

Public Comment on Federal Register Docket No. CDC-2020-0029

Management of Acute and Chronic Pain

by

Richard A Lawhern, Ph.D.

I write and speak widely as an advocate for chronic pain communities and as a critic of the misguided and damaging 2016 CDC Guidelines on prescription of opioid analgesics to adults with chronic non-cancer pain. I have previously commented both in my own name and with medical professional co-authors, on multiple Federal Register dockets. You may scan some of my published work at “The Lawhern Files”, <http://www.face-facts.org/Lawhern/>

My present task is to faithfully represent to the CDC, the concerns of tens of thousands of patient stakeholders who regularly read my work and who have been actively (some would say “maliciously”) harmed by misdirected public policy you have generated. The following is submitted with endorsements by ___ chronic pain patients, caregivers, and medical professionals (see separate attachment).

Be advised that extracts from this text will be published in multiple online venues.

--- --- ---

CDC has asked for stakeholder input to “ help CDC's understanding of stakeholders' values and preferences regarding pain management and ... complement CDC's ongoing work assessing the need for updating or expanding the CDC Guideline for Prescribing Opioids for Chronic Pain, published in 2016”. CDC seeks input in three areas:

- Experiences managing pain, which might include the benefits, risks, and/or harms of the pain management options listed [in the Docket announcement].
- Experiences choosing among the pain management options... including considering factors such as each option's accessibility, cost, benefits, and/or risks.
- Experiences getting information needed to make pain management decisions.

Based on extensive stakeholder commentaries in both social media and news, patients are asking that you hear – and act upon -- the following input from their lived

experience. Although the phrasing is mine, I have worked diligently to ensure that sentiments are accurate to those voiced by patients themselves.

1. The 2016 Guidelines were fatally flawed on facts, on science and on medical ethics. They should be immediately withdrawn with a public apology to the hundreds of thousands (if not millions) you have harmed, and to the surviving families of thousands who have committed suicide after being overwhelmed by untreated pain that you have directly caused.
2. Some patients go so far as to assert that CDC fits the definition of a Racketeer Influenced and Corrupt Organization, having been bribed by the insurance industry to maximize profits at the entirely predictable cost of patient disablement and death. In a more just world, CDC senior management would face both civil and criminal prosecution for fraudulent misrepresentation and careless disregard for consequences in your profound misdirection of public policy on regulation of prescription opioid analgesics.
3. Although CDC officials have asserted that current restrictions on prescription opioids represent a “misreading” of Guideline content, that assertion rings hollow. The over-restrictive reactions of the DEA, DoJ, State governments and medical boards were entirely predictable in advance and appear to have been intended by the CDC core experts group.
4. The FDA presently has declared no maximum safe dose limits for almost all commonly used opioid analgesics. Prescribing limits separately proposed by the CDC have been directly repudiated by the American Medical Association and other professional medical associations representing over half of all physicians and medical students. AMA has also advocated against the practice of “high prescriber” letters from State Medical Boards and Prosecutors’ offices, as a violation of due process and a deliberate effort to blacklist patients and doctors.
5. Details of the CDC deliberation process and the biases and financial conflicts of interest of core expert group contributors have been buried behind a stone wall of non-disclosure, despite multiple Freedom of Information Act requests. The public recognizes that CDC is outright lying, as are many fringe element zealots from organizations such as PROP and Shatterproof, whose unsupported opinions you have incorporated as public policy.

6. Thousands of patients and medical professionals demand that you engage with reality and reverse course. In various forms and forums, patient stakeholders have voiced all of the following points. Each is fully supportable from published medical and popular literature.
 - Prescription opioid analgesic therapy is safe and effective for the great majority of patients treated under medical supervision. Prescription opioids do not fully “eliminate” pain. But for millions, they are the only measures that substantially improve quality of life and function, allowing patients some measure of “normal” life outside their own beds.
 - There is no cause and effect relationship between rates of opioid prescribing versus rates of either addiction or overdose-related mortality. Published data of the CDC itself directly contradicts this silly notion. Restrictions imposed on opioid production by the US DEA -- with tacit CDC backing -- have created widespread shortages of both injectable and oral analgesics, causing hospice patients with terminal cancer to die in untreated agony and delaying needed surgeries in those with acute pain. Patients routinely face pharmacy “shortages” and delays in filling legitimate prescriptions. Covid-19 patients face shortages of analgesics required for effective use of respirators.
 - America’s public health crisis with opioid addiction and mortality is real, but not an “epidemic”. The term “opioid epidemic” was invented out of thin air, to justify the entry of CDC into medical policy making where it has no resident expertise and no legal charter. This invention was deliberate, in a politically inspired effort to do an end-run around the refusal of FDA to embrace misrepresentations of fringe element anti-opioid advocates in PROP petitions to restrict availability of opioids.
 - The American public health crisis is dominated by illegal street drugs, particularly but not exclusively illegal fentanyl and heroin. The contribution of diverted prescription drugs to overdose mortality is so small that it gets lost in the noise.
 - In multiple large scale demographic studies, best estimates of mortality attributable to prescription opioids are in the range of 0.02% for all patients at all doses, rising to the range 0.25-0.5% per year for the very small numbers who are managed at doses from 100 to above 500 MMED.

- Overdose mortality is dominated by self-administered poly-pharmacy involving alcohol and street drugs. Even when a prescription opioid is found, it is only rarely traceable to a State Prescription Drug Monitoring Program, and almost never the only contributing cause of death. Mortality from prescription opioids is less than observed for other prescription drugs routinely administered in medical disorders like post-stroke atrial fibrillation.
- As acknowledged in published work of Dr Nora Volkow (Director of the National Institute on Drug Abuse) and her colleagues, prescribing is not a predictable cause of patient addiction or mortality.
- Opioid use disorder is diagnosed in previously opioid-naïve post-surgical patients less than 0.6% of the time in follow up periods averaging 2.5 years. This rate is very likely inflated by the hostile regulatory environment, with doctors using the diagnosis to justify discharge of patients whom they perceive as a risk for attracting government persecution and license challenges.
- The US Agency for Healthcare Research and Quality has admitted that no presently available risk profiling instrument provides useful predictive accuracy for bad outcomes (dependency, addiction, or mortality) in individuals treated with prescription opioids. HHS “over-utilizer” profiling is similarly non-predictive. What AHRQ and HHS do not acknowledge is that this lack of predictive usefulness is a direct and natural consequence of the wide range in minimum effective opioid dose levels, due to genetics of metabolism. Patients may experience pain reduction at doses that vary between 20 and over 1,000 morphine milligram equivalents per day (MMED). Thus MMED is not now and never will be a useful measure of maximum safe dose for all patients. There is no one size fits all measure of merit in opioid prescribing.
- There are no published studies establishing positive outcomes from doctor-initiated or legally mandated tapering of opioid therapy, in patients who are otherwise well maintained on a medically supervised treatment plan. To the contrary, there are numerous patient reports of disastrous outcomes from involuntary or coerced tapering. FDA has acknowledged widespread medical collapses and suicides due to unmanageable breakthrough pain. Involuntary tapering of a patient in pain is never justified, even if they display indications of addiction.

- There are no published trials verifying “non-pharmaceutical, non-invasive alternatives” as replacements for opioid therapy. The most that can be said for such alternatives is that they may be helpful for some patients, some of the time, as additions to a program of opioids, NSAIDs, off-label antidepressant therapy or anticonvulsant therapy. And even in this role, use of NSAIDs is not risk free; hundreds of hospital admissions occur every year for liver toxicity, kidney failure or cardiac irregularities caused by high doses of Tylenol or Ibuprofen.
- In the absence of proven alternatives to opioid therapy, a policy of denying opioids to either legacy or new patients is unjustified and irresponsible to the extreme. But this is precisely the policy which CDC has advocated and supported.

CDC has requested input from patients and medical professionals in their own words. Thus I offer the following with the permission of those from whom I quote or paraphrase.

--- --- ---

“The CDC Has Ruined My Life”

“The CDC has ruined my life.”

It’s a message that I read in social media every week, and in my personal correspondence from thousands of people in agony who are being denied pain care in all 50 US States and Canada. It’s a message I also hear from medical professionals who’ve become aware of my volunteer advocacy on behalf of pain patients and their doctors.

I spent an hour on the phone recently with a doctor. The following is narrated in paraphrase from our talk, to protect him from targeted retaliation by the DEA and his State Medical Board, to suppress his voice.

“I recently attended a medical conference. Presentations from doctors on our State Medical Board were absolutely chilling for both their punitive tone and their lack of published evidentiary support. The messages were crystal clear even if not phrased quite so explicitly as here --

“A majority of patients who are prescribed opioids will become addicted.”

“Opioids aren’t effective for anybody except briefly for acute pain requiring surgery.”

“If you prescribe opioids for anybody, for any reason, we’ll be watching you closely. If you prescribe a lot of opioids, we’ll investigate you and destroy your medical practice, whether or not your case goes to court or in front of a Medical Board.”

Anyone who is board certified in pain management surely understands that claims that opioids don’t work, or that large numbers of patients become addicted, are outright distortions (aka “lies”) unsupported by rigorous medical research. But nobody in this doctor’s conference audience above felt free to speak in opposition, despite their discomfort with the message. They were looking over their shoulders for bureaucrats taking notes.

Patients also speak here in their own voices, edited only for clarity and brevity:

====

“How would you like it if after receiving medical care for 17 years for painful and incurable chronic illnesses, you are forced to choose which way you are going to be tortured to death? This has happened to me. It’s because the DEA is practicing medicine instead of doctors. When you try to fight back, you learn there is nothing you can do. You just have to die... Your Doctor cannot treat you or they will be targeted by the DEA. This is medical care now in America. It’s completely run by the DEA. I am dying and there is nothing I can do to fight for medical care I have received for 17 years. It’s just gone.” [KMT]

====

“The persecution I believe I am seeing has me terrified... I see a pattern in this. I have no doubts that the DEA tracked my former doctor’s patients [to the doctor who took over when he retired]. My former doctor told me that he was going to close his practice, and he instructed me to seek out a new provider. But I immediately ran up against pain clinics telling me they would not accept me unless my dose was below the CDC guidelines....”

“I know that the DEA and maybe others used our State’s prescription monitoring database to track the disposition of my former doctor’s displaced patients. And I am sure that my new doctor’s life has been made miserable by them. I believe he is operating now under restrictions as he talks about how his colleagues believe chronic high doses cause allodynia, etc.. His whole pain management philosophy has changed, and I believe it changed under duress. This is all so insane.” [LML]

===

“I am one of the many pain patients who are being mistreated and under treated for my pain. I have three herniated discs, arthritis in my spine, along with neuropathy and fibromyalgia. My pain management Dr -- an anesthesiologist -- refuses to give me more than 5mg IR oxymorphone twice a day. I'm in agony. “

===

“I was force tapered in June 2018. I'm on the “standard” 90 MME dosage now. While I did "get through it", I was in 4-6 weeks of hell. I am still not moving as I did before tapering. I lost so much control over my life during that time of "withdrawal" that I talked with my husband and two older boys about not wanting to "live like this with constant brutal pain, in bed". I'm not suicidal but I did buy three books about how to commit self euthanasia "safely". One was the *Final Exit*.” [DA]

===

“At 64 with an extensive medical history, I would rather die than keep fighting to have a decent quality of life. There is too much damage for surgeries and I cannot get injections due to the need of lifetime low-dose steroids. I now see NO HOPE for relief of the severe pain I am feeling. The Feds and doctors no longer care about the patient.

=====

“I used to be able to work 60+ hours a week for my job of 26 years. I used to be able to keep my house spotless. I used to go to all of my kids events. Now I just want to lay in my chair because of the pain.” [HA]

=====

“In March of 2016 my pain management MD suddenly stopped my high dose Dilaudid. At age 69, I went thru a hell no one should. In Dec 2016, the rest of the meds I had been on for over 20 years including Diazepam were discontinued. I had been on same dose of all meds including the Dilaudid, for 16 years with NO increases. I am still suffering the neurological deficits from the Diazepam being stopped cold turkey. No one, especially one who is 69-70 should ever endure what I did -- no one -- and my pain is often uncontrolled.

===

In 2017 and 2018, I was far more stable than I feel today -- because my opioid medications were lowered over my objections during that time. Simply put, when the CDC introduced the opioid guidelines, their action influenced many physicians, both Primary Care and Board-Certified pain management doctors. Supposedly they were just "guidelines," but the reality of the CDC's ill-conceived information and their lack of science-based facts... have hurt so many patients and physicians. What the CDC has

done is so inhumane and cruel. Congress must get involved to pass legislation to allow physicians and patients be able to work together. “

====

“I have multiple serious issues. In six short months I was forced to taper from 200 MMED to 40 MMED daily without even being told I was being tapered. I found out at my Pharmacy. I was also cut off Xanax I had been taking for 30 yrs, and Soma (for 5 years, that only muscle relaxer that worked for me). I suffered a medical collapse. I'm suffering horribly & barely existing.” [BJS]

====

“As a Canadian citizen, the 2016 CDC Guidelines have negatively impacted pain management and caused significant harm for me and countless disabled persons like me. Canada implemented the 2017 Canadian Guidelines for Opioids for Chronic Non-cancer Pain based largely on the CDC document, including the 50 MME watchful dose [recommended maximum dose for new patients] and the 90 MME hard cap.

As a direct result, we are misdiagnosed as "drug-seeking" or "addicts", discriminated against, medically abandoned, and have had our human rights regarding access to compassionate pain management obliterated, with the Guidelines cited as the reason. Doctor's are terrified and patients are being shamed and abandoned. “ [LR]

=== === ===

As a patient advocate, I see these narratives every week. They are not exceptions or testimony purchased by pharmaceutical companies anxious to maintain their profits. Instead, these reports reflect the lived experience of a significant majority of both legacy and new patients with chronic pain. And such experience is not an acceptable outcome of public policy promulgated under the guise of “voluntary guidelines.” Both patients and doctors alike know that you folks are speaking in code on behalf of insurance companies. You have lost nearly all credibility with the patients whom you have harmed.

Compounding widespread injury and insult, the CDC National Center for Injury Prevention and Control has announced that it will revise and expand the 2016 CDC guidelines to include acute as well as chronic pain. CDC accepted CVs from self-nominated “experts” through February 2020, for a proposed two-year review. But they have so far not announced the names of those selected – a typical failure of public transparency.

On behalf of those whom the CDC has already injured, I strongly assert that none of those who contributed to the 2016 guidelines should participate in the newly constituted NCIPC “opioid working group”. Dr Debra Houry and her senior staff should be

terminated immediately with extreme prejudice. Moreover, the entire conceptual framework of the Guidelines must be burned to the ground and started over from scratch.

Morphine Milligram Equivalent Daily Dose is now widely recognized as useless metric, unrelated to risk of bad outcomes from opioid therapy. Ample published evidence demonstrates beyond contradiction that physicians “over-prescribing” to their patients neither created nor are now sustaining our mislabeled “opioid epidemic.” The Drug Enforcement Administration must be removed from doctors’ offices and any revised guidelines must support this desperately needed policy change.

By fostering an unjustifiably restrictive policy on prescription of opioid analgesics, the US CDC is laying waste to hundreds of thousands of patient lives for no good purpose. You have already destroyed your own credibility and driven thousands of doctors out of practice. We implore you to STOP THIS MADNESS!

Finally, if CDC is to have any hope of regaining its credibility with chronic and acute pain patients and communities, there is an imperative that you cannot ignore: Within the month following the deadline for stakeholder comments, you should publish a summary of the primary themes represented in comments to the Federal Register. You must commit yourselves to turning this summary into “rules of engagement” for any opioid working group that attempts to revise the 2016 CDC guidelines on prescription of opioids.

=== === ===