential. is a vital accreditation to have, and not having it could mean going out of business.

To me in an eerie coincidence, I will use the emergency department I work at (Oconomowoc Memorial Hospital) as an example of the how this JCAHO issue plays out. Our emergency department has been able to achieve 10 consecutive years of patient satisfaction in the 95th percentile or above (usually the 99th) -every quarter in a row for the past 40 quarters measured by the Press Ganey company. There is literally no other ED in the entire US that has been able to accomplish this. I'm not saying it to brag, just to underscore that our patients are most likely very satisfied with how their pain is being managed. But in November, we had our routine JCAHO survey. They found that we were not documenting having asked our patients follow-up questions after pain medications were given, and we were cited for not being compliant. Coincidentally this measure comes directly from the Affordable Care Act, it is actually the piece about pain quality measures that Sen. Johnson's bill would repeal. Our hospital was given one quarter to get our compliance up to 90%. As you can imagine, providing emergency care is crazy most of time, and we are constantly running around time-managing what we really need to do to address the patients true needs. Well, we did not meet the 90% compliance goal, and we were just told that due to our 75% compliance, we did not meet the pain reassessment documentation requirement. Due to that alone, our JCAHO accreditation is at risk for the entire hospital. If we don't get the accreditation, it would likely cost the hospital huge resources (from tens to hundreds of thousands of dollars) to undergo a new survey and get reaccredited. This is for an emergency department that literally has the highest patient satisfaction in the country. Incidentally, our patient satisfaction continued to remain 99% for that same period. Isn't it common sense that our patients are most likely getting their pain management needs addressed? And the threat is to lose accreditation for the entire hospital. That is just one part of the craziness of the current state of excessive bureaucratic regulation in the day to day work of medicine, fighting the regulatory requirements to provide the care our patients deserve. We are seeing the bureaucratization of medicine as never seen before.

Coordination with JCAHO and healthcare quality and patient satisfaction measuring companies is also vital to help reverse the unintended consequences that the emphasis on pain measures has had, and needs to be concurrently undertaken along with prompt passage of the PROP Act. It is time remove the government from the middle of the doctor-patient relationship. In a related note, more than five dozen nonprofit groups and medical experts sent a letter this Wednesday to the Joint Commission asking it to revisit its standards for pain management. The medical and

addiction community are unifying behind the dismantling of the “pain as a fifth vital sign” movement.

2)The second area of potentially very useful federal legislative change I’d like to address is a way to decrease the supply of "leftover medications". One of the most impactful ways to address the current opioid crisis is to simply decrease the availability/supply of opiate pills prescribed. It is estimated that 80% of heroin users start by using prescription opiates first. It is also estimated that over 50% of prescription opiate abusers obtain their pills by diverting them from a relative. Many times kids end up stealing them from pill bottles kept from old prescriptions (ie raiding mom and dad's or grandma's medicine chest). There are over 9 billion (with a “B") individual Vicodin pills prescribed in America alone every year. It is estimated that only 1/3-2/3 of these pills are taken. That leaves 3-6 billion leftover Vicodin pills lying around, waiting to be mis-used. Any change in prescriptive practice that would decrease the amount of excess opiate pills and hence downstream supply, would go a long way in addressing the current epidemic.

This is where a legislative tweak to the federal Controlled Substances Act could further such a change. As current federal law (and state law that mirrors federal) stands, it is not legal to provide a refill for schedule II narcotics, a physical prescription must be taken to the pharmacy, and cannot be phoned-in or faxed. And now with the recent change to reclassify hydrocodone medications as schedule II, this makes it even all the more difficult to prescribe.

The unintended consequence of not allowing refills is that proceduralists (surgeons, dentists, and doctors that perform procedures with painful after-effects) and providers that treat acute pain are usually going to err on the side of over-prescription. They are more likely to prescribe more than they think the patient will likely need. This is done to make sure the patient doesn’t suffer from unnecessary pain, and so the patient will not have to call the doctor (or perhaps the doctor's on call covering partner) back at night or on the weekend or during the busy daytime asking for a little more pain medicine. I think of this as the "hassle factor"--it is real. By prescribing a larger amount in this way, the patient and the doctor aren't likely to be inconvenienced by having to get a physical prescription refill. But, this almost always ensures there will be leftover opiate pills, in many cases in significant numbers. Almost everyone you talk to has stories of something like getting a tooth pulled or breaking their hand and then having 48 vicodin left over, sitting in the medicine cabinet. Therein is the excess supply that enables and is a catalyst for abuse.

For example, the way this plays out for a surgeon who performs a hand surgery is that he expects the patient to be in pain for 4-5 days afterwards, so he estimates at maximum the patient would need 20 vicodin. But some patients are more sensitive to pain, so not being able to write for a refill, he is likely to give a quantity of pills that would be likely more than most patients would need--like 40 pills. If he could instead write a time-limited small-volume refill that would expire after one week, then the patient would be able to control the amount dispensed, and there would be significantly fewer "left-overs". If most patients need less than 20-which is likely, then that many less would be in circulation. Again, it is estimated that there are 3-6 billion leftover Vicodin pills every year!

So what we propose as a solution would be to amend USC Title 21 Section 829 which states no refills of schedule II drugs . The statute is found here https://www.law.cornell.edu/uscode/text/21/829 . We have extensively looked at ways to decrease this over-prescribing behavior. I

would propose a change to allow an exemption for one refill of hydrocodone based prescriptions that would expire in 1 week for quantities of less than 20 intended only for cases of acute pain management. After that time, if the patient had more symptoms he would need a physical prescription for any further quantities-as is the case now.

There would be no change to chronic pain management. It would not touch how those medicines are currently prescribed, or how those patients are currently treated. Medications for chronic pain would continue to be prescribed for as is, and still require new prescriptions every single time with no refills allowed (as is the law now). The argument that this change would negatively affect chronic-pain patients has no validity, because there would be no restrictions to or changes in the way prescriptions are currently handled. There would just be the new availability for prescribers to write for less than 20 pills with a one time refill limited to a week. We think this would go a long way to help meet the goal of decreasing the availability of prescription opiates and keep them out of the hands of our children and adolescents.

There are things that the federal government is doing that are working well and where federal legislation can have a significant impact in the battle. It is in the ability to bring resources to the states themselves to use for grant programs for health and law enforcement efforts. Wisconsin lawmakers are helping lead the way in this critical area. The most recent example other than the PROP Act is the Comprehensive Addiction and Recovery Act (CARA). It is a great example of the bipartisan legislative action in the battle against prescription drug abuse. I applaud both Wisconsin Senators Johnson and Baldwin for their support of this important bill, as well as Wisconsin Congressman Sensenbrenner for releasing it.

Senator Baldwin has also done some very good work in this area of prescription drug abuse reform. She has authored the Jason Simkakoski Memorial Opioid Safety Act, which passed a Senate Committee hearing and has some very good reforms to affect change in prescriptive practice within the VA. It mirrors what we have done in Wisconsin with our reforms, taking what has worked at the state level and applying it in the VA system. It has emphasis on best-practice prescribing guidelines, targeted opioid continuing medical education for prescribers, encouraging use of prescription drug monitoring programs, and oversight by the regulatory body to ensure minimum standards are met, among other things.

Senator Baldwin also has authored a bill the Heroin and Prescription Drug Abuse Prevention and Reduction Act which covers prevention, crisis, treatment and recovery. In it are great pieces that cover expanding access to buphrenorphine to help with medication assisted treatment, and also increasing availability of naloxone to reverse opioid overdoses,as well as expanding access to treatment.

The question of justifying expenditures and funding is a very important one, and I feel the money put into prevention, management and treatment will deliver a significant return on investment as far as total costs/benefits to society and the quality of life in America. I have heard of an economic impact analysis that was done on a buprenorphine program in Peoria Illinois. They spent $600,000 on the program. Sadly, as is common the case with medication assisted treatment and treatment opioid treatment in general, the compliance/success rate was less than 20%. Even with that compliance rate, the estimated savings to society in Peoria was estimated to be $12,000,000 due to money that wasn't spent on incarceration, medical costs, and losses from crime associated with continued abuse related crimes. Truly the case seems to be strong that the the return on investment is likely worth the expenditure.

In closing, I applaud the efforts that Wisconsin federal and state legislators and leaders, and for that matter the government in general is taking in battling the scourge of prescription opioid and heroin abuse. We are seeing some great energy and interest in understanding and looking at how to best address this epidemic. The legislation so far has been thoughtful and not over-reaching. The legislation Sen. Baldwin has been leading would be very useful in helping the Veterans Affairs system, the states and our communities in battling this epidemic. I literally cannot say how excited I am about Sen. Johnson's PROP bill -(the Act to Reduce Pressure to Overprescribe Painkillers). It puts us on a simple, straightforward and commonsense path. It moves us back towards allowing the medical community to do what we do best, take care of our patients without artificial interference.

I think it is wise to remember that legislation and regulation is difficult to repeal and filled with unintended consequences that can be worse than the problem that is being addressed. The case in point is taken from the movement and follows federal policy in the 1990's that was trying to address the perceived problem that pain was being under-treated by health providers, which was the spark for the current prescription drug epidemic. This quote is from a press release taken from Surgeon General Murtha that was released just this last Tuesday, April 8th. "*I came across a training document from the early 1990s that was directed at nurses and doctors. And one of the lines stood out to me clearly," he said. "It said, 'If your patient is concerned that they may develop dependence on opioids, you can safely reassure them that addiction to opioids is very rare in patients who have pain." "That one line haunts me" he said. "I remember being taught that during my training and having to unlearn it. And I know there are many clinicians who were taught the same and still practice based on this teaching — with the best of intentions."*

The last opioid overdose death that I treated was this past week. I could not resuscitate him. He was in his early 20's. He told his friend he was going to shoot up and to give him narcan if he wasn't breathing. His friend came in 30 minutes later and he was flatline. He was the 4th kid to die from opioids in his high school class, from the local high school that sits next to my hospital. The police couldn't locate his family, and he was taken to the morgue with no family having said goodbye. The coroner who took him away said the Milwaukee County Medical Examiner's office was seeing about 2 opioid deaths per day. There have been 30 fentanyl-related deaths in Milwaukee County alone so far this year. There were 5 fentanyl-related deaths in 2012. This is the public health crisis of our times. It is not easy work we are doing in setting policy and regulations, but it will make a difference if we do it right.

Thank you for the opportunity to contribute and testify in this hearing.