Damoth, Debbie@DCA

From: MONTY GODDARD <montygoddard@msn.com>
Sent: Friday, July 26, 2024 2:49 PM
To: Damoth, Debbie@DCA
Cc: Richard Lawhern; Stephen Nadeau; Mark Ibsen MD; Jay Joshi; Pat Irving; KRISTEN OGDEN; Louis Ogden; Susan Franzheim; Jonelle Elgaway; Ashley Rodgers
Subject: CORRECTED: CA Board of Pharmacy 31 -August 1 Full Board Mtg July
Attachments: FDA Listening Session Minutes - Publication Draft V1.1 (1).docx

Good afternoon Debbie,

(My apologies. My initial email had some formatting issues when not viewed on a computer screen.)

My name is Monty Goddard. I am a resident of CA. I am a member of the Speakers Bureau of the National Campaign to Protect People in Pain. (The "Cc" addressees of this email comprise the remainder of the Speakers Bureau.)

I intend to make public comment at this coming board meeting during Agenda Item # II. *Public Comments on Items Not on the Agenda/Agenda Items for Future Meetings*.

I am requesting you please disseminate this email, with its attachment, to your board members so they will have the opportunity to examine it prior to hearing my public comment this coming Wednesday.

This attached information was briefed Tuesday, July 23rd, to senior officials at the FDA Center for Drug Evaluation and Research. It has also been published online and shared with organizations noted below:

Administrators, National Institutes of Health, HEAL Initiative RFI (expiring July 30)

Office of the Director, National Institute on Drug Abuse

Office of the Executive Secretary, US Centers for Disease Control and Prevention
attention, CDC Director and senior staff
CDC-Info online gateway

Board of Scientific Counselors, National Center for Injury Prevention and Control.

Immediate Office of the Secretary of Health and Human Services
Assistant Secretary of Health
Office of the Inspector General

Office of the US Surgeon General

National Office for Drug Control Policy, Executive Office of the President

US Drug Enforcement Agency, Division of Diversion Control
for all senior DEA Staff

AMA Substance Use and Pain Care Task Force,
and all 29 participating organizations

Offices of US Colleges of Medicine and Board Certification organizations including
American Academy of Family Physicians
American Psychiatric Association
American Academy of Pediatrics
American College of Obstetricians and Gynecologists
American College of Physicians
American Osteopathic Association

Editors of healthcare media organizations, including
Medscape
Kaiser Permanente Health
Reason Magazine
KevinMD
STAT News
Pain News Network
American Council on Science and Health
Journal of Medicine of the National Association of Medical Doctors
Medical Research Archives of the European Society of Medicine
PAINWeek

Multiple investigative reporters and editors in US National media.

Legislative Directors and Chiefs of Staff in the US House of Representatives and Senate committees and subcommittees on health and judiciary

Our campaign's lead POC, and nationally renowned subject matter expert is:

Richard A "Red" Lawhern PhD
Patient Advocate
Twitter: @Lawhern1
Facebook: https://www.facebook.com/red.lawhern
My Publications: http://www.face-facts.org/Lawhern
Personal Website: http://www.lawhern.org

If any Board Members desire or require further information of clarification on this email, please contact me via email at montygoddard@msn.com.

Thank you Debbie!

Sincerely,
Monty Goddard MSCE PE
Patient Advocate

The Real Opioid Crisis in Three Charts

– An FDA Listening Session--

Richard A Lawhern, PhD, Pat Irving, RN, Monty Goddard, Kristen and Louis Ogden, Steven E Nadeau, MD, L Joseph Parker MD

July 23, 2024

INTRODUCTION:

On July 23, 2024, seven members of the Speakers Bureau of the National Campaign to Protect People in Pain participated in a one-hour “listening session” to brief senior officials in the US FDA Office of Communications, Professional Affairs and Stakeholder Engagement (PASE), Center for Drug Evaluation and Research (CDER).

Presenting and Supporting Attendees comprised authors as above.

FDA Audience: A group of six to eight FDA officials was headed by Marta Sokolowska, Ph.D., Deputy Center Director for Substance Use and Behavioral Health in the FDA's Center for Drug Evaluation and Research (CDER)

Subject: “The Real Opioid Crisis in Three Charts”, with four additional speaker presentations.

Session ground rules (reviewed as we began the session, by Christopher Melton, PASE staff): Listening sessions are informal venues in which neither the presenters nor the FDA are committed to take specific actions.

- From the FDA side, no information is provided that is not public domain, nor may FDA choose to later communicate decisions made on the basis of information offered.

- From the presenters’ side, no restrictions are placed on public disclosure of materials or speaker notes offered during the Listening Session.

- It was understood by all that meeting notes may be communicated widely by presenters in social media, print media, and online networks.

Text offered in the present review is from speaker notes prepared before the Listening Session. Minor additions and revised emphasis during the live Session were incorporated during the session.

INITIAL PRESENTATION: Richard A Lawhern, PhD for the Speakers Bureau of the National Campaign to Protect People in Pain.

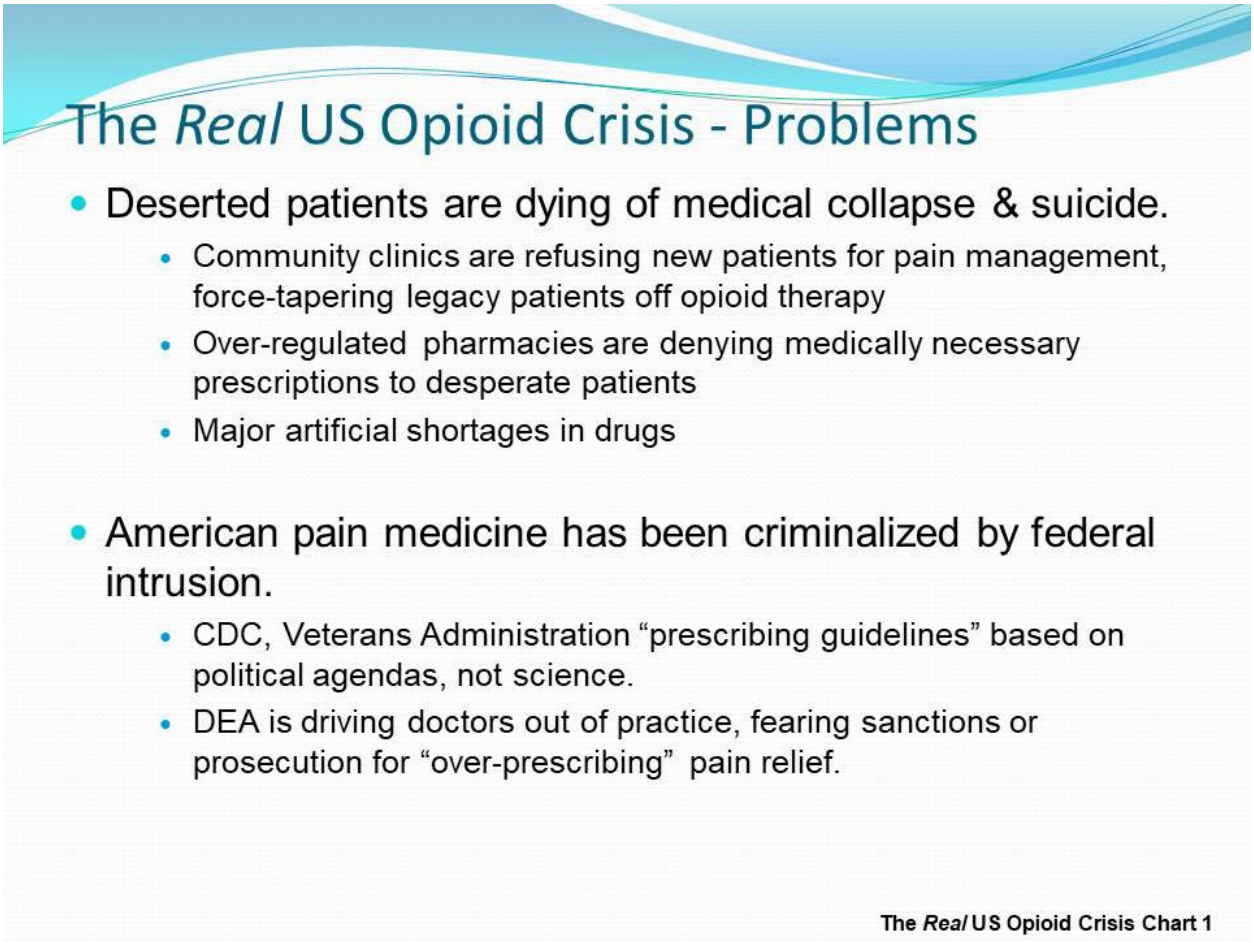
Good afternoon and thank you for convening this listening session. I speak on behalf of thousands of patients and doctors who are being deeply harmed by misdirected National public health policy for treatment of chronic and acute pain, including those assessed to be victims of opioid addiction. This is arguably the single most important issue in American healthcare today. As the premier US Agency that validates accepted prescribing practices for the treatment of pain, we believe it is essential that your Agency take action to engage with this issue and to correct public narratives that are destroying lives.

My presentation is supported by a National alliance of doctors, subject matter experts and patient advocates. This network has literally thousands of years' experience in

clinical practice, patient safety education, patient advocacy and healthcare writing. Our Speakers Bureau members have no financial conflicts of interest; all of us are unpaid volunteers. Follow-up contact data is provided later in this briefing.

Your presenter is Richard A Lawhern PhD. I am a healthcare writer, data analyst, and subject matter expert on public policy for the treatment of pain employing prescription opioid pain relievers. Over the past 27 years, I have authored or coauthored over 250 papers, articles and interviews in a mixture of peer-reviewed and editor-reviewed clinical journals and mass media. Like my colleagues in the Alliance, I am easily found in searches of Google Scholar or Perplexity.ai .

Information presented herein has a currency cutoff date of June 2024. The presentations were offered by Zoom meeting session, on July 23, 2024.



This is the first of three charts that describe the "Real" opioid crisis in terms of

- Problems
- Realities
- Needed Legislative Solutions

This presentation was originally constructed for legislative staff in the US House and Senate, and has been adapted for this listening session. Our unifying theme is that the FDA is charged with oversight and practice standards for appropriate prescribing practice. This mission is now being usurped by the US DEA, which has prosecuted and imprisoned or sanctioned hundreds of clinicians for prescribing in a manner authorized by the FDA. This misdirection has been compounded by mission creep in the US CDC and the Veterans Administration, and by the inappropriate application of CDC practice guidelines that violate both basic science and medical ethics.

It is common these days to speak of the US "opioid crisis" or sometimes the "opioid epidemic". However, I emphasize the term "real" in this briefing. In many ways almost everything the government thought it knew about this crisis has turned out to be wrong; on science; on ethics; and on public health policy.

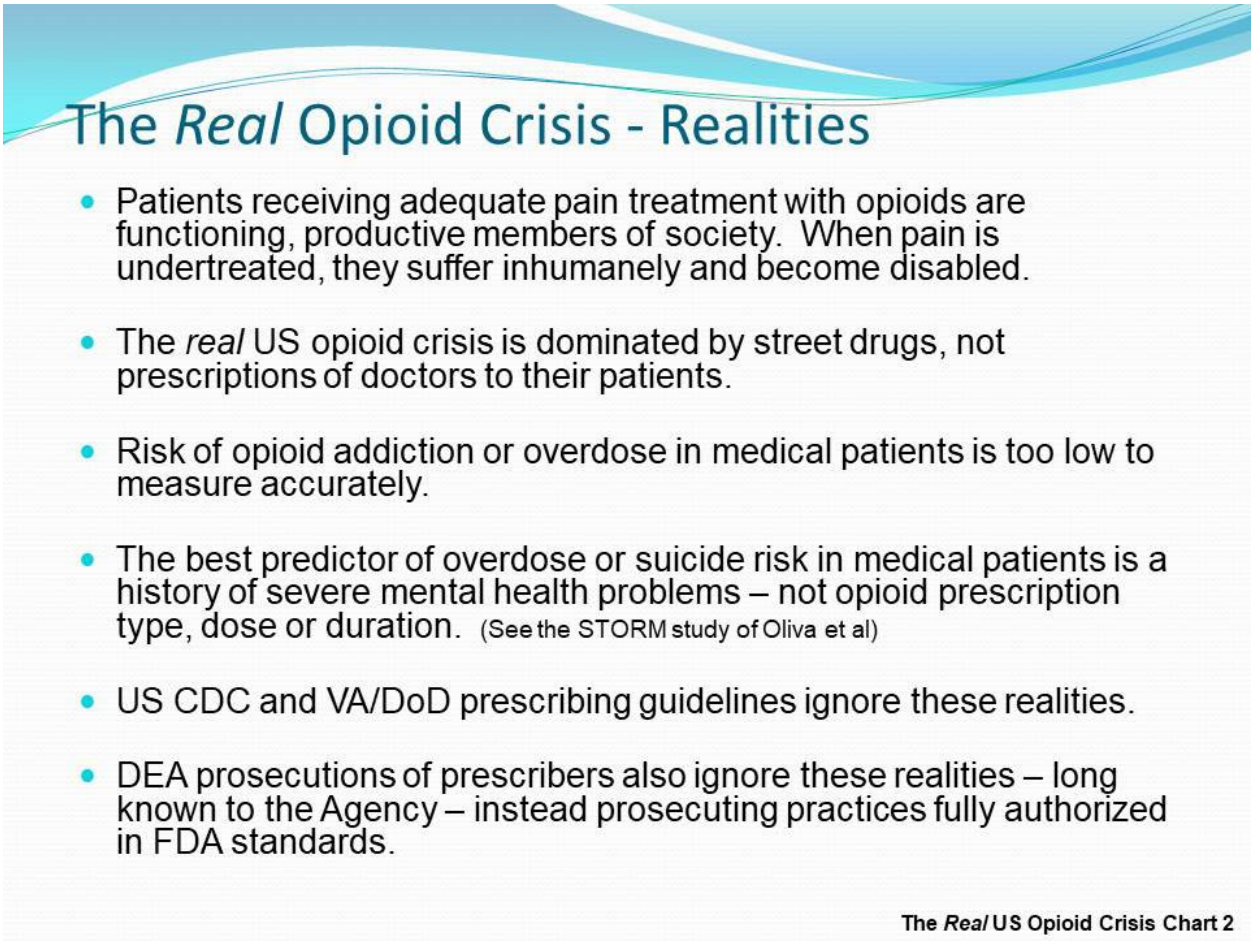
Pain is one of the most terrible afflictions known to humanity, and yet it is the most common symptom that brings patients to a doctor's office. The National Academies of Medicine estimate that over 100 million Americans experience clinically significant pain each year – possibly 40 million of whom at levels that compromise daily quality of life and shorten life expectancy. Costs in lost productivity are over $1 Trillion every year.

But these days, large numbers of new and legacy patients are being abandoned or turned away when they ask for help in managing their pain. Legacy patients in many clinical practices are being force-tapered to ineffective doses of the only safe and effective therapies we have that work to manage their pain. By this I mean prescription opioid pain relievers.

These patients are being abandoned when their doctors are shut down or become too frightened to treat pain or addiction, using FDA-approved medications and therapies. Thousands are dying from medical collapse and suicide. Millions are struggling with DEA-mandated artificial prescription drug shortages, even if they have found the rare doctor who is still willing to treat them.

It is not going too far to say that the two main culprits in this torture are the opioid prescribing guidelines published by US Centers for Disease Control, greatly magnified by an unjustifiable nationwide witch hunt conducted against pain doctors by the US Drug Enforcement Agency. In their zeal to eliminate every possibility of drug diversion, they are destroying the practice of pain medicine in America.

Let's look now at some realities related to this debacle of misdirected policy.



Many acute and chronic pain patients who receive adequate treatment continue to be productive members of society despite their ongoing medical issues. When denied pain treatment, however, they suffer needlessly and often lapse into disability and social isolation, with loss of employment and even homelessness. I have personally talked with people in pain who were ***living in their cars*** due to loss of employment and inability to pay home mortgages. Thousands commit suicide.

This situation is simply unacceptable. In the name of "saving" a tiny fraction of people in pain from addiction or overdose death, US public health policy is now condemning and criminalizing their doctors and driving millions of patients into agony and death.

I say that we're dealing with a "tiny" fraction of people. Multiple published studies estimate overdose mortality among clinically managed patients somewhere between 2% and two-tenths of 1% - two patient deaths per thousand who are treated by a doctor. Such numbers are confounded by misdiagnoses of opioid use disorder by doctors

untrained or poorly trained in the field of addiction. Another factor is the long-standing confusion between physiologic dependence on opioids versus addiction. As noted by authorities such as Dr Nora Volkow of the National Institute on Drug Abuse, these medical conditions are not the same thing. References at the end of this briefing will confirm this truth.

Arguably and as I have myself written for publication, “there is no such thing as opioid use disorder”. The term first appeared in the Diagnostic and Statistical Manual for Mental Disorders of the American Psychiatric Association (DSM-5). That document was publicly repudiated two weeks before publication by the US National Institutes of Health as a basis for organizing mental health research.

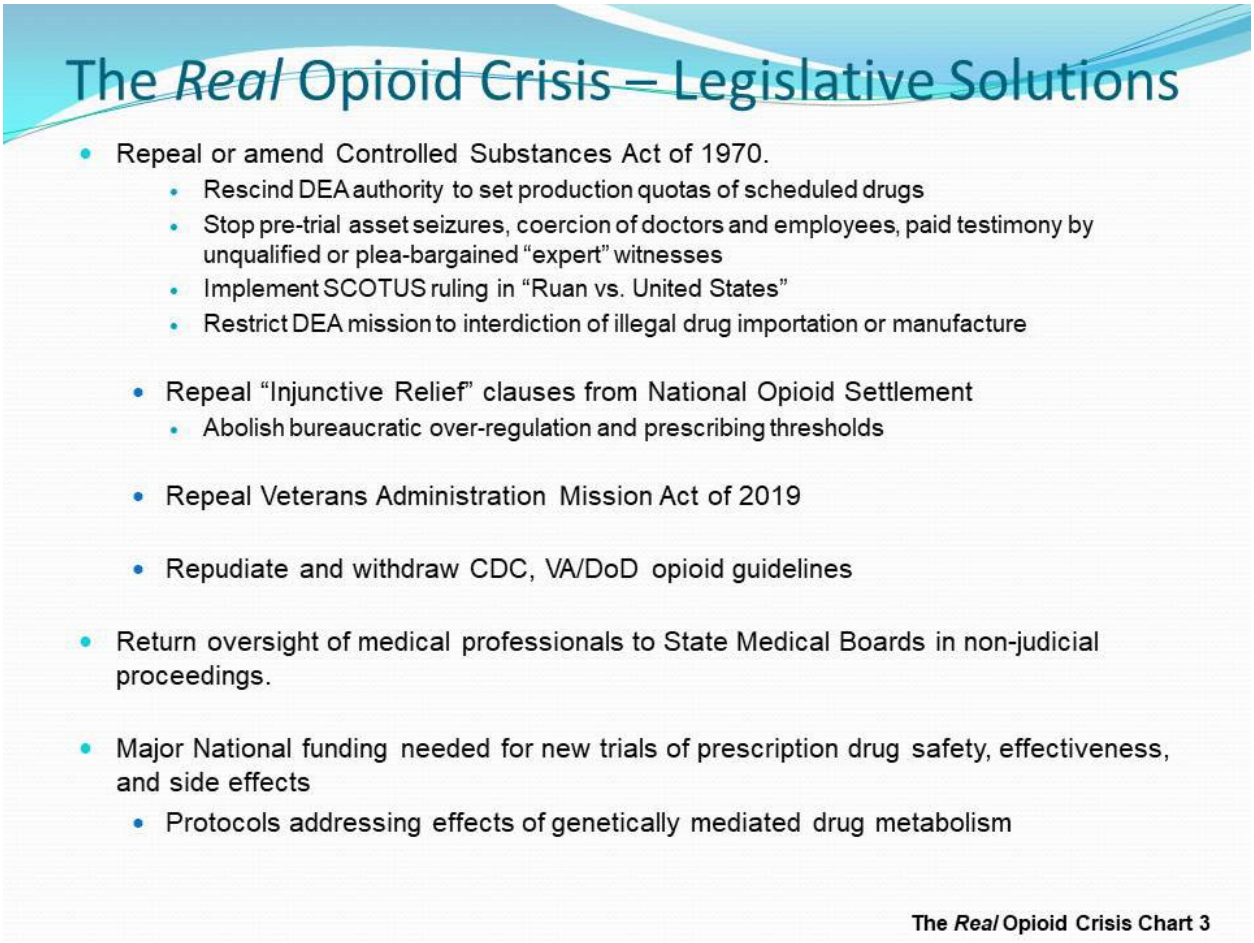
Risks of opioid addiction or overdose among patients who are treated in an on-going doctor-patient relationship are too small to accurately measure. As belatedly acknowledged by US CDC, mortality statistics are dominated by street drugs. And as not yet acknowledged by CDC and DEA, these statistics always have been! CDC guideline writers knew or should have known these realities even in 2016, and certainly knew them in 2022 before they published. DEA senior management has known since at least as far back as 2019.

When prescription drugs are found in a postmortem blood screen, they are almost always combined with several other toxic substances plus alcohol – something that almost never occurs in chronic pain patients. The great majority of people who overdose don’t have a current prescription. And a huge majority of patients will never overdose, even if they go through withdrawal symptoms when a doctor tapers them off medication too rapidly.

Based on the studies of Elizabeth M Oliva and her colleagues in the STORM model, analyzing records of more than 1.1 million US Veterans, the best predictor for patients who might have problems with opioids is a history of severe mental health problems. These include bipolar disorder, clinical depression, chronic anxiety, past hospitalization for overdose, or previous suicide attempts. These factors are four to 20 times more predictive of near-term overdose or suicide events than past treatment with opioids of any kind.

Unfortunately, these realities were utterly ignored in the prescribing guidelines issued by the US CDC and Veterans Administration. US DEA has likewise ignored the reality that prescription opioid pain relievers are only one of eight factors that contribute to accidental drug deaths in America – and that prescriptions have never been a dominant driver of deaths in the so-called “opioid crisis.” DEA-published studies addressed this reality in 2019, when the opioid crisis had become a moral panic. But DEA still -- half a decade later -- continues to target doctors who prescribe opioids; including doctors who

take on the patients of other doctors whom the DEA has forced out of practice or sent to prison.



Major and unjustifiable damage has been done to doctors and their patients by restrictions on prescription of opioid pain relievers. The National Campaign to Protect People in Pain believes that this damage can only be remedied by Federal legislation to decriminalize American pain medicine and put treatment decisions back in the hands of clinicians rather than unqualified law enforcement authorities. This legislation will likely involve:

- Repealing or amending the Controlled Substances Act of 1970
- Removing DEA authority to set production quotas on Federally controlled substances
- Eliminating abusive prosecutorial and Administrative Court Judge practices that unfairly deny clinicians resources to defend themselves or otherwise bias court proceedings against defendants, including the use of "expert" witnesses who hold extreme opinions not representative of the general medical

consensus.

  - Stop pre-trial asset seizures against doctors,
  - Stop the coercion of employees of doctors to testify against them,
  - Stop the use of plea-bargained testimony by otherwise unqualified witnesses selected to support assertions of prosecutors who lack medical training,
  - Require that “expert witnesses” are actually qualified by training and hands-on clinical practice to testify to dangerous or unprofessional behavior of defendants,
  - Direct judges and juries to entertain good-faith defenses of clinicians under the terms of the Supreme Court decision in Ruan vs. the United States.

- Restrict the mission of the Drug Enforcement Administration to interdiction of illegally imported or manufactured narcotics, and apprehension of distributors and street sellers of illegal drugs – leaving the policing of medicine to appropriate authorities, which are State medical boards, as the Supreme Court has made clear in multiple rulings.

Also vital is the immediate repeal of the (secretly crafted) Injunctive Relief clauses of the National Opioid Settlement, which we will shortly address in a further short presentation. These clauses have created a nightmarish maze of pharmacy over-regulation that is widely causing rejections of legitimate prescriptions, as well as shortages of prescription drug inventories at pharmacies.

Repeal is also needed of the Veterans Administration Act of 2019, to remedy a de facto system-wide VA policy of “no opioids to any patient for any reason.”

The 2016 and 2022 CDC guidelines on prescription of opioids are widely recognized as biased by anti-opioid misinformation compounded by very weak, inadequate and cherry-picked research. These guidelines must be publicly repudiated and withdrawn without replacement. While correction of unprofessional or dangerous clinician behavior is appropriate and needed, the appropriate authorities are at the level of State Medical Boards, not Federal Agencies or law enforcement.

As a footnote directed specifically to this audience at FDA, I must also assert that there is abundant published evidence that the entire trials literature on safety and effectiveness of prescription opioid pain relievers must be (figuratively) burned to the ground and done over. No published trial – including those reviewed for the US CDC guidelines by the US Agency for Healthcare Research and Quality -- has employed protocols that account for genetically mediated polymorphism in liver enzymes that

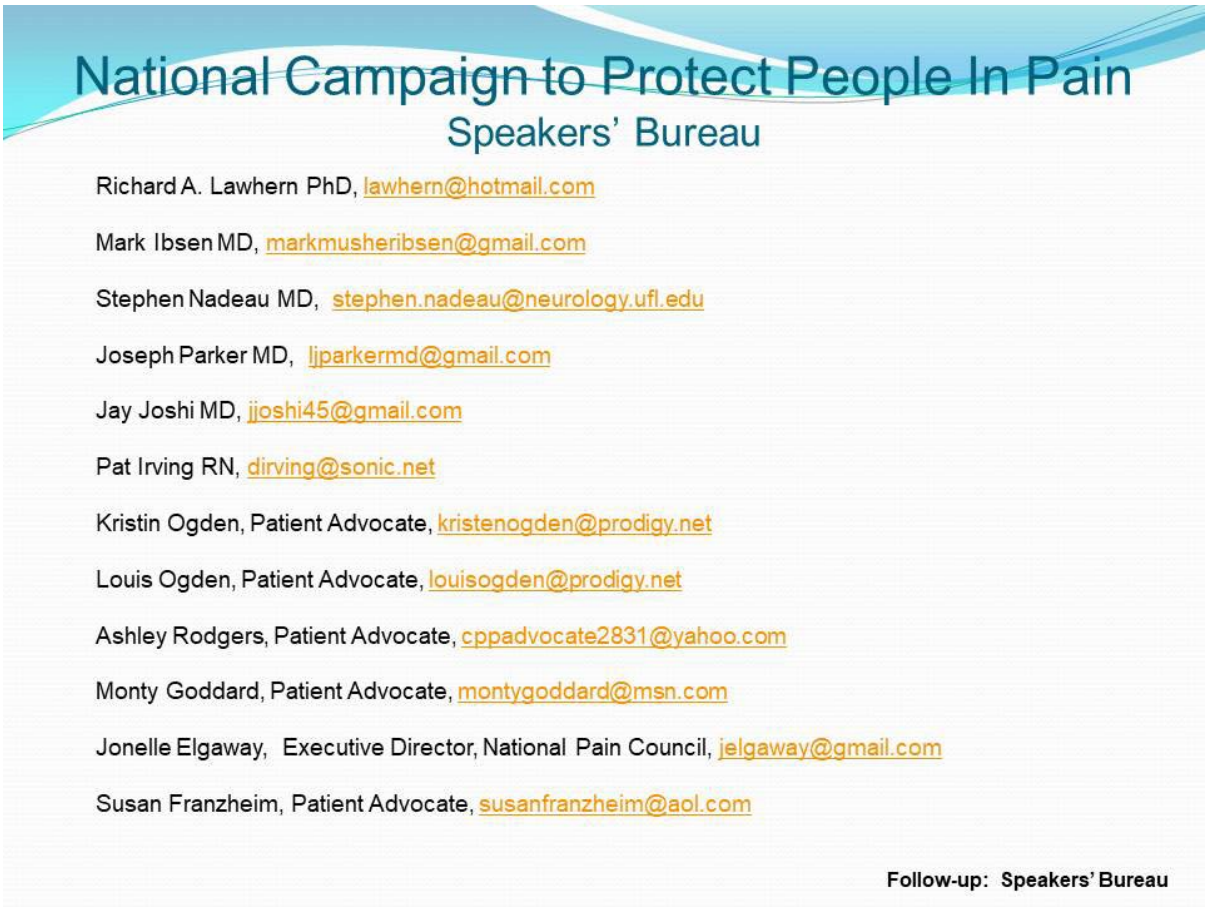
metabolize opioids in the liver. Omission of this 25-year established medical literature has rendered CDC prescribing guidelines fatally flawed and actively dangerous to patients and their clinicians. There is no such thing as an average individual patient.

The crisis among legacy pain patients has been heightened by both artificial and inappropriate DEA limits on opioid production, and horrendous bureaucratic barriers created by the Injunctive Relief provisions of the National Opioid Settlement. We urge you to take public action to address both.

We must also point out that present FDA procedures for determining the adequacy of prescription opioid supplies are seriously deficient. The FDA has no grasp on shortages that happen BETWEEN THE MANUFACTURER AND THE PHARMACY, caused by Thresholds imposed by the Injunctive Relief provisions of the National Opioid Settlement. By contrast, estimates performed by the American Society of Health-System Pharmacists (ASHP) clearly show shortages at the pharmacies of Norco and Oxycodone, although the FDA shows adequate supplies. It is crucial that the FDA amend their measurement process.

SOURCES AND FURTHER PRESENTATIONS

The following are the 12 members of the Speakers Bureau of the National Campaign to Protect People in Pain, several of whom are present today. We are available for follow-up discussions or clarifications, should FDA wish to do so – if necessary, under confidentiality agreements.



The next two pages comprise a list of 10 supporting references drawn from hundreds of papers and articles in clinical and popular literature. This material can help to prepare senior officials of the FDA for further discussions or a request for public comment in the Federal Register.

The *Real* Opioid Crisis – References 1

1. American Academy of Family Physicians, "Frontline Physicians Call on Politicians to End Political Interference in Evidence Based Medicine", May 15, 2019 https://www.aafp.org/news/media-center/more-statements/physicians-call-on-politicians-to-end-political-interference-in-the-delivery-of-evidence-based-medicine.html

2. L. Joseph Parker MD, "The Persecution of Pain Management Doctors", *Journal of Medicine*, National Association of Medical Doctors, August 23, 2023 https://www.namd.org/journal-of-medicine/3104-the-persecution-of-pain-management-doctors.html

3. Richard A. Lawhern, PhD, "Everything the Government Thinks It Knows About the Opioid Crisis is Wrong", *KevinMD*, July 1, 2023 https://www.kevinmd.com/2023/07/everything-the-government-thinks-it-knows-about-the-opioid-crisis-is-wrong.html

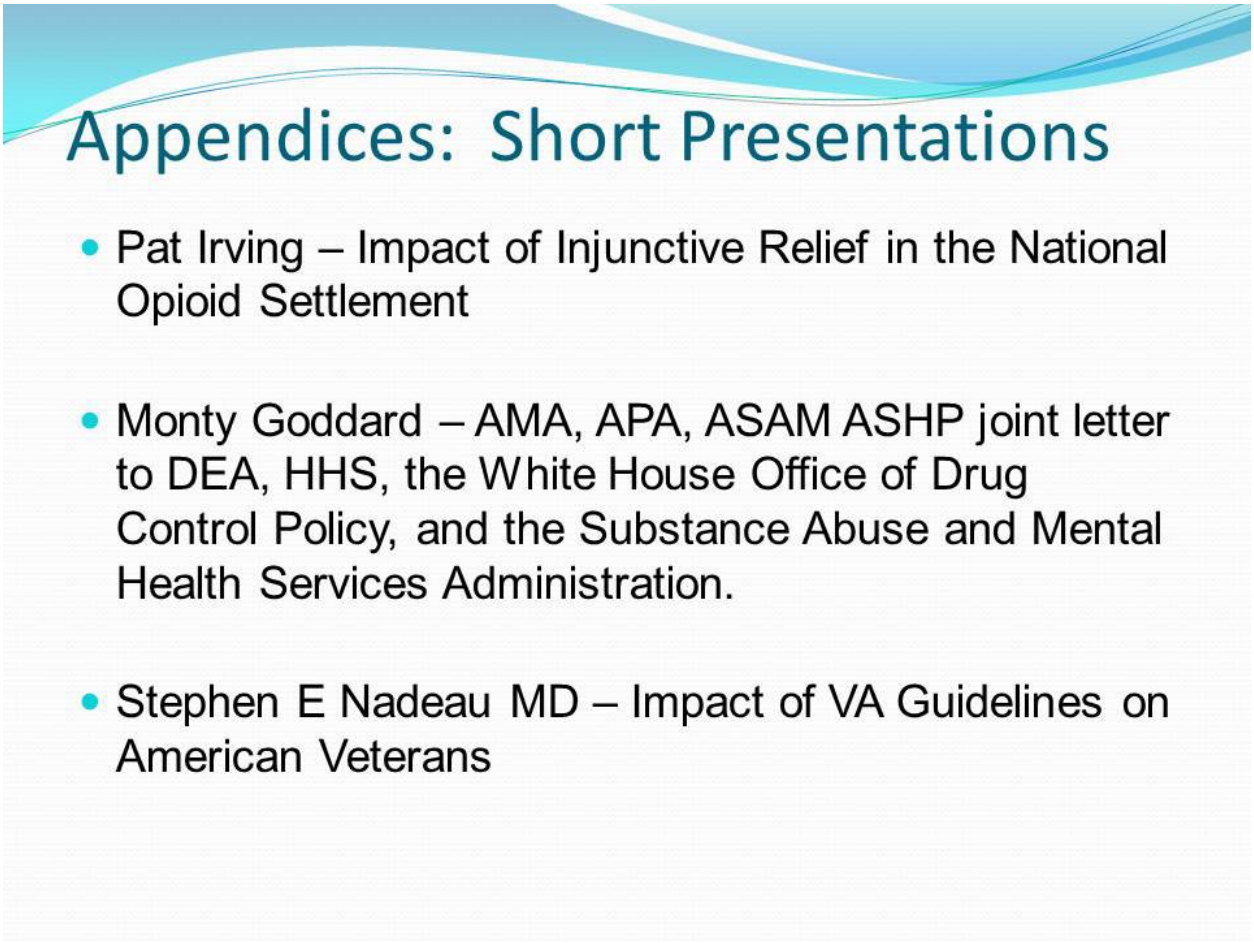
4. Steven E Nadeau MD and Richard A Lawhern, PhD, "The Two Opioid Crises – Problems, Causes, and Potential Solutions: An Analytic Review", *Medical Research Archives* of the European Society of Medical Doctors, December 31, 2023 https://esmed.org/MRA/mra/article/view/4846/99193547539

5. Richard A Lawhern, PhD, "Resources for Clinicians in Pain Medicine – Correcting Medical Mythologies on Prescription of Opioid Analgesics", *Medical Research Archives*, of the European Society of Medical Doctors, https://esmed.org/MRA/mra/article/view/4860

The *Real* Opioid Crisis – References 1

As an additional resource for FDA, we also offer our deep experience with the literature of pain medicine and addiction. I (Dr Lawhern) maintain bookmark files on over 15,000 papers, articles and presentations in this field. Members of the Speakers Bureau are networked by email and in social media with thousands of practicing clinicians and tens of thousands of suffering patients and family caregivers. We can deploy announcements to over 100,000 potential readers in 15 minutes, should you wish to do so.

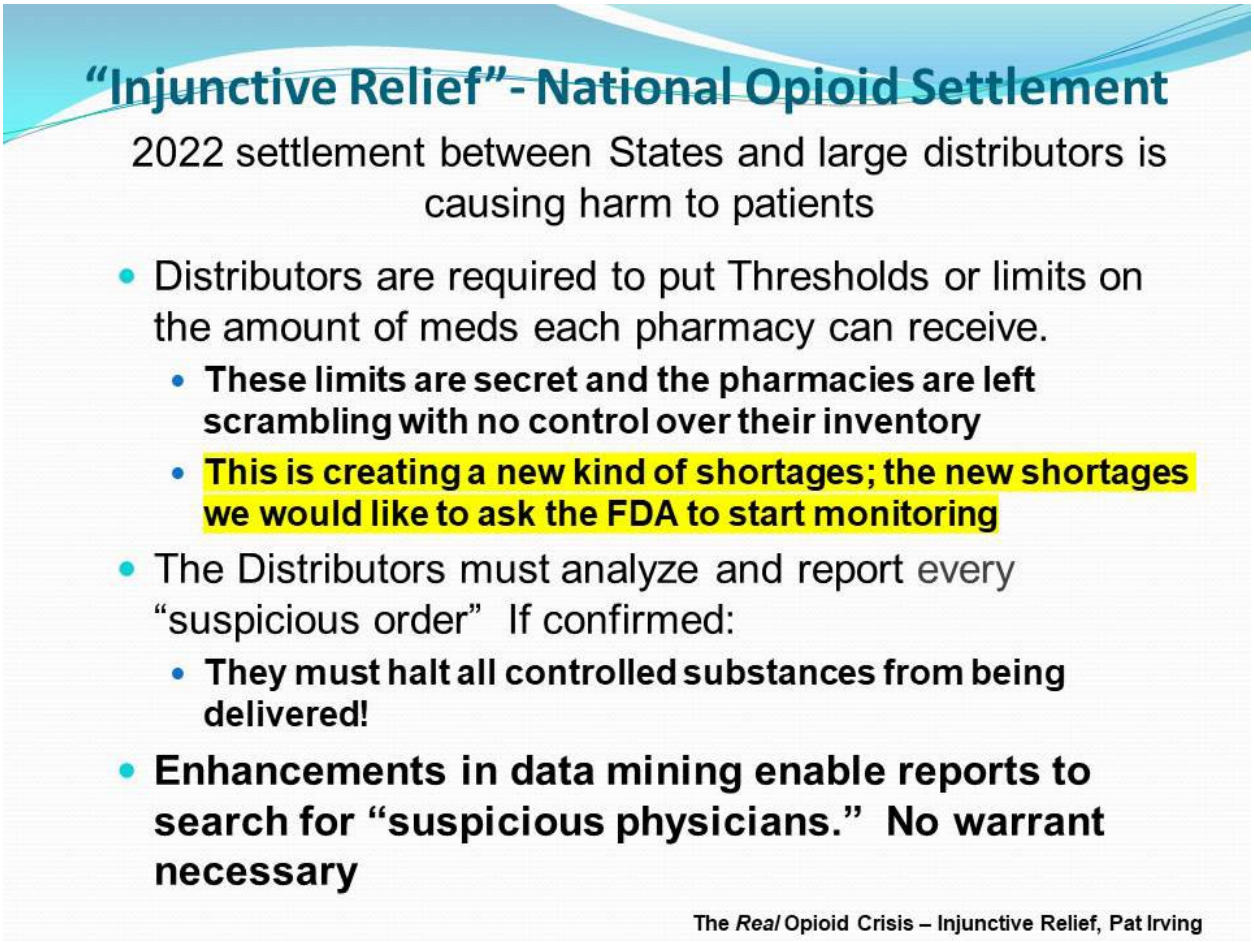
Thank you for your time and attention. We will next offer short presentations by Alliance colleagues who are also in attendance at this Listening Session. We have added one presentation by patient advocate Kristen Ogden and her husband Louis Ogden. to the agenda initially transmitted to FDA. Mrs. Ogden will speak third, followed by Doctor Steven E Nadeau.



PRESENTATION BY PAT IRVING, RN

Hello. My name is Pat Irving and I am an RN with over 40 years of healthcare risk assessment and patient safety experience. I have been an advocate for patients with chronic pain since having endured a forced taper of my own legitimate pain medication.

I am eager to speak to you today about a crisis in healthcare that may be unknown to you, or at the very least the impact of which has not been well appreciated. I am referring to the negative impacts of the National Opioid Settlement Injunction and specifically how the injunction relates directly to the work of the FDA.



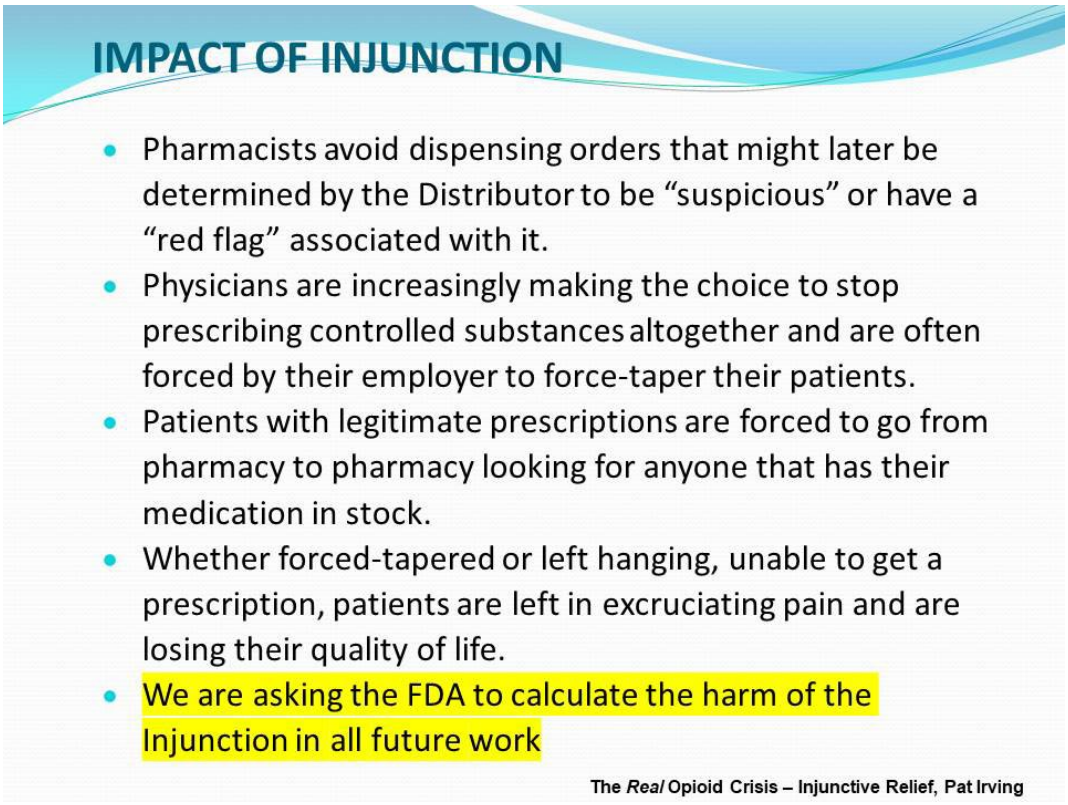
First, some background. In 2022, as part of the Opioid Settlement there is a corresponding Injunction that was designed to increase oversight by Distributors over pharmacies ordering controlled substances. These restrictions unfortunately were fueled by erroneous beliefs that prescription medications (not street medications) were the primary driver of the opioid crisis. We now have abundant evidence that this is not, nor was it ever, true.

Because prescribing guidelines were driven by an overt anti-opioid sentiment, the Injunctive Relief mandates do not follow either science or any current government guidelines. The injunction instead implemented restrictions in the pharmacy chain that were so strict that artificial shortages are occurring and patients with legitimate prescriptions are unable to pick up the medications they desperately need.

The mechanisms for this harm are as follows:

First, the Injunction forces the Distributors to implement thresholds dictating the amount of controlled substances any given pharmacy can obtain in a month. These thresholds are calculated by algorithms that are hidden from the pharmacies and the threshold amounts are mandated to be held secret. Pharmacies now have no way of knowing what their future inventory is going to be…and what is worse, if they fill more than their quotas they are reported both to the DEA as well as their state's AG.

Patients are left scrambling, trying to pick up their legitimate prescriptions. Unfortunately, the system is now driven by fear and no one can help them. The obvious next question is: Can you, the FDA, see these secret algorithms and the cuts they are making in the supply chain? Are you measuring them? My colleague Monty Goddard will explore implications of this question in his upcoming comments.



The second mechanism for harm woven into the Injunction is that Distributors are "deputized" as mini-arms of the DEA. The Distributors are now expected to pre-emptively determine whether an order is a "suspicious order" or if it has "Red Flags." If a pharmacist assesses one or both these conditions to exist, they must immediately halt the order. Before the Injunction, there would have been ample communication between Distributors, pharmacies and physicians.

But remember that the system is now run by fear. Doctors and patients can no longer call their pharmacists to resolve issues. There is just the arbitrary halting of legitimate medications. In the patient's world, they have been shorted the amount of medication they have been prescribed. And there is often no effective recovery from this action.

I hope it is evident in this short description, that the Injunction embedded in the National Opioid Settlement is something the FDA must be aware of. We plead with you to assess effects of the Injunction as you move forward into this very new landscape. I will now hand you over to Monty Goddard who will further discuss the impact of the Injunction on the FDA and the patients whom your organization is tasked to protect.

PRESENTATION BY MONTY GODDARD

My name is Monty Goddard, I have a master's degree in civil engineering and have been a licensed professional engineer in California for over 45 years. I retired as a GS-15 equivalent, NSPS-YD3 in 2010, after over 36 years of federal service. Five years ago, nine years after I retired, I was "forced" to become a pain patient advocate when my wife's quality of life and our "Golden Years" were destroyed by our own governments' mis-targeted "War on the Opioid Epidemic".

After six years of surgeries and after all other pain control protocols were tried and failed to provide adequate pain relief, 22 years ago, in 2002, my wife was placed on high dose opioid medications. For a decade and a half, these medications gave my wife her life back. She could once again physically function! Tragically, unjustly, inhumanely, my innocent wife has been force-tapered to a dosage which no longer enables enough pain control to allow her enough physical function to enjoy a reasonable quality of life.

Before I expand on Pat's comments, I have two other items I would like to share.

First, I have researched the American Society of Health-System Pharmacists (ASPH.org) drug shortages database, which for at least a year has listed significant

shortages of Hydrocodone and both variants of Oxycodone. I also viewed the FDA drug shortages database, which for this same period has listed ZERO hydrocodone and oxycodone shortages. This dichotomy is a major problem. If the FDA does not even acknowledge there is a shortage of these two essential pain medicines, then FDA can certainly take no related remedial action, as you did in concert with the DEA, in November of last year to address ADHD medication shortages with the manufacturers.

The FDA needs to modify its methodology for collecting and reporting drug shortages to better reflect the reality experienced by pain patients whose legitimate prescriptions go unfilled due to shortages on pharmacy shelves. These all-too-real shortages, which are not currently acknowledged by the FDA, are negatively impacting prescribers, pharmacists, and most importantly innocent suffering patients.

Second, the DEA's November 2023 proposed 2024 controlled substances production quota announcement in the Federal Register contained this statement: "FDA predicts that levels of medical need for schedule II opioids in the United States in calendar year 2024 will decline on average 7.9 percent from calendar year 2023 levels." At a time when the population is growing older, States are enacting laws easing the legitimate prescribing of opioids, and State Medical Boards (like California's) are publishing guidance encouraging physicians to return to the practice of pain medicine, this FDA recommendation appears illogical.

The FDA needs to reevaluate and publish the rationale for this and future related recommendations.

I'll conclude with a brief follow-on to Pat Irving's comment about the State AGs' nationwide opioid settlement's harm to the controlled substances supply chain to pharmacy shelves.

On May 10th of this year, the American Medical Association, the American Pharmacists Association, the Association of Addiction Medicine, and the American Society of Health-System Pharmacists sent a joint letter to the DEA, HHS, the White House Office of Drug Control Policy, and the Substance Abuse and Mental Health Services Administration. This letter unequivocally documented all four co-signers' agreement concerning the harms being done to patients as a direct result of the state AGs' nationwide opioid settlement with three major distributors of controlled substances. The letter requests the addressees to influence some relief of the AGs' settlement harm to the supply of medications for opioid use disorder (MOUDs) -- **but not for other similarly impacted controlled substances**.

To that end, those of us meeting with you today have initiated correspondence to the signatories of the May 10th letter suggesting they expand their "ask" to encompass all controlled substances and to include the state AG's on distribution of their all-inclusive request.

PRESENTATION BY KRISTEN OGDEN (Spoken Without Charts)

Good afternoon. My name is Kristen Ogden. I am not a medical professional or a scientist. I am an advocate and caregiver for my husband of 51 years, Louis Ogden. I have been advocating for him for the past 25 years and have been more fully engaged in advocacy since I retired from Federal service in 2014 with 36 years of service. I am a 1975 graduate of the College of William and Mary, and at the time of my retirement, I was serving as Director of Strategic Planning and Performance Management for the Defense Commissary Agency.

Louis has suffered from chronic pain since age 6. In 2010, after years of seeking help for his severe constant pain with no success, he was accepted as a patient by well-known California pain specialist, Dr. Forest Tennant, and we began quarterly trips to CA from our home in Virginia which continue to the present. Upon retiring in 2014, I decided to focus my advocacy efforts on one specific pain patient population: persons who suffer from severe, incurable pain and have failed all traditional treatments. These were the patients accepted for medical care in Dr. Tennant's pain clinic in West Covina, CA, and I had the privilege of getting to know many of them through my advocacy efforts and serving as a volunteer in Dr. Tennant's clinic.

We engaged these patients and their family members in advocacy, and I co-founded a small advocacy group called Families for Intractable Pain Relief. Our goals are 1) to raise awareness of severe, constant intractable pain and the challenges faced by those who suffer from it, and 2) to ensure access to whatever treatments are needed to properly care for these individuals. We support the appropriate prescribing of opioids at any dose by qualified physicians as a last resort treatment to relieve the severe intractable pain of any patient for whom such dose is deemed necessary to stabilize function and enable a decent qualify of life. As Louis first said publicly at our first FDA meeting in 2014, high-dose opioid therapy gave him the best quality of life he had ever experienced as an adult. He still believes that, as do I, and he is now 74 years old.

Louis' quality of life and our lives as a couple improved tremendously in late 2010 as Dr. Tennant's approach to pain care began working: pain medications, hormone management, attention to diet, and gentle exercise. Our improved quality of life continued through early 2013, but then things headed downhill, gradually at first and then drastically. In late 2017, the DEA raided Dr. Tennant's clinic, home, and office. Although they never identified any failure or wrongdoing on his part and never charged him with any infraction, they pressured him to retire and, on the advice of his attorneys, he closed his clinic June 30, 2018. Before closing, Dr. Tennant provided each patient with 3 30-day prescriptions, wrote referrals, and assisted patients to find other care as best he could.

Fast forward to November 1, 2022. The DEA delivered to Louis' then physician, Dr. David Bockoff, an Order to Show Cause and Immediate Suspension of Registration. By then, many of Dr. Tennant's former patients had found Dr. Bockoff and were receiving care from him. This time, all 240 of Dr. Bockoff's patients were immediately cut off with no prescriptions and no referrals. In effect, the DEA ordered Dr. Bockoff to abandon his patients; that is illegal in California and most other states.

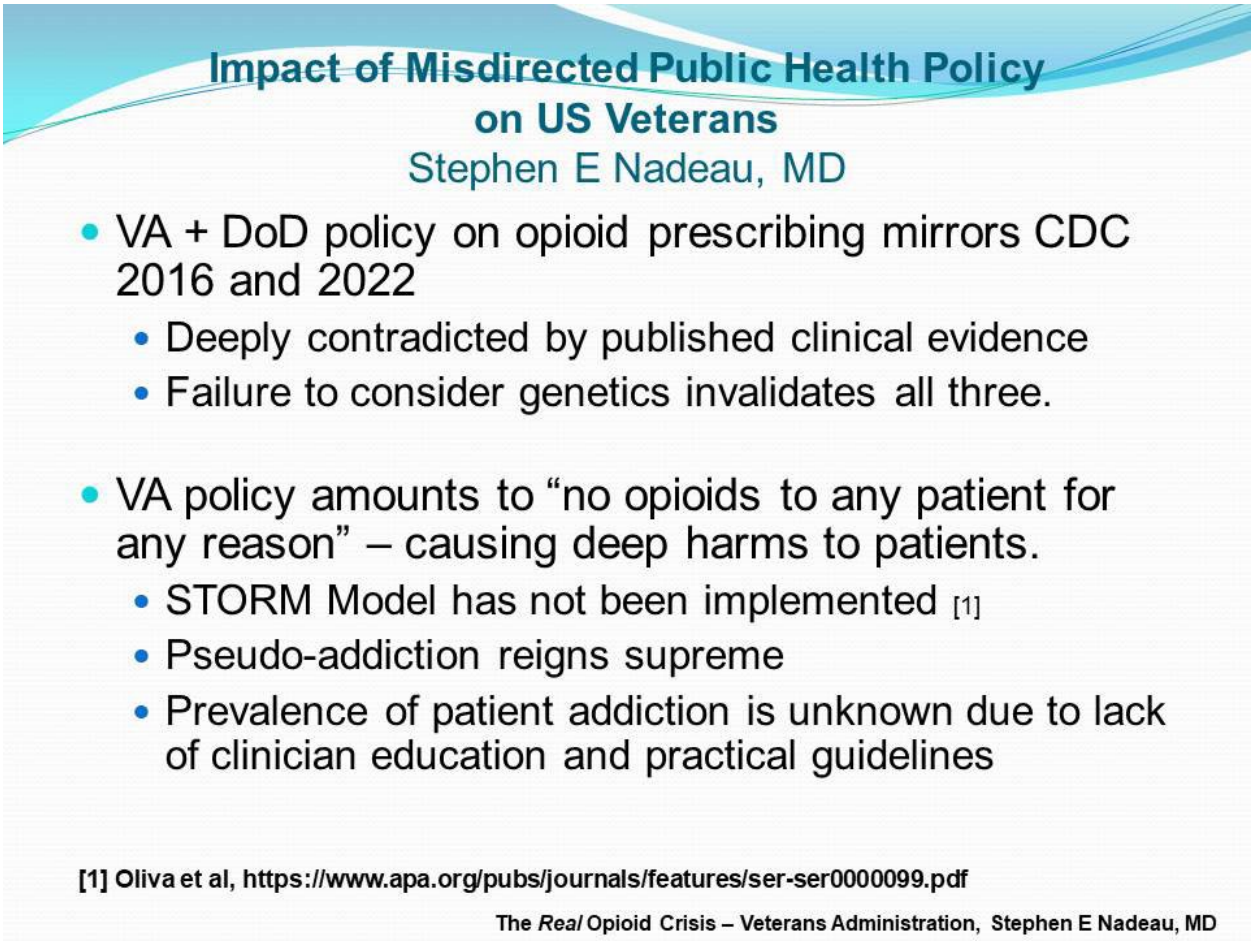
By this time, many doctors had already left the practice of pain care, and the few still practicing were reluctant to accept these patients. Within a short period of time, patient Danny Elliott and his wife committed suicide. At least two other patients died from the sudden loss of their medications. These individuals had been doing well and would probably be alive today had Dr. Bockoff not been shut down.

Despite all efforts to inform and educate CDC and DEA about the existence of severe, intractable pain patients, those agencies continue to show no regard for the needs of such patients. To the CDC and DEA, they are all addicts or drug traffickers. The stigma against persons who use opioids … "those drugs" … continues. We have not been allowed to fill Louis' prescriptions for pain medications in Virginia since late 2018. Since June 2019, I have flown from VA to CA and back every month to get his prescriptions filled.

My purpose in sharing these events is to say to you that **what you do matters**. When FDA develops policies that address opioids, **it matters**. When you put a black box warning on benzodiazepines, **it matters**. When you underestimate the magnitude and impact of drug shortages, **it matters**. If I had enough time today, I would give the presentations I gave at FDA in January 2018 and June 2019 about the value of opioids to the many patients with the kind of pain my husband endures if he has no pain medications. Instead, please just know that we face ridiculous, almost unbelievable barriers every day to obtain care and medications. We continue our fight against these barriers, "red flags, unwarranted dose ceilings and the many myths and misconceptions that underlie the stigma and hysteria caused by anti-opioid zealots. Our motto is "Never Give Up!" ***And we won't!***

I appreciate this 6th opportunity to speak to FDA representatives. Thank you for your time.

PRESENTATION BY STEPHEN E NADEAU MD



FDA Conversation: My prospective contributions: Nadeau

I am Steve Nadeau. I am a professor of neurology in the University of Florida, College of Medicine and a staff neurologist at the Malcom Randall VA Medical Center in Gainesville. My research interests have been in cognitive and computational neuroscience, neurorehabilitation, and more recently, the use of opioids and other drugs in management of chronic pain and the nature and solutions to the clinical and illicit opioid crises. I have published 8 papers in peer reviewed literature, most with Red Lawhern, since 2015. I have been in clinical practice for 42 years and much of my clinic population has been comprised of people with chronic pain.

VA policies bearing on opioid prescriptions, both in practice and expressed in its guideline documents, have mirrored the CDC guideline documents of 2016 and 2022. However, at least at my VA Medical Center, these guidelines have been pushed to what is very close to a no opioid policy. They have not incorporated the recent innovations by Oliva et al, published in 2017, and the adoption of the STORM system that she and her colleagues created — a most enlightened approach.

I constantly see patients in inadequately treated chronic pain, some in so much pain that it is difficult for them to even communicate, many with disability that could easily be remedied by treatment with a modest opioid regimen, many getting alternative, often very expensive, and generally ineffective invasive treatments, and nearly all suffering a vast reduction in quality of life, often abjectly suffering.

The concept of pseudo-addiction seems to have been originally ventured by Weisman and Haddox and by Fishbain and colleagues in 2008. It referred to a common and easily understandable phenomenon. Physicians to this day receive little training in managing chronic pain and are very conscious of the crisis of opioid addiction that has plagued this country since the aftermath of the civil war. Thus, they have always been very hesitant about prescribing opioids, particularly in higher dosage.

When patients still in pain ask for higher opioid doses to relieve their pain, this is often interpreted as incipient addiction. More recently, DSM-5 has codified this notion of incipient addiction in terms of the definition of opioid use disorder (OUD), a check list of 11 items. Unfortunately, someone in severe pain desperately seeking relief would receive a high OUD score. Scientific data on the incidence of addiction, as traditionally defined, have been severely clouded by the concept of OUD. In my 42 years of practice, I have encountered exactly two patients with actual addiction, both faculty members in existential crisis

Interface between pain and addiction. The fog created by the DSM codification of OUD has made it all but impossible to discern the prevalence of true addiction, as traditionally defined, in clinical populations. My own personal experience over 42 years of practice has been that addiction does exist in clinical patients but it is exceedingly rare and is it typically observed by clinicians in the context of a mental health crisis. Oliva et al, in their pioneering VA funded study published in 2017, identified the major predictors of overdoses and suicide attempts. These were

- severe psychiatric disease,
- multiple inpatient psychiatric admissions,
- multiple suicide attempts and
- multiple ER visits for drug overdose.

All patients were on an opioid regimen, undoubtedly because of concurrent severe physical pain. The contribution of opioid dose to outcome measures was nil. In effect, opioids were implicated in these events as innocent bystanders to a deeper existential crisis. Severe mental health problems, often accompanied by physical pain, social isolation, unemployment, and hopelessness are the major drivers of illicit drug use and overdose. For those using illicit drugs, the drugs likely provide a means of temporarily escaping suffering through achievement of oblivion.

Impact of misdirected public health and law enforcement policy on patients and clinicians. In my personal observation, the major factor driving physician behavior in the wake of CDC 2016 has been policies adopted by health care providers. These providers were informed by their legal departments that the Guidelines posed increased liability risk if certain clinicians were allowed to prescribe in excess of CDC guidelines. Practitioners are closely monitored and if they exceed the guidelines, their clinical privileges are threatened. Much has been made of DEA prosecutions of clinicians, sometimes leading to imprisonment.

Indirect effects of such prosecutions have been very consequential. Many pain management specialists have left their practices and many primary care physicians have ceased prescribing opioids. All clinicians are now guided almost entirely by CDC guidelines. Closely examined, the scientific basis for those guidelines appears to be close to nil, as we have shown in this Listening Session and in extensive published peer-reviewed papers.

FINAL REMARKS

As the Listening Session neared 2 PM, Dr Lawhern spoke again to summarize main points of the hour:

1. If the FDA audience carries away nothing else from this session, you should remember this: There is no such thing as opioid use disorder. Data published by the CDC itself completely discredits the notion that doctors prescribing to their patients are responsible for the US opioid crisis. And both CDC and DEA have known this reality for years.

2. US CDC and US DEA are usurping missions delegated to the FDA by law, in the establishment of safety standards for prescription drugs.

3. The consequence of this usurpation is the ongoing destruction of American pain medicine.

    a. CDC prescribing guidelines incorporate outright fraud:

        i. Failure to address genetically moderated opioid metabolism

ii. Misrepresentation of the effectiveness of non-opioid alternative therapies.

iii. One-size-fits all MMED dose criteria unsupported by science

iv. Misrepresentation of opioid therapy, especially high-dose opioid therapy, as ineffective for long-term use

b. DEA prosecutions are grounded on non-representative "expert witnesses" who testify to anything DEA wants, no matter how false.

c. Administrative court judges deny defendants adequate representation by pre-trial asset confiscations and by rulings biased in favor of the DEA.

4. It is now known beyond contradiction that incidence of iatrogenic addiction and overdose is too small to measure accurately within the existing confounds of diagnosis and poor clinician training. Law enforcement is particularly ill-equipped to comment on this issue.

5. It is also known to CDC and DEA that doctors overprescribing to patients were ***never*** a significant cause of the US opioid crisis -- and are not now.

6. We appeal to FDA to take public action to repudiate and demand withdrawal of injunctive relief provisions and systems imposed by the National Opioid Settlement

7. We encourage FDA to take immediate action to correct its own databases concerning shortages of prescription opioids created by the opioid settlement injunction.

8. We also ask FDA to publicly repudiate and demand withdrawal of CDC/VA/DoD prescribing guidelines without replacement.

9. We ask FDA to publish minutes of this meeting for public review, consistent with prevailing policy and public law. We intend to publish our own notes widely in social media platforms that generate hundreds of thousands of views per week.

10. In a spirit of transparency, we also disclose that stakeholder participants in this session are co-complainants in formal complaint actions filed May 21, 2024 with the US DoJ Office of Civil Rights and the Office of the Inspector General of DHHS, alleging criminal fraud and denial of US citizens' civil rights on the part of CDC authors and approving officials for the 2016 and 2022 published opioid prescribing guidelines.

11. Individually and as a group, we are available to support further FDA deliberations in this most important issue in American healthcare.

QUESTIONS FOR CLARIFICATION

The FDA audience chose not to ask clarifying questions. Marta Sokolowska, Ph.D., Deputy Center Director for Substance Use and Behavioral Health in the FDA's Center for Drug Evaluation and Research (CDER), thanked the presenters for their input, particularly with respect to patient lived experiences and FDA database issues.

A message was received from FDA/PASE on the next day, from the session administrator:

> I want to express another huge thank you to you and all of your associates from the National Campaign to Protect People in Pain (NCPPP), for sharing your perspectives related to Opioids.
>
> Your primary objective of educating US FDA senior staff on the lack of any consistent relationship between rates of opioid prescribing versus risk of iatrogenic opioid addiction, hospitalization, or overdose-related mortality was accomplished during yesterday's Listening Session.
>
> The presentation provided insights that were impactful, helpful, and important to FDA / CDER. All of us on the call are incredibly grateful to be a part of the Listening Session with you and your colleagues. Hearing your perspective is critical to ensuring that the FDA / CDER can better understand the challenges faced by the public.
>
> If you have any questions, concerns, or additional feedback, you are welcome to contact us by replying to this email. Again, thanks so much for your time.
>
> Thank you again for your efforts to execute the … Listening Session!
>
> As we continue working to provide the best service possible to our constituents, we ask that you please complete [a] brief voluntary feedback survey link.
>
> The link is omitted here to avoid swamping FDA with immediate feedback that they may not be staffed to process formally.

==========

Meeting notes herein have been shared with FDA/PASE, with our encouragement to circulate them further. FDA has made no commitment to do so as of the date of publication.

WE ARE A NATION IN PAIN AND WE WILL NOT BE SILENCED!