A Nation In Pain Appeals to Our Legislators: Stop the Anti-Opioid Madness!

Script for Desktop Briefing

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Slide 1: Briefing to Legislative Staff

Good day. My name is _____. I am a chronic pain patient who lives in your (State or District). For the next few minutes I will present a briefing originally authored by chronic pain advocate and subject matter expert, Richard A Lawhern (PhD). Dr Lawhern may be contacted with follow-up questions that arise that I may not be able to address immediately.

Slide 2: A Nation in Pain

America is a nation in pain and I (your speaker) am one of those who suffer. According to the US National Academies of Science, over 100 million US citizens experience medically significant pain every year -- of whom about 40 million have high impact pain every day that severely limits quality of life. **This is me!**

As recently as 2016, about 20 million patients were treated with opioid pain relievers, and about 3 million renewed opioid prescriptions for longer than 90 days. Due to massive mis-directions of US public health policy, many of these patients can no longer obtain effective pain care, despite the established safety and effectiveness of this class of medications.

Slide 3: A Nation Denied Pain Relief

We are a nation being denied pain relief by deeply misdirected public health policy. A primary source of this misdirection is the CDC opioid prescribing guidelines of 2016, recently revised and greatly expanded in November 2022. As noted by no less than the American Medical Association, the CDC guidelines have become a de facto standard of practice embedded in multiple State laws. However, these guidelines are fatally flawed on basic science and medical ethics, causing thousands of medical practices to stop accepting new patients for pain management and leading to forced tapers or outright

discharge of legacy patients for whom opioid analgesic pain relievers have been the only effective means of pain management. US DEA is a major culprit in these trends.

The US Veterans Administration has compounded problems in the CDC guidelines with issuance of a system-wide so-called "Opioid Safety Initiative" written into law in the 2018 Veterans Administration Mission Act. The VA is currently denying opioid pain therapy to all veterans nationwide, despite the destructive effects of this policy.

Slide 4: A Nation Denied Pain Relief – 2

The CDC guidelines have been used by the US Drug Enforcement Agency and State authorities as an excuse to investigate and persecute pain management doctors all across the US. These are clinicians whose only real crime has been that they prescribe opioid pain relievers, sometimes to large numbers of patients who have been deserted by previous doctors.

DEA employs many tactics to make it hard for individual doctors to defend themselves. Not least of these are asset confiscations, prominent public announcements of investigations, and delays in court dates – measures designed to ruin the doctor's business and blacken their reputations even if the case is later dropped as they sometimes are.

A unanimous Supreme Court verdict in June 2022 -- Ruan Vs. the United States -- has been discussed widely in media and may eventually provide significant protection for clinicians whom the DEA has targeted. Under this verdict, prosecutors must demonstrate that doctors accused of prescribing opioids outside the range of accepted practice must also be shown to have known they were doing so. We have already heard of at least one recent case in which a local superior court judge refused to allow a doctor to defend himself on the grounds established by SCUS. So the fighting isn't over on these issues just yet.

In another notorious case in California, US DEA suspended a doctor's license to prescribe scheduled drugs and threw 240 of his patients onto the street – where all but a few were unable to find a doctor to take over their pain management. One of those patients and her care giver committed suicide.

Slide 5: CDC Guidelines Are Fatally Flawed

The CDC guidelines in both the 2016 and 2022 versions are fatally flawed, and this chart indicates some of the reasons why.

One of the largest and most glaring faults in this document is that not ONCE does either version address the natural genetic variability in individual patent's metabolism. As a

consequence, both documents (despite disclaimers in the 2022 version) reflect one-size-fits-all thinking and unacknowledged biases.

There is in fact a wide natural range in minimum effective dose between individuals – perhaps 15 to one. This reality puts the lie to the unfounded assertion of the CDC writers that there is any threshold beyond which treatment with opioids shows diminishing returns in pain relief and greatly increased risk of addiction.

Slide 6: CDC Guidelines Have Been Publicly Repudiated

…By multiple professional medical academies and associations, including the American Medical Association, the American Academy of Family Physicians, the American Psychiatric Association and others. It is widely recognized that the 2016 version of the guidelines has harmed millions of patients in agony by denying them care. And there is ample evidence that despite disclaimers, the 2022 version is continuing this damage.

Slide 7: What does AMA Resolution 235 Say?

In the Fall of 2018, a resolution was passed at the semi-annual meeting of the AMA House of Delegates directly contradicting the logic of the 2016 CDC opioid guidelines. Wording on this chart is a direct quotation.

Although the 2022 revised and expanded guidelines removed hard limits on dose or duration, they continue to employ what amounts to junk science, to assert that there is a point of diminishing returns at 90 MMED. That assertion has no basis in science. In fact, there are four different math models for what MMED comprises – and they produce different measures of assumed equivalence between various opioids.

Slide 8: Fundamental Realities of the "Opioid Crisis"

America does have a real public health crisis in rising numbers of opioid overdose deaths. But the causes of that crisis are vastly different from those claimed by the CDC.

As we'll see in the next three charts, the real drivers of death and destruction are found in street drugs. In a landmark paper published in August 2022, authors Larry Aubry and B Thomas Carr performed a re-analysis of overdose mortality and hospitalization data published by the CDC. They demonstrated conclusively that although trends in mortality were parallel to increases in prescribing before 2010, mortality continued to skyrocket even as prescribing fell off by 40% between 2010 and the present. You cannot get that result from any model of medical causes and effects.

Contrary to the assertions of CDC senior leadership, doctors prescribing to their patients did not create and are not now sustaining our public health crisis. The real causes lie in what are called the "social determinants of health". An entire generation

has fallen into a crisis of wage stagnation, ever-increasing inequality of wealth and income, hollowing-out of formerly industrial or inner-city communities and structural unemployment. Drug cartels took advantage of these distractions to aggressively market chemical bliss to ever-increasing numbers of people otherwise facing hopelessness.

The demographics of opioid mortality also confirm these factors, as we see on the next two charts.

Slide 9: Prescribing Rates per Hundred Population by Age

Although this chart is from 2016, the shape of the age curve is much the same in other years – although lower overall as prescribing has continued to drop.

Kids and youth below age 20 are rarely prescribed opioid pain relievers. As we age through the 20s through the 50's, chronic pain conditions tend to accumulate. Seniors over age 65 receive about double the number of prescriptions of young adults.

Slide 10: Overdose Mortality 2001-2020

This chart shows 20 years of overdose death rates, organized by age. Clearly overdose deaths have been trending upward sharply. But the differences between age groups are startling:

Seniors have the lowest overdose death rates of any age group, with youth only slightly higher. However adults age 25 to 44 have mortality rates four times higher than seniors despite their significantly lower rates of medical prescriptions.

We also see an interesting pattern in 2006 to 2012. In those years, there is a relatively flat plateau in mortality for most age groups. After 2012, the deaths take off in a skyrocket. 2012 was the year when illegal street Fentanyl began to dominate the death curve. 2008 was the year of the US financial collapse and 2010 was when US FDA forced the reformulation of Oxycontin into abuse-resistant form. Prescribing dropped like a stone even as deaths due to heroin and illegal fentanyl took off.

Slide 11: A Different View of Opioid Mortality

This chart serves to amplify on what we have just seen. Using data published by the CDC itself, it is plain as the nose on our faces:

- Deaths due to prescription opioids are almost flat across the decade. But total opioid deaths nearly double as opioid related hospital admissions rise by a factor of

five.

- Total volume of opioids prescribed drops even more sharply than the number of prescriptions during the same period. The only way this can happen is for the prescription opioid deaths to be caused mostly by diverted drugs used by non-patients.

Slide 12: Conclusions

- The public narrative driving opioid regulatory policy is based on mythology
  - Doctors over-prescribing to pain patients did not cause the opioid crisis and aren't sustaining it
  - From multiple published sources, we know that abuse risk among medically managed patients is likely under 0.6% -- too low to measure accurately [4, 8]
- National policy on opioid regulation must change
  - Stop the exodus of practitioners out of pain management
  - Free doctors to practice evidence-based medicine without fear
  - Reclaim the lives of patients now denied safe and effective treatment for pain.
- Legislation is needed to halt Federal and State regulatory over-reach
  - Immediately change policy at CDC, CMS, DEA and DoJ
  - Then change State-level drug enforcement and Medical Board policy

Slide 13: Some Thoughts About Legislation

State laws on opioid prescribing are beginning to change even though the Federal level remains confused and contradictory. Particularly hopeful are measures in Minnesota and Arizona that substantially protect doctors and patients who employ prescription opioids to manage pain.

The author of this briefing has prepared a draft "Bill to Deter Departure of Providers from Pain Management". Combined with wording from recent state laws, such a new Federal law might significantly turn the tide of death and destruction caused by CDC and insane over-regulation by DEA.

- AMA Resolution 235 might be useful as a starting point for new US policy by CDC, FDA, NIH, and HHS Centers for Medicare and Medicaid Services (CMS)
- Clearly 2016 and 2022 CDC Guidelines must be withdrawn and rewritten AGAIN, to recognize indispensible role of opioids – or withdraw outright
- Also needed is repeal of Section 131 of the “Veterans Administration Mission Act”, to repudiate the so-called “Opioid Safety Initiative” and rewrite VHA pain practice guidelines to track AMA Resolution 235
- HHS/CMS must also withdraw rule changes authorizing Medicare Part D insurers to deny patient refills subject to “safety edits” of prescriptions above 100 MMED
- State legislation is also needed to require a court warrant establishing that a crime has likely been committed, before law enforcement may access to Prescription Drug Monitoring Program data

Finally, we need to remove all State references to CDC guidelines in their public health regulations and laws.