**Federal lawmakers must immediately direct CDC to withdraw   
2016 opioid prescription guidelines and related physician CME   
for review and revision.   
 We must correct a tidal wave of unintended consequences**

**including patient abuse, desertion and death by suicide.**

* An estimated 100 -120 Million people in America will experience long-lasting pain at some point in their lives due to injury, disease, or medical error.
* About 18 million people have pain lasting longer than 90 days in any given year.
* 2.7 to 3.3 million will be prescribed an opioid for longer than 90 days.
* Fewer than 10% will continue their prescription longer than one year. [Ref 1]
* Faulty public policy on prescription of opioids is damaging hundreds of thousands of people whose only offense is that they hurt. Some are dying. Many more are being forced into disability. [Ref 2]
* Pain patients who have been stable and well managed on opioid analgesics for years are being forcibly tapered down or outright denied the only medicines which make their pain bearable.
* The widespread result is a wave of agony and disability as patients become bed-ridden and lose function.
* Some patients are forced into unmanaged opioid withdrawal because of too-rapid tapering or outright cold-turkey desertion.
* Some who are unable to bear their agony are dying by suicide.
* Scores of doctors are deserting their patients and leaving pain management practice for fear of losing their medical licenses.
* In a larger context, enough medical students commit suicide every year to fill a class of medical students. 50% of doctors suffer from burnout syndrome. [Ref 2A]
* No one can now predict the future effects of the resulting shortage of doctors on chronic pain patients – even before large numbers have stopped prescribing opioids to patients in pain. [Ref 2B]
* The US Drug Enforcement Administration is using extra-judicial persecution to drive pain doctors out of practice. [Ref 3]
* Confiscation of doctor assets and patient records without judicial trial or verdict
* Public announcements intended to destroy doctors practices
* Coercion and suborning of prosecution witnesses using plea bargains
* Prolonged delays in court cases to increase financial pressure and force consent decrees.
* A key element in denial of pain treatment is the US Centers for Disease Control and Prevention 2016 Guidelines on prescription of opioids to adult non-cancer chronic pain patients. [Ref 4]
* Although written as voluntary, the Guidelines are widely being used to justify mandatory and scientifically unsupported limits on opioid dosing.
* The US Veterans Administration was directed by Congress in December 2015 to make adherence to the Guidelines mandatory, not voluntary (four months before publication). Multiple Veteran suicides are a direct result.
* Several US States have enacted arbitrary restrictions on opioid prescribing, referencing the CDC guidelines as a standard.
* Even where not required by State laws, many medical practices are denying renewal of prescriptions or discharging patients without referral.
* The CDC opioid guidelines are fatally flawed by a uncritical anti-opioid bias, weak medical evidence, cherry picking of research and dangerously incomplete analysis. [Ref 1, 5]
* The “core experts group” selected by CDC was unduly influenced by anti-opioid partisans from “Physicians for Responsible Opioid Prescribing (PROP).
* PROP had previously lobbied FDA against opioids but major elements of their proposals were rejected as ill-founded. PROP then targeted CDC. [Ref 6]
* Congress directed CDC to open its deliberations to public review, following complaints of violations of transparency laws. [Ref 7]
* None of the core experts group had ever worked in community pain management outside a hospital. [ibid Ref 7]
* Although available to CDC, medical ethics experts were not invited. [ibid Ref]
* Research was selected in a manner calculated to disqualify opioid analgesics in favor of non-opioid medication or behavioral therapies – neither of which were better supported by medical evidence or studied longer. [Ref 10]
* Research on opioids is mostly in studies of less than one year duration.
* But Guidelines falsely state that there is no long term benefit from opioids. [ibid Ref 1, Ref 8]
* CDC Guidelines drew “strong” conclusions from “weak” evidence and personal opinion, omitting many confounding factors and reservations and ignoring contradictions between studies. [ibid Ref 1, 9, 10]
* Particularly disqualifying, the Guidelines make no mention of natural genetic variations (polymorphism) between individual patients’ which affect ability to metabolize opioids and benefit from their effects. [Ref 11- 13]
* “Hyper”-metabolizers may over-dose on some medications (codeine, tramadol) or so rapidly process others that pain is relieved only for minutes rather than hours.
* “Poor” metabolizers need far higher dose levels to get the same pain management as “normal” metabolizers.
* Published case reports ignored by CDC indicate that thousands of US patients well managed on ultra doses over 2500 MMED, with little risk of addiction.
* Genetic polymorphism means there can be no “one size fits all” threshold of risk or maximum safe dose applied to all patients.
* Patients must be evaluated and managed individually.
* This reality was completely missed or deliberately ignored in the CDC guideline writers.
* The US has a real opioid crisis, but it wasn’t created by prescriptions managed by doctors -- and it won’t be solved by restricting treatment of patients in agony. [Ref 14]
* ~90% of all addicts first begin abusing alcohol or drugs in their teens – long before they are ever seen by a doctor for any pain condition. [Ref 15]
* A second reliable predictor for addiction is a history of sustained unemployment or family trauma. [Ibid Ref 14]
* Although some sources assert that 75% of addicts may “begin with prescription drugs”, the real source isn’t a doctor’s prescription to a genuine pain patient. [Ref 16]
* Most drugs first abused by addicts are stolen from a family medicine cabinet or diverted by a family member who hasn’t used up a previous prescription.
* Millions of doses hit the street every year from pharmacy and hospital thefts. [Ref 17]
* Among deaths which involve an opioid drug of any kind, less than a quarter of the victims have a current prescription. Many deaths involve alcohol or an anti-anxiety agent. Some deaths labeled “accidental” are likely suicides by under-treated patients. [Ref 18]
* Addiction is not primarily a disorder of drug exposure. It is a “disease” of social disintegration and alienation among people at the margins of failing social and family systems.
* Addiction is not deterred by fear of prison or other punishment. [Ref 19]
* Yet we imprison millions of non-violent drug offenders who consume tens of billions in resources.
* Finding solutions for addiction and separately for the management of intractable pain will not be cheap or easy – but this is not an either/or issue.
* Some pain patients can become dependent on pain killers when used for long periods (weeks or longer). But patients rarely become addicts and addiction overall is rare (2% of US population). Dependency and addiction are different medical entities calling for different medical therapies. [Ref 20]
* Opioids should not be prescribed carelessly or casually-- and for the most part they aren’t.
* Pain patients are tried on opioids only after other therapies have failed.
* For the most severe pain, behavioral therapy is never a substitute for opioid or non-opioid analgesics.
* Non-opioid analgesics also have risks: ~30,000 hospital admissions per year for Tylenol toxicity, with 1500 deaths [Ref 21].
* Clearly, additional research is needed on safer medications for chronic pain, and cures for many underlying conditions which cause it.
* Pill counting and limitations on prescribing opioids will not “solve” a crisis created by aggressive marketing of street drugs to kids and compounded by adult unemployment and desperation. [Ref 22]
* The purpose of all pain treatment is to relive suffering and promote function. Denial of effective treatment for chronic pain is a fundamental abuse of human rights and a violation of the principle “First Do No Harm”.
* To correct harms now being done to pain patients, a first step must be withdrawal and rewriting of the CDC opioid prescription guidelines to address biased policy and implement known best practices of pain management. Initiatives are also needed to better educate physicians and patients. Both must be led by physicians qualified in community practice of pain management, supported by addiction specialists and pain patients themselves.
* The central role of physicians and patients in selecting and managing care must be restored, with appropriate and prudent oversight of prescribers and patients, to detect drug diversion and “pill mills”.
* Increased medical education and research funding must better define acute and chronic pain, opioid therapy and co-therapies, and the risks and benefits of both opioids and alternative therapies.
* Patients need to know about risk of stomach ulcer and bleeds, liver toxicity or failure, heart attack and stroke from NSAIDs, aspirin and acetaminophen.
* State laws fixing maximum dose rate limits must be immediately repealed as unscientific, unsupported by evidence and abusive of patients.
* It is time to STOP THE WAR AGAINST PAIN PATIENTS!

REFERENCES:

1. Stephen A. Martin, MD, EdM; Ruth A. Potee, MD, DABAM; and Andrew Lazris, MD, **“**Neat, Plausible, and Generally Wrong: A Response to the CDC Recommendations for Chronic Opioid Use**”**
2. Pat Anson, “Survey Finds CDC Opioid Guidelines Harming Patients,” Pain News Network, March 15, 2017. [Observations reinforced by hundreds of postings in Facebook groups focused on chronic pain patients, families, and medical professionals].  
     
   Also revealing: Bob Tedeschi, “A ‘civil war’ over painkillers rips apart the medical community — and leaves patients in fear” STAT News, January 17, 2017, https://www.statnews.com/2017/01/17/chronic-pain-management-opioids/   
     
   **Ref 2a:** Association of American Medical Colleges. “Physician Shortage and Projections. Data and Reports. Workforce. Data and Analysis. AAMC.   
     
   https://www.aamc.org/data/workforce/reports/439206/physicianshortageandprojections.html

**Ref 2b:** BC Government News. “#BC is committed to listening to all voices in order to save lives and overcome the #opioid crisis.” July 28, 2017. Accessed August 9, 2017. https://twitter.com/BCGovNews/status/892151820394606592

1. Funtony “ The War On Doctors: How The DEA is Scaring Doctors from Prescribing Pain Medications” *Daily Kos,* Apr 15, 2015 <https://www.dailykos.com/stories/2015/4/15/1375189/-The-War-On-Doctors-How-The-DEA-is-Scaring-Doctors-from-Prescribing-Pain-Medications>
2. “CDC Guideline for Prescribing Opioids for Chronic Pain” — United States, 2016 <http://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>

# .Richard A. Lawhern, Ph.D. “Warning to the FDA: Beware of Simple Solutions In Chronic Pain and Addiction”. National Pain Report, Jund 1, 2017, <http://nationalpainreport.com/warning-to-the-fda-beware-of-simple-solutions-in-chronic-pain-and-addiction-8833744.html>

# 

# 4. Mark Maginn, “Living with Pain: FDA Ruling a Victory for Pain Patients and PROP” National Pain Report [Opinion], September 10, 2013, http://nationalpainreport.com/living-pain-fda-ruling-victory-pain-patients-prop-8821625.html

1. Congress of the United States, House of Representatives Committee on Government Reform, Letter to Thomas Frieden, MD, Director CDC, December 18, 2015
2. Christina Porucznik, PhD MSPH, “Observations presented to the National Center for Injury Prevention and Control’s Board of Scientific Counselors on behalf of the Opioid Guideline Workgroup” [CDC Briefing, Spring 2016]
3. Baraa O. Tayeb, MD Ana E. Barreiro, MPH Ylisabyth S. Bradshaw, DO, MS Kenneth K. H. Chui, PhD, Daniel B. Carr, AM, MD, DABPM, FFPMANZCA (Hon)  “Durations of Opioid, Nonopioid Drug, and Behavioral Clinical Trials for Chronic Pain: Adequate or Inadequate?”  Pain Med. 2016 Nov; 17(11):2036-2046
4. Richard A. Lawhern, Ph.D. “The CDC Opioid Guidelines Violate Standards of Scientific Research” - American Council for Science and Health, March 25, 2017. http://www.acsh.org/news/2017/03/25/cdc-opioid-guidelines-violate-standards-science-research-11050
5. Richard A. Lawhern, Ph.D. “Tracking Down the ‘Research’ Behind the CDC’s Opioid Prescribing Guidelines, National Pain Report, August 10, 2016
6. Steven H. Richeimer, MD and John J. Lee, MD “Genetic Testing in Pain Medicine—The Future Is Coming,” Practical Pain Management, October 17, 2016.
7. Tom Lynch, PharmD and Amy Price MD, “The Effect of Cytochrome P450 Metabolism on Drug Response, Interactions, and Adverse Events,” American Family Physician,  August 1, 2007.
8. Jennifer Schneider, MD; Alfred Anderson, MD; and Forest Tennant MD, Dr PH, “Patients Who Require Ultra-High Opioid Doses,” Practical Pain Management,  September 2009
9. Maia Szlavavitz, “Opioid Addiction Is a Huge Problem, but Pain Prescriptions Are Not the Cause –  Cracking down on highly effective pain medications will make patients suffer for no good reason,” Scientific American, May 10, 2016
10. Podcast of the President’s Commission on Combating Addiction and the Opiod Crisis – Observations by a subject matter expert from the National Institute on Drug Abuse, June 2017.
11. Pat Anson, Editor, Pennsylvania Overdoses Soar, But Not from Painkillers *Pain News Network, July 27, 2017*
12. David E. Joranson, MSSW, Aaron M. Gilson, PhD, Pain & Policy Studies Group,University of Wisconsin — Madison Comprehensive Cancer Center; and World Health Organization Collaborating Center for Policy and Communications Madison, Wisconsin, USA “Drug Crime Is a Source of Abused Pain Medication in the United States” *Letters,* Journal of Pain and Symptom Management , Vol. 30 No. 4 October 2005, Response to “How Prescription Drugs Get Onto the Street”.
13. Roger Chriss, “The Myth of the Opioid Addicted Chronic Pain Patient” Pain News Network, July 25, 2017, https://www.painnewsnetwork.org/stories/2017/7/25/the-myth-of-the-opioid-addicted-chronic-pain-patient?rq=25%25
14. Pew Charitable Trusts / Research and Analysis, “ Pew Analysis Finds No Relationship Between Drug Imprisonment and Drug Problems” , June 19, 2017, http://www.pewtrusts.org/en/research-and-analysis/speeches-and-testimony/2017/06/pew-analysis-finds-no-relationship-between-drug-imprisonment-and-drug-problems
15. Silvia Minozzi, Laura Amato & Marina Davoli, Department of Epidemiology, Lazio Regional Health Service, Cochrane Drugs and Alcohol Group, Rome, Italy “Development of dependence following treatment with opioid analgesics for pain relief: a systematic review” *Addiction Review,*  pp1360-0443.2012. March 5 2012  
      
    Main points of this paper are reinforced by a 2010 Cochrane Review.
16. Eric Yoon, Arooj Babar, Moaz Choudhary, Matthew Kutner, and Nikolaos Pyrsopoulos “Acetaminophen-Induced Hepatotoxicity: a Comprehensive Update” Journal of Clinical and Translational Hepatology, June 28, 2016, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4913076/
17. Mallika L. Mundur, MD, MPH, Adam J. Gordon , MD, MPH & Stefan G. Kertesz, MD, MSc “Will strict limits on opioid prescription duration prevent addiction? advocating for evidence-based policymaking” 20 Jun 2017, http://www.tandfonline.com/doi/full/10.1080/08897077.2017.1345194

**A resource on opioid policy:** “The Lawhern Files” at http://www.face-facts.org/Lawhern