NfmCPA
National Fibromyalgia & Chronic Pain Association
31 Federal Avenue • Logan, UT 84321 • 801.200.3627 (o) 435.752.3556 (f) • FMcpAware.org

*Testimony of*

Jan Favero Chambers, President
National Fibromyalgia & Chronic Pain Association

U.S. Senate Committee on the Judiciary
"Oversight of the Ensuring Patient Access and Effective Drug Enforcement Act"

*December 12, 2017*

*Thank you for the invitation to share my testimony with you today on behalf of millions of people with chronic pain patients. We appreciate your support to help people with chronic pain and/or substance use disorder maintain access to life-saving prescriptions.*

*The Ensuring Patient Access & Effective Drug Enforcement Act of 2016 was passed to safeguard that pain patients are still part of the equation at the DEA. Without it we're not.*

As caring doctors and other registrants try to navigate the minefield of maintaining a DEA license to prescribe legal prescription opioid drugs to their patients for relief of severe and disabling chronic pain or substance use disorder, the DEA's evolution after 40 years needs Congressional direction for effective adjudication processes at this critical point. Two sides of the same coin, the dual and interrelated crises of untreated chronic pain and substance use disorder require immediate attention.

Now law, the Ensuring Patient Access & Effective Drug Enforcement Act of 2016 (EPAEDEA) has received criticism that the growing illegal opioid crisis is related to law enforcement's ability to use one specific tool, the immediate suspension order, to curb diversion by registrants.[1] The problems run much broader and deeper, and started long before April 19, 2016, when the bi-partisan EPAEDEA with unanimous Congressional support was signed into law by President Obama.

Referring to the immediate suspension order (ISO) tool, former DEA employee Joe Rannazzisi told CBS 60 Minutes correspondent Bill Whitaker that the EPAEDEA "restricts or prevents us from filing immediate suspension orders to stop."[2] Without understanding the dilemmas facing the DEA and its

[1] Registrants include prescribing physicians, researchers, pharmacies, distributors, and manufacturers licensed to distribute controlled substances, including prescription opioids. The term distributor can also refer to all registrants.
[2] https://www.cbsnews.com/news/meet-60-minutes-dea-whistleblower/ (accessed 12.10.17).

registrants licensed to distribute controlled substances, including prescription opioids, many Americans were incensed over the misbegotten idea that Congress had interfered with illegal drug enforcement. Some believed that the DEA no longer had the ISO as a tool.

The ISO is available to DEA investigators and "is used sparingly," said DEA media contact Barbara Correno. On his law firm's FDA Law Blog, Attorney Andrew J. Hull explains the steps that a DEA registrant can take after receiving an ISO or an order to show cause.[3]

As Congress, state legislatures and attorneys general grapple with how to address the illegal opioid crisis, the chronic pain crisis has been the minimally acknowledged sidecar of a careening motorcycle on a destructive path. My testimony is offered to witness that the two are inexorably connected and to advocate for significantly increased research funding and compassionate policies for both communities of people who are suffering and dying.

## HOW WERE PEOPLE WITH CHRONIC PAIN IMPACTED BEFORE AND AFTER THE EPAEDEA?

### PAIN PATIENT SURVEYS

Practical Pain Management, March 2014

After the FDA Drug Safety and Risk Management advisory committee recommended to reschedule hydrocodones from schedule III to schedule II and before the Final Rule was published on October 6, 2014, patients reported barriers to access prescription opioid pain medications. The National Fibromyalgia & Chronic Pain Association (NFCPA) developed a survey to measure patient concerns and worries amidst the time that some retail pharmacists were encouraged to exercise extraordinary discretion *e.g.,* make diagnostic decisions including changing prescription dosages based on their judgment of the appropriateness of the prescribing physician's diagnosis and prescribing.

Patients reported experiences of negative treatment (many reported being treated as "criminals" by "pharmacists who had been filling their pain medications for many years") and inconveniences encountered (descriptions of "nightmarish" additional travel to doctor's offices, sometimes to cities many miles from their residences to get a replacement prescription"), even as withdrawal began or was looming due to the delay in obtaining medications.

A frequent comment by the NFCPA constituents concerned the "degradation and embarrassment" they experienced from being treated as a "drug seeker," often indiscreetly in small towns where "everyone in the pharmacy including other customers knew [them]." Complaints came from school teachers, church choir members and/or medical professionals alike; all reported shame and demoralization. With this as a backdrop, questions were created for this survey.

[3] http://www.fdalawblog.net/2017/11/what-to-do-when-you-receive-a-dea-order-to-show-cause/ (accessed 12.10.17).

The level of education reported was most often a college (22.1%) or high school (19.1%) degree, followed by those who had two (17.2%) or one (13.2%) year(s) of college experience. A total of 609 respondents (12.4%) reported having obtained a graduate degree. The most often cited pain complaints (not mutually exclusive) were fibromyalgia (91.9%), low back (64.8%), and neck (49.2%) pain, followed by migraines (42.2%) and neuropathic pain (42.2%) (Table 1).

Overall, 846 respondents (18%) stated that they had been denied having a prescription filled by a pharmacist on at least one occasion, with 63.6% reporting that they had obtained opioid prescriptions at the same pharmacy on more than 10 different occasions previously and 18% reporting that they had successfully filled opioid prescriptions at the same pharmacy from 3 to 10 times previously. Only 8.5% of the respondents who reported being denied the filling of their prescription had never previously used the pharmacy that denied the prescription.

Respondents with a history of being denied a prescription were asked to relate what reasons the pharmacy gave them for failing to fill the opioid prescription. The most frequent reason cited was that the pharmacy did not have enough medication in stock (52.9%). Other reasons for denial included having the pharmacist feel the dosage was inappropriate (23.3%), the pharmacy was no longer stocking the drug (21.8%), or that there was a national shortage of the opioid (20.7%). For those denied, the vast majority (86.3%) stated that the pharmacist did not help them find an alternate pharmacy that might be able to fill the prescription.

After experiencing a denial, a majority (n=506, 67.3%) managed to fill their prescription somewhere else within 1 week, but 123 patients (16.4%) were never able to get the prescription filled. Of those getting the prescription filled elsewhere, most reported that they either visited 1 pharmacy (50.9%) or 2 to 4 more pharmacies (36.3%) to have the prescription successfully filled. This led to the majority of respondents who experienced a denial being out of their medications for 1 to 2 days (34.5%) or 3 to 6 days (29.3%).

***Impact of Prescription Denial:*** The final portion of the survey concerned the global impact on those who had experienced the denial of having a prescription filled. Physical manifestation resulting from not having their medications included signs of acute withdrawal such as muscle tension (66.3%), sweating (56.1%), and nausea, vomiting, and diarrhea (46.3%). Regarding the emotional impact of being out of their medications, most patients reported anxiety (76.5%), irritability (70.8%), restlessness (59.5%), or insomnia (57.4%) (Table 3). A specific item on suicidality found that 287 (37.7%) had considered suicide after being denied access to their medications. The cited reasons for this were increased pain (100%) and opioid withdrawal (35.5%).

What was clear from the results reported was that consistent access to opioid medications, even for those with long-standing prescriptions, was threatened to the point where a subset of patients were traumatized.

Additionally, medication agreements frequently ask the patient to agree to fill their prescriptions at one and only one pharmacy (that they, the patient, delegate). This survey suggests that this is getting increasingly difficult for some people with pain to abide by. Further, when physicians come under scrutiny by medical board review, one of the factors that they may be expected to be aware of, and prohibit, is their patients filling prescriptions at multiple pharmacies.

***Summary**:* A total of 5,159 respondents with either fibromyalgia or other types of chronic pain consented to take part in the survey, which was designed by NFCPA to evaluate access to pain medications in the current political and regulatory environment. The survey explored the experiences of people with chronic pain during a time when changes in laws and policies meant to curb the problems of prescription opioid misuse, abuse, addiction, overdose, and diversion have become frequent occurrences. Of those who responded, 3,879 (75.2%) reported that they were currently taking a prescription pain medication; a majority (69.2%) reported being on the medications for over a year. A total of 846 (18%) patients noted that they had been denied having a prescription filled by a pharmacist on at least one occasion, with a majority (63.6%) reporting that they had obtained opioid prescriptions at the same pharmacy on more than 10 different occasions previously. The survey results begin to reveal the unintended negative consequences of policy changes and new laws for people with chronic pain conditions, including stigmatization, traumatization, and ostracism.[4]

Pain Medicine, December 2015 (Abstract from PubMed)

***Objective*:** To conduct an Internet patient survey through the National Fibromyalgia & Chronic Pain Association on reactions to the first 100 days following the rescheduling of hydrocodone.

***Methods***: Face-valid survey questions were created with expert consensus along with repurposed questions used on previous NFMCPA surveys covering domains such as demographics and symptoms. The questionnaire was designed to be administered over the Internet.

***Results***: 6,420 responders met screening criteria and completed the survey. Most (5,181, or 82.5%) had been prescribed hydrocodone for more than 1 year. 2,296, (39.0%) reported no changes in access to hydrocodone, while the majority experienced some barriers. Of those who could no longer get hydrocodone, 1,067 (18.1%) borrowed pain medications, 1,007 (17.1%) turned to marijuana, 773 (13.1%) used alcohol, and 135 (2.3%) used illicit drugs. Most respondents had to visit their healthcare providers more often (N = 3,699, 64.2%) and 1,735 (30.3%) reported some type of issue interacting with their pharmacy. Most felt that the rescheduling was neither a fair nor appropriate solution to the abuse of hydrocodone (N = 4,938, 88.3%). For those still working, 801 (46.2%) reported that they had missed work because of the stricter regulations. 1,462 (27.2%) reported having thoughts of suicide since the rescheduling.

[4] Gleason R, et al. Current Access to Opioids: Survey of Chronic Pain Patients. Prac Pain Man. Mar 2014. 5159 survey responders. https://www.practicalpainmanagement.com/issue/0314 (accessed 12.10.17)

***Significance***: The unintended consequences for people with chronic pain that have been caused by the rescheduling effort to impede hydrocodone abuse are negatively impacting thousands. These consequences include suffering from being placed on less effective drugs, increased cost, inconvenience, and negative influence on physician-patient and pharmacist-patient relationships.[5]

Chronic Pain National Health Insurance Survey (December 2017 - in progress)

Initial survey results from almost 500 people indicate that 48% of people have at least a moderate level of pain that cannot be ignored and gets them out of bed for pain medication. (This is significant since lack of sleep increases pain symptoms.)

The most effective non pharmacologic treatments a patient has ever used:

heating pads (57%)
TENS unit (43%)
full body massage (45%)
warm water exercise (41%)
chiropractic (38%)
nutritional supplements (37%)
exercise (36%)
prayer (36%)
physical therapy (36%)
education about condition (28%)
cognitive training in meditation (26%)
massage with an electrical device (22%)
acupuncture (20%)
cognitive training in mindfulness (17.6%)
electric massage chair (14%)

Respondents completed this statement: "If I had access to the most effective treatments for me, I would be able to: (1) participate in activities like grocery shopping, vacuuming and cooking (57%), (2) provide more of my own care (35%), and work part time (20%).

To afford their prescriptions, 37% of patients cut back on groceries or other daily needs, stopped taking medications (34%), skipped taking the correct dose of medications (31%), and skipped therapy (28%).

Have you or your immediate family that you live with been forced to take out bankruptcy due to your medical expenses? 7% said yes.

Respondents completed this phrase: "I was taking a stable prescription opioid long term that reduced my pain and enabled me to be productive. My doctor: "

- suddenly refused to prescribe it any longer (5%).
- suddenly refused to prescribe it any longer and gave me an excuse that didn't seem truthful (5%).
- suddenly refused to prescribe it any longer and switched me to a less effective non-opioid prescription medicine (8%).

[5] Chambers J, et al. An Online Survey of Patients' Experiences Since the Rescheduling of Hydrocodone: The First 100 Days. Pain Med. 2016 Sep;17(9):1686-93. doi: 10.1093/pm/pnv064. Epub 2015 Dec 26. 6420 survey responders. https://www.ncbi.nlm.nih.gov/pubmed/26814291 (accessed 12.10.17).

- suddenly refused to prescribe it any longer and told me I had to find another doctor for pain management (9%).
- increased random urine drug tests that increase the cost of my pain management (11%).

Respondents completed this phrase: "I was taking a stable prescription opioid medication long term that reduced my pain and enabled me to be productive. My doctor refused to prescribe opioids any longer for my pain control. I had no choice but to:"

- endure withdrawal from long-term opioid therapy as there was no tapering off period with my doctor (8%).
- cut down on my prescribed doses until I could get stable on a different pain medication (5%).
- worry and have fear about how to manage my pain (20%).

Respondents answered this question: "If your doctor stopped prescribing a stable prescription opioid long term that reduced your pain and enabled you to be productive, what happened next?"

- I'm suffering more significantly without pain control (14%).
- Nothing. I feel out of control because of increased pain. I've lost the progress I had when my pain was properly managed with prescription opioids (9%).
- My doctor said he/she would no longer treat my chronic pain and that I had to find another physician for pain management (9%).

More than 15% of patient respondents said yes to the question: "If you were taking a stable prescription opioid long term that reduced your pain and enabled you to be productive, did your doctor refuse to prescribe it any longer and turned you away as a patient?"

Females were 93% of the respondents and were living in California, Florida, Illinois, Michigan, Ohio, Pennsylvania, North Carolina, Texas or Washington.

When asked about their education levels, respondents replied that they had either a Bachelor's degree (18%), some graduate school (8%), or completed graduate school (19%). (This is consistent with all major surveys conducted by the National Fibromyalgia & Chronic Pain Association.)

**INVESTIGATIONS ON PRESCRIBERS IMPACTS PAIN PATIENTS**

Immediate harm to patients occurs when pharmacies, physician offices and clinics are immediately shuttered without notice or patient files are confiscated. For example, in 2013, prior to enactment of the EPAEDEA, during business hours and in front of patients, DEA raided the pain clinic of Dr. Lynn Webster of Salt Lake City, Utah. The agency's investigation concluded four years later with no charges filed. But by that point it was too late. According to Dr. Webster:

> Vindication implies that I was accused of wrongdoing. I was never accused of any wrongdoing, but when the DEA makes an inquiry, the implication is that there is something fishy and the perception of wrongdoing takes root. As a physician who has treated people in pain all my professional life, I always grieved for patients we treated but died. The fact is that some patients at our clinic died in spite of their treatment, but not because of it.

Journalist Maia Szalavitz covered the most recent DEA investigation of a high-profile pain specialist.

> One of the few remaining physicians willing to prescribe—and advocate for—high-dose opioids for certain patients with hard-to-treat chronic pain is now under investigation by the Drug Enforcement Agency (DEA). The case of California pain and addiction specialist Forest Tennant terrifies pain patients and their physicians, who fear that it could lead to de facto prohibition of opioid prescribing for chronic pain and even hamper end-of-life care.
>
> The DEA raided Tennant's home and offices on November 15, while he was traveling after serving as an expert witness in the trial of another doctor accused (and later convicted) of illegal prescribing. Tennant is accused of "profiting from the illicit diversion of controlled substances" and being part of a "drug trafficking organization." Agents confiscated patient records and financial documents during the raid.
>
> Tennant is the author of more than 100 scientific publications listed in PubMed. He's the recent recipient of a lifetime achievement award for his research and work with the most difficult-to-treat patients. He helped write California's "Pain Patients' Bill of Rights" legislation. He served as mayor of his town, West Covina, twice. And he is widely known as the doctor of last resort for "pain refugees" whose doctors have either quit prescribing opioids or refuse to use high doses. This would be quite an unusual resume for a "pill mill" proprietor.
>
> Tennant's record is not spotless, however: in 1997 he was fined $625,000 by the federal government in a case related to the methadone programs he ran at the time for failing to comply with the notoriously complex regulations on the storage and dosing of the medication. And, in the early 00s, he was convicted of insurance fraud, which meant that his medical license was probationary for four years. But since then, his license is current and he remains respected in his field.
>
> Following the 2016 introduction of the Centers for Disease Control and Prevention's opioid prescribing guidelines, many patients report either being forced to reduce their dose, even if they are more functional on the higher dose, or to stop taking opioids entirely. Although the CDC guidelines were not intended as rigid mandates, many doctors fear criminal prosecution if they do not comply—and Tennant's case seems likely to amplify and justify those fears.

“I think it’s a really disturbing example of the irresponsible way in which law enforcement, including the DEA, have been deploying their resources,” says Leo Beletsky, associate professor of law and health sciences at Northeastern University, of the Tennant case. Beletsky explains that, in order to ensure balance between access to medication and drug control, targets for prosecution must be chosen carefully. He says he hopes Tennant wasn’t targeted because of his advocacy “but it certainly seems like a strange coincidence that he has also been an outspoken critic.”

Tennant’s current practice includes around 150 patients—around 15 percent require end-of-life palliative care, he tells Tonic. That’s hardly enough to make even an ordinary practice excessively profitable (a typical primary care doc has a patient load of around 2,000 and pill mills squeeze in many more). No overdose deaths associated with Tennant’s practice were mentioned in the search warrant and no undercover agent was reported to be able to get an illegitimate prescription from him.

His patients say that Tennant spends hours examining and counseling them and requires tons of paperwork—again, the opposite of what happens in a pill mill, which typically involves a rushed exchange of payment for a prescription with little examination or record-keeping.

The main evidence presented in the search warrant in the case against Tennant is that he has prescribed extremely high doses of opioids to some patients, based on prescription drug monitoring data. The document alleges that these dosages were so high that patients must be selling some of the drugs, even though they present no evidence of any such activity by patients.

“I’ve read the search warrant,” says Stefan Kertesz, associate professor of preventive medicine at the University of Alabama and an expert on opioid safety. “The core case is that a physician in California who teaches about opioid prescribing believes that [Tennant’s] prescribing is not appropriate,” he says. “There are lots of discussions we should be having about high doses and the risk they present, but prescribing or embracing high doses of opioids does not signify a criminal intention.”

Tennant’s prescribing of fentanyl and receipt of speaking fees from one manufacturer, Insys, were also cited as evidence of criminal behavior in the warrant, because the company is under investigation for illegally marketing that drug. Tennant, however, says he last received such fees in 2015, before that investigation was public and he is far from alone in the profession in taking pharmaceutical money for speaking. In addition, his ties to a pharmacy used by many of his patients were mentioned—but evidence of actual wrongdoing was not provided. Finally, the fact that many of his patients traveled long distances to see him was touted as a further “red flag.”

“If you didn’t know what I did and who I was, I could see how you might think that,” Tennant says of the way the warrant described his prescribing patterns and the high number of out-of-

state patients, "But everyone knows I've been taking these difficult cases who fail other treatment… it goes beyond my comprehension: why didn't [they] just come and talk to me? This has been an open book. Patients pay low fees and there are some charity cases. We're not a pill mill."[6]

**PHARMACY CLOSURES AND DISRUPTIONS IMPACT PAIN PATIENTS**

According to a survey of their membership conducted by the National Community Pharmacists Association (NCPA) conducted in December 2013 which at the time dispensed nearly 40% of all prescriptions, "many pharmacies are increasingly unable to procure controlled substances which is of great concern for patients who need these medications."[7] Key highlights of the survey included:

- Approximately 75% of respondents experienced three or more delays or issues caused by stopped shipments with their controlled substance orders, over the past 18 months,
- On average, 55 patients-per-pharmacy were impacted by these delays,
- 89% of impacted pharmacies received no advanced notice of the delay; they only found out when their order arrived and included just non-controlled substances,
- 60% said the delays in receiving these requested medications lasted at least one week,
- 67.9% were unable to procure controlled substances from an alternate source, such as a secondary wholesaler, and
- Most reported having to turn patients away and referring them to a local competitor.

The survey included an open-ended comments section. One pharmacist said, "This situation has literally brought customers to tears in our store. I fully understand the diversion and abuse of these powerful chemicals. I agree that something must be done, but to deny pain management to deserving individuals is inhumane at best. We have to find a way to curb the abuse and still provide relief from pain for those truly suffering."

We all want distribution centers that have engaged in illegal activities shut down. But we also want to be certain that innocent Americans struggling with debilitating chronic conditions do not have their access to treatment cut off. Unless and until new, non-addictive pain medications become available or patients have access to effective non-pharmacological treatments, eliminating access to appropriately prescribed medications for severe pain is inhumane and akin to inflicting torture.

In its June 2015 report, the U.S. Government Accountability Office started with this statement: "The CSA was enacted in 1970 to regulate and facilitate the use of controlled substances, including certain prescription drugs such as opioid pain relievers, for legitimate medical, scientific, research, and industrial purposes while preventing them from being diverted for illegal uses. DEA's Office of Diversion

[6] https://tonic.vice.com/amp/en_us/article/a3jd94/dea-raided-chronic-pain-doctor-forest-tennant?__twitter_impression=true (accessed 12.10.17).
[7] http://www.ncpanet.org/pdf/survey/2014/controlled-substances-access-survey.pdf (accessed 11.1.2017)

Control is responsible for administering and enforcing the provisions of the CSA as they pertain to ensuring the availability of controlled substances for legitimate uses while limiting their availability for abuse and diversion."[8]

In part, the Ensuring Patient Access & Effective Drug Enforcement Act of 2016 responded to the long-standing call for more effective communication with the DEA by DEA registrants[9] and to reports from pain patient advocates that they were being turned away from doctor's offices, emergency rooms, and pain clinics because of policy changes, some of which doctors explained in odd or incorrect ways to them.

As a pain patient advocate, I was alarmed after studying the "Marquette Law Review" article Current Navigation Points in Drug Diversion Law; Hidden Rocks in Shallow, Murky, Drug-Infested Waters by DEA Chief Administrative Judge John J. Mulrooney, II and Marquette Law School graduate Katherine E. Legel. Others have culled out specific points from the article to support their criticisms of the EPAEDEA, which misses the elephant in the room that the authors discuss. Per Mulrooney and Legel, the DEA, to its detriment, is entrenched in misguided self-direction and self-governance at a crucial period and crossroads in our nation. Per Mulrooney, a significant aspect of this is that DEA does not have to comply with the APA and issues policy via an adjudication process with registrants on a case-by-case basis.

Just as there are the practices of medicine and law, it would be appropriate to also say the DEA is a practice of drug enforcement. Professional experience and public input have evolved medicine and law. Due to the confluence of the short 40-year history of the DEA's adjudication structure and the explosion of issues related to illegal opioids, America can ill afford for the DEA to continue its closed system of adjudicating registrations to legally distribute prescription opioids.

Pain patients and substance use disorder patients stand to lose prescribers by the droves if the EPAEDEA is repealed. Tweaking the law makes more sense. After years of registrant requests to have increased and more effective communication with the DEA, the guidelines in the EPAEDEA represent a combined effort for accountability by both registrants and the DEA.

Nowhere else can I find a historical narrative that is publicly available to inform both people with pain and people with substance use disorder of the historical events and division of responsibilities leading to the final arbitration on the disposition of a registrant's license to prescribe controlled substances.

---

[88] https://www.gao.gov/assets/680/671032.pdf, p 9 (accessed 11.1.2017).

[9] "Some distributors, individual pharmacies, and chain pharmacy corporate offices want improved guidance from, and additional communication with, DEA about their CSA roles and responsibilities. For example, 36 of 55 distributors commented that more communication or information from, or interactions with, DEA would be helpful. DEA officials indicated that they do not believe there is a need for more registrant guidance or communication. " GAO Report More DEA Information about Registrants' Controlled Substances Roles Could Improve Their Understanding and Help Ensure Access, https://www.gao.gov/assets/680/671032.pdf, p 1, (accessed 12.10.2017).

Awareness of the slippery slopes and additional requirements demanded of a registrant throughout the DEA legal process may engender deeper patient appreciation and support for their prescribers' responsibilities.

Education for prescribers and all medical personnel handling prescriptions for opioids should be mandated. Education about prescription opioids should also be mandated for people with chronic pain and/or substance use disorder.

Are pain patients still part of the equation at the DEA? Bluntly stated, if one is to accept the assessments made in the Marquette article, how can we expect doctors to continue providing pain care when faced with discretionary and unpredictable registrant rules and adjudications?

I have the advantage of being married to an attorney and being the mother and mother-in-law to four additional attorneys and two doctors. After years of watching them prepare their legal cases for trial and study medicine, I can begin to understand the vulnerability, frustration and fear of doctors and pharmacists who may have to defend themselves inside the unorchestrated DEA closed legal system. Engaging with defensive doctors stigmatizes and harms millions of people with chronic pain and/or substance use disorder.

**WHAT ABOUT CHRONIC PAIN?**

"Chronic pain is a debilitating disease that takes a toll on the person, their family, and society and costs our nation in excess of half a trillion dollars each year," explains Sean Mackey, MD, PhD, Redlich Professor and Chief of the Division of Pain Medicine at Stanford University "Pain is the leading cause of why people are out of work.

"More than 100 million adults in the United States have pain that lasts longer than three months, or longer than the time you'd expect for tissue healing. Pain ranges from those who are still managing at home and are functional to those who have catastrophic pain and may not even be able to get out of bed or maybe end-of-life-care, and everything in between."[10]

The International Association for the Study of Pain (IASP) defines pain as, "An unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage." Pain is a subjective experience in which there is no method for determining if an individual is in pain. Every person experiences chronic pain in a different way which makes it difficult to treat.

**INSTITUTE OF MEDICINE REPORT ON PAIN**

The 2010 Patient Protection and Affordable Care Act required the Department of Health and Human Services (HHS) to enlist the IOM (now National Academy of Medicine) in examining pain as a public

[10] https://www.youtube.com/watch?v=GTmE5X8NcXM (accessed 12.10.17).

health problem. In the report, the IOM offered a blueprint for action in transforming prevention, care, education, and research, with the goal of providing relief for people with pain in America and reducing reliance on prescription opioid therapy.

Better data are needed to help shape efforts, especially on the groups of people currently underdiagnosed and undertreated, and the report encouraged federal and state agencies and private organizations to accelerate the collection of data on pain incidence, prevalence, and treatments. Because pain varies from patient to patient, healthcare providers should increasingly aim at tailoring pain care to each person's experience, and self-management of pain should be promoted. In addition, because there are major gaps in knowledge about pain across health care and society alike, the IOM recommends that federal agencies and other stakeholders redesign education programs to bridge these gaps.

The report found that pain is a major driver for visits to physicians, a major reason for taking medications, a major cause of disability, and a key factor in quality of life and productivity. Given the burden of pain in human lives, dollars, and social consequences, relieving pain should be a national priority.[11]

To date, Congress has not asked for a follow-up hearing to learn of the recommendations and progress of the IOM report that it mandated from DHHS in 2010. From a logical point of view on the dual crises of chronic pain and substance use disorder, a hearing is critical in providing Congress well-designed solutions from America's highly trusted experts to reducing reliance on prescription opioid therapy.

**NATIONAL INSTITUTES OF HEALTH**

National Pain Strategy

Through the Interagency Pain Research Coordinating Committee, NIH worked with HHS and agencies across government to develop the National Pain Strategy,[12] the government's first broad-ranging effort to improve how pain is perceived, assessed, and treated, which highlights the need for evidence based treatments. NIH is actively working with other Departments and Agencies and external stakeholders to implement the Strategy.[13] To date, no Congressional funding has been appropriated for its implementation. This has hampered changes towards non-opioid pain treatment therapies.

[11] http://www.nationalacademies.org/hmd/Reports/2011/Relieving-Pain-in-America-A-Blueprint-for-Transforming-Prevention-Care-Education-Research.aspx (accessed 12.10.17).
[12] Developed from the 2011 IOM Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education and Research, http://www.nationalacademies.org/hmd/Reports/2011/Relieving-Pain-in-America-A-Blueprint-for-Transforming-Prevention-Care-Education-Research.aspx (accessed 12.10.17).
[13] https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2017/federal-efforts-to-combat-opioid-crisis-status-update-cara-other-initiatives (accessed 12.10.17).

Federal Pain Research Strategy

Again through the Interagency Pain Research Coordinating Committee, NIH developed the Federal Pain Research Strategy, a long-term strategic plan to coordinate and advance the federal research agenda on pain. The Strategy's research priorities include prevention of acute and chronic pain, management of acute pain, transition from acute to chronic pain, and understanding the disparities that influence pain and pain management. Ongoing projects that already are advancing the goals laid out in the Strategy include the NIH-DoD-VA Pain Management Collaboratory program, which recently announced $81 million in research funding to implement cost-effective large-scale clinical research in military and veteran healthcare delivery organizations, focusing on non-pharmacologic approaches to pain management and other comorbid conditions.[14]

National Fibromyalgia & Chronic Pain Association Together Walks

A developing outcome of two succeeding Patient-Centered Outcomes Research Institute (PCORI) Pipeline to Proposal award, the National Fibromyalgia & Chronic Pain Association is building a Patient-Directed, Patient-Centric Research Community (PPCRC) to engage patients in learning what matters most to them in research. The PPCRC is designed to correlate directly with patient research fundraising.

Organized by volunteers in cities across the United States, public Together Walks raise research money for pilot projects to engage research in areas that are important to patients. The NFCPA is delighted to announce the inaugural 2018 Hope Award of $9087 to Drs. Anna Wilson and Kim Jones at Oregon Health & Sciences University to investigate the impact of intermittent light on people with central sensitization.[15]

**HHS FIVE-POINT OPIOID STRATEGY**

In April 2017, HHS outlined its five-point Opioid Strategy, which provides the overarching framework to leverage the expertise and resources of HHS agencies in a strategic and coordinated manner. Advancing pain management is one of the five pillars. The comprehensive, evidence-based Opioid Strategy aims to:

- Improve access to prevention, treatment, and recovery support services to prevent the health, social, and economic consequences associated with opioid addiction and to enable individuals to achieve long-term recovery;
- Target the availability and distribution of overdose-reversing drugs to ensure the broad provision of these drugs to people likely to experience or respond to an overdose, with a particular focus on targeting high-risk populations;
- Strengthen public health data reporting and collection to improve the timeliness and specificity of data and to inform a real-time public health response as the epidemic evolves;

[14] Ibid.
[15] https://events.fibroandpain.org/ (accessed 12.10.17)

- Support cutting-edge research that advances our understanding of pain and addiction, leads to the development of new treatments, and identifies effective public health interventions to reduce opioid-related health harms; and
- Advance the practice of pain management to enable access to high-quality, evidence-based pain care that reduces the burden of pain for individuals, families, and society while also reducing the inappropriate use of opioids and opioid-related harms.[16]

**WHAT DOES CHRONIC PAIN LOOK LIKE?**

In December 2005, my world changed after hysterectomy surgery--electrifying, shocking pain went through my body, and I hurt everywhere. Curled up on the couch and practically debilitated for the following 16 months, additional health problems and multiple headaches developed. Nobody could touch me because of so much pain, and I lay with 7 or 8 pillows to keep my legs and arms from touching each other. Not sleeping, just waiting for the hours and days to pass. People cannot think about anything but not moving and stare at something while holding on and praying that the pains will stop. They don't dare move to breathe.

I lost count of how many physicians I went to who couldn't diagnose anything wrong with me. I typed up a two-page, single-spaced list of health problems that developed over the previous year. I saw a psychologist, and doctors told me "nobody can have that many things wrong with them." They told me that not all of my problems could be addressed because it would take up too much appointment time.

We spent tens of thousands of dollars on doctors and tests and got no diagnoses for the pains. I could not work, my family became my caregivers, as well as taking on my share of daily life tasks. I felt like a burden to my family and completely misunderstood, stigmatized, and rejected by the medical community. Every day got more painful, and I was afraid that it would never end. I kept thinking that a body cannot experience so many pains.

I wanted to give up, many times. My daughter was 12 at the time, and I just didn't feel like it was fair to leave her alone. She was our youngest. I thought about my husband: If I die, if I take my life, or if I find a way to get out of this mess, he doesn't deserve to have to rebuild his life. It felt wrong for me to do that to him. Those were the only two things that kept me focused once in a while during the suicidal depressions.

Eventually I was diagnosed and treated for fibromyalgia, positional cervical cord compression, and thyroid cancer. I was fortunate to find help.

*(More patient stories are available upon request.)*

---

[16] https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2017/federal-efforts-to-combat-opioid-crisis-status-update-cara-other-initiatives (accessed 12.10.17)

**SHORT HISTORY OF PRESCRIPTION OPIOIDS THAT AFFECTS HOW WE RESPOND**

Notice of the proliferation of pill mills in Florida, Kentucky, and other states in about 2005 led the DEA to significantly increase enforcement efforts. Following their investigation of doctors who wrote, and pharmacists who filled, high numbers of opioid prescriptions, pain patients began to have report difficulty filling their prescriptions for opioid medications within a couple of years. Pharmacies began turning legitimate patients away, asking for cash, and only giving partial fills.

Pain patient advocacy organizations began hearing about wholesale and mid-level distributors, pharmacies, and prescribers being unsure of what they were being investigated for by the DEA. Shutdowns of pharmacies and doctors' offices were happening, patients were scared and in pain, and doctors reported that the DEA was holding local meetings with prescribers to warn them and give them a heads up about red flags in overprescribing. But the red flags were reported to be not clearly defined and ambiguous.

Doctors began requiring random and frequent urine drug tests (UDTs) and very confining contracts of their pain patients[17] limiting where they could fill their prescription, on which days, etc. At meetings, doctors told me they were nervous to treat people with chronic pain because they didn't know who might be lying to them just to get a prescription for opioids. They resented the defensive position they were in to protect their livelihoods and that their families were fearful of them making a mistake and going to jail. The general response of the primary care and internal medicine doctors ultimately was to stop treating people with chronic pain.

Insurance companies, including Centers for Medicare and Medicaid, are squarely to share the blame for the skyrocketing use of prescription opioids rather than non-pharmacological treatments. Paying for an opioid, especially a generic opioid, is simply cheaper than paying for integrative health treatments. Step therapies, fail-first treatments, and similar continually set back people with serious pain and cause harm to them by increasing the symptoms of their disease, chronic pain.

Doctors pointed to the ruined reputations of their pain management colleagues under DEA investigation. Two doctors under investigation asked me to help them find other doctors to provide care for their patients. I never could.

The CDC Guidelines for Prescribing Opioids for Chronic Pain – United States, 2016 was released with fanfare and press releases by HHS on Tuesday, March 15, 2016. These are recommendations, not laws nor statutes. State legislatures are implementing them as if they are hard, fast standard practice rules. This is significantly harming people who need higher doses of prescription opioids for legitimate medical

[17] For a sample patient contract see http://pmp.pharmacy.state.mn.us/assets/files/PDFs/Sample%20Pain%20Management%20Contract.pdf (accessed 12.10.2017).

reasons that are documented between a doctor and patient. That's where the decisions should be made, and not at the pharmacy window nor with pharmacy benefit managers.

The National Pain Strategy was quietly published by HHS in the Federal Register on Friday, March 18, 2016. This left little doubt in the minds of millions and millions of people of how much they don't matter to federal officials who are charged with increasing equity and dignity in vulnerable populations. As one of 85 volunteer experts in the U.S. who created the National Pain Strategy after more than a year of work, it was tatamount to being stigmatized and slighted publicly. Perhaps pain patients will someday fill the halls of Congress and HHS and FDA and DEA to share their despair and hopelessness about being placed in liminality and about their future with chronic pain in the United States.

Four months ago, a staff member in my office called five primary care doctors' offices in northern Utah to find a new doctor to help her with chronic pain on her chest wall and a feeling of unwellness. All of them said that if she was seeking care for pain, they were not taking new patients. Then she found a lump in her breast and last week had a double mastectomy for stage 2 breast cancer which metastasized to her lymph nodes. With follow-up chemotherapy and radiation treatments she will try to gain more years of life to spend with her young grandchildren.

Awareness of increasing DEA investigations of high prescribers through media reports, discussions at medical meetings, growing lists on the Drug Diversion Division of the DEA website, etc., caused a chilling effect on doctors willing to treat legitimate chronic pain patients.

Patient access to care was affected significantly after the rescheduling of hydrocodones from controlled substances schedule III to schedule II on October 6, 2014. At the conclusion of the FDA rescheduling hearing on January 24-25, 2013, 12 of 29 panel members specifically mentioned they were concerned about the impact to chronic pain patients.

As a member of the panel, I spoke Deputy Center Director for Regulatory Programs Dr. Douglas Throckmorton about who was going to monitor the unintended consequences and impact to the people who needed, but could no longer get, a prescription for hydrocodones for pain relief. After several months passed with no action by the federal government to measure the impact, our non-profit organization sponsored a national survey, which is included earlier in this testimony.

**CONCLUSION**

Where is the committee for the Ensuring Patient Access & Effective Drug Enforcement Act of 2016? It should be monitoring the impact now of how policies are affecting access to healthcare for chronic pain and substance abuse disorder.

At the conclusion of the FDA meeting in 2013 to upschedule hydrocodones, Dr. Hernandez-Diaz said, "I'm aware that we may be asking for a sacrifice from individual patients in pain and their doctors in the name of public health and the younger generation of Americans, and I'm sorry about that."

Testifying in front of the Senate Banking Committee on December 5th, Jerome Powell, President Trump's Federal Reserve Nominee, agreed with Sen. Elizabeth Warren that the opioid crisis has lowered labor market participation and Congress, not the Federal Government. "The tools for dealing with the opioid crisis and with the long-term sixty-year decline in participation by prime-age males, those are tools that Congress really has to wield."

Since 2000 the rate of suicide has increased 28% in the United States. Montana ranks among the top five states in suicide. In Montana during 2014 and 2015, 555 suicides occurred - 53% were between the ages of 35-64, 91% were white, 79% were male, 9% had chronic pain, and 5% died by drug overdose.[18]

Suicide rates remain the highest among white males over the age of 45. While suicide occurs in all patient sectors, suicides among 50-ish year old men were at the center of research by Princeton University economic professors Anne Case and her husband, Angus Deaton, the 2015 Nobel laureate in economics They co-authored the White Mortality Paper in the Proceedings of the National Academy of Science about the startling rise in suicides among middle-aged white men since 1999. When they looked at illness (morbidity), "there was a large and statistically significant decline in the fraction reporting excellent or very good health" that was matched by increased reports of physical pain, according to the study.[19]

---

I hope to be of help in the future in finding solid solutions that work to create a brighter future for America. For more information about the results of our current and future surveys, please contact me at: jan.f.chambers@gmail.com or 801-200-3627.

[18] https://www.sprc.org/sites/default/files/resource-program/2016%20Montana%20Suicide%20Mortality%20Review%20Report.pdf (accessed 12.10.17).

[1919] http://wws.princeton.edu/faculty-research/research/item/rising-morbidity-and-mortalitymidlife-among-white-non-hispanic (accessed 12.10.17).