



# **Speaking in Tongues: Guidelines and Paradigms Post-CDC**

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# Title and Affiliation

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# Disclosure

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- Advisory Board: Kalyra Pharma, Creative Biopeptides

# Learning Objectives

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- Describe what has happened to chronic pain patient treatment since September 2019
- Discuss the recommendations of groups other than the CDC, if at all possible
- Summarize the changes in the medical world vs. the political/financial groups that are exacerbating the “opioids are bad” meme
- Cite the ways you can help the chronic pain patient and remember how to practice good medicine

# The Right Kind of Chronic Pain Patient

*(an older paper)*

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- Chronic pain disproportionately burdens patients who are less privileged in terms of education, race, gender and class
- “Ultimately, the combination of poorly understood guidelines, insufficiently nuanced prescribing policies and defensive prescribing practices makes it challenging for clinicians to uphold their primary responsibility for their patients’ health and well being”
  - With the upshot- patients wondering “what to do now”

Huang CJ. On Being the “Right” Kind of Chronic Pain Patient. *Narrat Ing Bioeth*, 2018; 8(3): 239-245

# Frontline Physicians Call on Politicians to End Political Interference in the Delivery of Evidence Based Medicine

*(another older paper May 15, 2019)*

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- 6 medical organizations representing more than 560,000 physicians state they are firmly opposed to efforts in state legislatures throughout the USA that inappropriately interfere with the patient-physician relationship, which unnecessarily regulate the evidence-based practice of medicine and, in some cases, “even criminalize physicians who deliver safe, legal and necessary medical care.”
  - “Outside interference endangers our patients’ health by limiting, and sometimes altogether eliminating, access to medically accurate information and the full range of health care”
  - “Physicians should never face imprisonment or other penalties for providing necessary care. These laws force physicians to decide between their patients and facing criminal proceedings”

<https://www.aafp.org/media-center/releases-statements/all/2019/physicians-call-on-politicians-to-end-political-interference-in-the-delivery-of-evidence-based-medicine.html> Accessed July 4, 2020

# Stop Persecuting Doctors for Legitimately Prescribing Opioids for Chronic Pain (1)

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- Information from online posts:
  - My doctor forced me to taper down opioid therapy below a level that had for years given me relief from pain and good quality of life for years. Now I'm totally disabled and in constant pain.
  - My doctor's practice says they will no longer prescribe opioids to anyone. But no other pain center in our area is taking new patients.
  - My doctor wants me to take Tylenol and learn to meditate.
  - I can't take much more of this.
- One would think doctors should have gotten the message that deserting patients is a violation of medical practice standards, not to mention human rights. But it hasn't happened....Because:

<https://www.statnews.com/2019/06/28/stop-persecuting-doctors-legitimately-prescribing-opioids-chronic-pain/> Accessed: July 4, 2020

# Stop Persecuting Doctors for Legitimately Prescribing Opioids for Chronic Pain (2)

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- The physicians have been hearing about other doctors who got raided by Drug Enforcement Agency SWAT teams, whose patients are terrorized, their medical records seized, and practices ruined by announcements in local news media.
- Compounding such brutal DEA tactics, chain pharmacies have compiled high prescriber lists, blacklisting “top prescribing” physicians and denying prescription pain medication to their patients.
- And yes, much of the mess described by patients stems directly from the 2016 Centers for Disease Control and Prevention’s “Guideline for Prescribing Opioids for Chronic Pain. For those who may forget, the CDC urged practitioners to avoid increasing opioid doses for new patients above daily doses of 50 morphine milligram equivalents (MME). For patients maintained on doses above 90 MME, doctors were told to conduct and document risk and benefit reviews.

<https://www.statnews.com/2019/06/28/stop-persecuting-doctors-legitimately-prescribing-opioids-chronic-pain/> Accessed: July 4, 2020



# Stop Persecuting Doctors for Legitimately Prescribing Opioids for Chronic Pain (3)

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- In November 2018, the American Medical Association's House of Delegates issued its groundbreaking Resolution 235. It reads in part:
- "... no entity should use MME (morphine milligram equivalents) thresholds as anything more than guidance, and physicians should not be subject to professional discipline, loss of board certification, loss of clinical privileges, criminal prosecution, civil liability, or other penalties or practice limitations solely for prescribing opioids at a quantitative level above the MME thresholds found in the CDC Guideline for Prescribing Opioids."

<https://www.statnews.com/2019/06/28/stop-persecuting-doctors-legitimately-prescribing-opioids-chronic-pain/> Accessed: July 4, 2020

# Stop Persecuting Doctors for Legitimately Prescribing Opioids for Chronic Pain (4)

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- In April 2019, the CDC advised against “misapplication” of the guideline. Writing in the New England Journal of Medicine, three authors of the guideline said it was never intended to become a mandated standard, even though more than 30 states had incorporated it into legislation in the three years since its publication (including North Carolina). At about the same time, the FDA issued a safety warning against rapidly tapering individuals off opioids or suddenly stopping their administration, based on known harms to patients.
- The month prior, the American Academy of Family Physicians and five other professional groups representing 560,000 physicians and students called on politicians to “end political interference in the delivery of evidence-based medicine.” As they noted, “physicians should never face imprisonment or other penalties for providing necessary care.”

<https://www.statnews.com/2019/06/28/stop-persecuting-doctors-legitimately-prescribing-opioids-chronic-pain/> Accessed: July 4, 2020.

<https://www.aafp.org/media-center/releases-statements/all/2019/physicians-call-on-politicians-to-end-political-interference-in-the-delivery-of-evidence-based-medicine.html> Accessed July 4, 2020

# Stop Persecuting Doctors for Legitimately Prescribing Opioids for Chronic Pain (5)

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- On June 10, the AMA issued Board of Trustees Report 22 which condemned the use of “high prescriber” lists by national pharmacy chains to blacklist high-prescribing physicians and prevent their patients from having pain prescriptions filled.
- Regional U.S. attorneys are sending intimidating letters to “high prescribers,” warning them that their “prescribing practices may be contributing to the flow of prescription opioids into illegal markets and fueling dangerous addictions.” (Wisconsin, discussed last year)

Richard A. Lawhern, PhD, “Stop Persecuting Doctors for Legitimately Prescribing Opioids For Chronic Pain”, STAT News, June 28, 2019. <https://www.statnews.com/2019/06/28/stop-persecuting-doctors-legitimately-prescribing-opioids-chronic-pain/>

# Opioid Crackdown Forces Patients to Taper Off Drugs They Say They Need- September 11, 2019

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- In a biased article (J. Ballantyne MD, a President of PROP, helped write the CDC guidelines here described as a pain specialist) the Washington Post makes it sound as if the fiction that the opioid crisis was solely secondary to physician prescribing was true
- They correctly noted that many physicians have stopped prescribing opioids altogether and some patients have become “opioid refugees” and travel long distances to find a physician who would prescribe an opioid for them

[https://www.washingtonpost.com/health/opioid-crackdown-forces-pain-patients-to-taper-off-drugs-they-say-they-need/2019/09/10/3920f220-c8da-11e9-a4f3-c081a126de70\\_story.html](https://www.washingtonpost.com/health/opioid-crackdown-forces-pain-patients-to-taper-off-drugs-they-say-they-need/2019/09/10/3920f220-c8da-11e9-a4f3-c081a126de70_story.html) Accessed July 4, 2020

# Suicide Deaths are a Major Component of the Opioid Crisis that Must Be Addressed: Sept. 19, 2019

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- Drs. Volkow and Gordon (Directors NIDA and NIMH) make several significant statements in a Blog
  - They note: “In 2017, 47,600 people died from overdoses involving prescription or illicit opioids. But the opioid overdose epidemic is not limited to people with opioid addiction who accidentally take too much of a pain reliever or unknowingly inject a tainted heroin product. Concealed in the alarming number of overdose deaths is a significant number of people who have decided to take their own life.”
  - “With current initiatives to reduce opioid prescribing, many pain patients find themselves either unable to get treatment they need or stigmatized as “addicts” by the healthcare system, compounding their difficulties.”
  - According to the CDC, US National prescribing rates for pain are six times higher in seniors over age 62 than among young people under age 19. But opioid overdose deaths from all sources (legal, diverted, or illegal) are six times higher in youth than in seniors. Moreover, opioid mortality in seniors has been largely stable at the lowest levels in any age group, while it has skyrocketed in youth during the past 20 years.
  - Dr. Volkow noted that addiction is not a predictable outcome of prescribing and addiction in medical patients is rare.
  - Prescribing by doctors is NOT the central problem in overdose mortality or addiction itself (Sullum)

NIDA. Suicide Deaths Are a Major Component of the Opioid Crisis that Must Be Addressed. National Institute on Drug Abuse website. <https://www.drugabuse.gov/about-nida/noras-blog/2019/09/suicide-deaths-are-major-component-opioid-crisis-must-be-addressed>. November 25, 2019 Accessed July 4, 2020. Richard A. Lawhern, PhD, “Stop Persecuting Doctors for Legitimately Prescribing Opioids For Chronic Pain”, STAT News, June 28, 2019. <https://www.statnews.com/2019/06/28/stop-persecuting-doctors-legitimately-prescribing-opioids-chronic-pain/> Nora D Volkow, MD, and Thomas A McLellan, Ph.D. “Opioid Abuse in Chronic Pain — Misconceptions and Mitigation Strategies” . NEMJ 2016; 374:1253-1263 March 31, 2016]. <http://www.nejm.org/doi/full/10.1056/NEJMr1507771> Accessed July 4, 2020.000 Jacob Sullum, “New Survey Data Confirm that Opioid Deaths Do Not Correlate with Pain Pill Abuse or Addiction Rates.” Reason Magazine, August 21, 2019. <https://reason.com/2019/08/21/new-survey-data-confirm-that-opioid-deaths-do-not-correlate-with-pain-pill-abuse-or-addiction-rates/> Accessed July 4, 2020

## VA Study (October 2019)

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- As noted in VAntage Point, Official Blog of the US Dept of Veterans Affairs
- Suicide rate among Veterans is 1.5 times the general population
- VA's Behavioral Health Autopsy Program: Executive Summary: Pain is the most common factor Veterans experience before they die by suicide
- A VISN 2 Center of Excellence (CoE) for Suicide Prevention studied the line between reported pain intensity and suicide attempts:
  - Based on data from 2012-2014, moderate and severe pain over the course of a year increased the risk of a suicide attempt, even after considering other factors including a Veteran's history of suicide attempts

<https://www.blogs.va.gov/VAntage/67708/va-study-uncovers-link-pain-intensity-suicide-attempts/>; [https://www.jpain.org/article/S1526-5900\(19\)30087-2/fulltext](https://www.jpain.org/article/S1526-5900(19)30087-2/fulltext))

# Ludicrous State Legislation Secondary to Inaccurate Information: November 2019

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- Multiple states have shot themselves in the foot secondary to idiocy
  - Massachusetts State House Bill 3656 (Jan. 22, 2019): Docs must pay for addiction associated hospital treatment if their prescription “caused” the addiction (?)
  - Arizona Opioid Epidemic Act (2014): “75% of heroin users in treatment ‘started with painkillers, according to a 2014 study by JAMA”- but wrong journal, wrong facts, ad nauseum
  - Nevada: Any provider who prescribes a controlled substance must “conduct an investigation, including, without limitation, appropriate hematological and radiological studies, to determine an evidence-based diagnosis for the cause of the pain” (Maldynia; small fiber peripheral neuropathy et al)

Schatman ME, Shapiro H, Damaging State Legislation regarding opioids the need to scrutinize sources of inaccurate information provided to lawmakers. J Pain Res, 2019; 12:3049-3053. Office of the Governor Doug Ducey. Arizona opioid epidemic act; 2018. Available from : [https://azgovernor.gov/sites/default/files/opioidepidemicactweb\\_0.pdf](https://azgovernor.gov/sites/default/files/opioidepidemicactweb_0.pdf) Accessed July 4, 2020. Nevada Assembly Committee on Health and Human Services. Assembly Bill No. 474, 79<sup>th</sup> Session, 2017. Available from : [https://www.leg.state.nv.us/Session/79th2017/Bills/AB/AB474\\_EN.pdf](https://www.leg.state.nv.us/Session/79th2017/Bills/AB/AB474_EN.pdf) Accessed July 4, 2020

# Misperceptions about the “Opioid Epidemic”: Exploring the Facts: February 2020

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- This excellent article goes into specifics regarding the way data has been manipulated and presented to generally manifest the false reality that encompasses many aspects of the “Opioid Epidemic” (starting with that term!)
  - They note, as this author has presented for years, that “Deaths reported as ‘prescription opioid deaths’ indicate that prescribed opioids are the direct cause of death” when in fact, if any nanogram amount of prescription opioid is present in the blood at the time of death it is considered an opioid overdose death, regardless of the alcohol, methamphetamine, acetaminophen or cocaine also found in the blood.
    - The reality therefore is that the deaths may have involved prescription opioids but they were not the cause of death
- Despite bringing light to misconceptions about opioid use, the authors acknowledge the issue is still worrisome. “Nonetheless, we feel data are being conflated and sensationalized to make opioid misuse and overdose a more interesting, [compelling] problem,”
- Either way, the treatment of people with acute or chronic pain who need opioids is being denied or limited to a very short supply

Oliver JE, Carlson C. Misperceptions about the ‘Opioid Epidemic:’ Exploring the Facts. Pain Management Nursing 21(2020): 100-109.



# Survey Finds Medical Student Bias Against Pain Patients: 10/22/2019

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- A survey showed that medical studies had more negative perceptions of chronic pain patients in terms of their health , self-care, self-discipline and compliance (at Michigan State University College of Human Medicine)
  - Students felt that chronic pain patients would require more patience, be more annoying and students felt less positive towards a chronic pain patient compared to a control.
- A Tweet (Jun 19, 2020) by @speakingabtpain stated: “its not just medical students who show bias against people with #ChronicPain. I speak at a lot of doctor’s conferences- at one for #PainManagement specialists, a speaker asked people to raise their hands if they like treating pain patients, only one person raised their hand

Pourzan G, Tamayo A, Nabeel M. Are Medical Students biased towards chronic pain patients? American Society of Anesthesiologists 2019 Annual Meeting. Abstract A4107

# An Old Story

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- Physicians continue the same prejudices and biases that were present decades ago
  - Barriers to pain management (2008)
    - Barriers not moral issues, but clinical aberrations and not explain continued poor treatment
    - Barriers do not explain certain types of cases where there appear to be specific unfounded concerns related to a specific class of medication: Opioids
    - Many physicians had the same prejudices towards patients taking opioid analgesic that were described in the 1970s
  - Survey at Texas Cancer Pain Initiative (2000)
    - Significant number of physicians revealed opiophobia; a lack of knowledge about pain and its treatment and had negative views about patients with chronic pain
  - The process of medical training may reinforce negative attitudes including psychologic characteristics associated with reluctance to prescribe opioids and fears of patient addiction and drug regulatory agency sanctions (2000)

## Forever True

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- “We must all die. But that I can save him from days of torture, that is what I feel as my great and ever new privilege. Pain is a more terrible lord of mankind than even death itself.”

Albert Schweitzer

## Human Rights Watch (2018)

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- “An estimated 40 million adults in the United States suffer from significant levels of chronic pain, making it one of the most common health problems and the leading cause of disability in the country. Despite the extent of this problem and its medical, social, economic impacts, many patients in the U.S. do not have access to adequate treatment for chronic pain.”

# Chronic Postoperative Pain (CPOP) incidence by Surgical Procedure from Recent Studies

Surgery	CPOP incidence	Moderate-to-severe CPOP incidence
Abdominal*	17–31% <sup>#</sup>	-
Breast	30–60% <sup>‡</sup>	14%
Cardiac	4–43% <sup>‡</sup>	-
Hysterectomy	26%	9–10%
Inguinal hernia	9–43% <sup>#</sup>	-
Orthopedic <sup>▽</sup>	19–22%	-
Outpatient <sup>+</sup>	15%	-
Total knee arthroplasty	16–58%	22%
Thoracotomy	39–57% <sup>#</sup>	-
Video-assisted thoracoscopy	11–30%	-
Thyroidectomy	37%	-

\* liver donation, laparoscopic colorectal, emergency laparotomy, and abdominally based autologous breast reconstruction

▽ shoulder replacement and ankle or wrist fracture repair

+ those with highest risk are urology, general, plastic, and orthopedic

# no decrease in incidence over time

‡ decrease in incidence over time

(anxiety in abdominal surgery<sup>9</sup> and thyroidectomy<sup>45</sup>, distress<sup>18</sup> and PTSD<sup>15</sup> in breast surgery, catastrophizing in cardiac surgery<sup>21</sup> and lumbar laminectomy<sup>37</sup>, and fear and lack of optimism in outpatient surgery<sup>7</sup>), and postoperative pain (in breast<sup>17,20</sup>, cardiac<sup>21</sup>, shoulder replacement<sup>36</sup>, and outpatient surgery<sup>7</sup>, hysterectomy<sup>24,25</sup>,

- Could this explain the use of opioids? Very possibly!
- It may also involve:
  - Method of measurement
  - Age
  - Psychological factors
  - Intraoperative nerve injury
  - Acute postoperative pain
  - Genetics

Correll D. Chronic postoperative pain: recent findings in understanding and management. F1000 Research 2017; 6:1054. Bruce J, Quinlan J. Chronic Post Surgical Pain. Rev Pain. 2011; 5(3):23-29.

# Surgery and Chronic Postoperative Pain

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## ■ Issues:

- Most studies look at immediate post-operative pain, but don't look at the development of chronic post-operative pain
- No study looks at postoperative injury induced pain
  - i.e. surgical problems
- States have gotten into the act and on the non-scientific/non-medical basis, placed laws limiting the amount/duration of postoperative pain analgesic medications
- More patients in my practice ask me what to do when their surgeon tells them that they won't be getting postoperative opioid analgesics
  - Especially if they have a history of need of post-operative analgesics, and if they are opioid naïve, I recommend that they go for a second surgical opinion; re: find a physician who will take care of them correctly- a friend who was more blunt than I suggested that they tell the surgeon that they will return when s/he regains respect for their patient's needs/their hypocritical oath

# Opioid-Induced Hyperalgesia (OIH)-1

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- Is it “a thing”
  - Well, you may think so as OIH is not uncommonly cited by insurance companies as a reason not to pay for opioids for chronic pain
- OIH may be defined as when exposure to exogenous opioids causes decreased pain tolerance/increased pain sensitivity, or hyperalgesia
  - It has been reportedly associated with COT
    - There are papers that show (including reviews) statistically significant increases in human pain hypersensitivity/decreased pain tolerance with COT
  - OIH has nothing to do with tolerance (or decreased analgesic efficacy of opioids in some patient treated with ‘chronically high dosages of opioids)
  - Claims of OIH in preclinical studies does not, in this author’s experience decree that it will occur in humans
  - This author has not, in 41+ years of treating pain, seen evidence of OIH in patients

McAnally H. Correspondence: Opioid-induced hyperalgesia: pain care in older adults. Practical Pain management. January/February 2020 20(1): 11-12

# Opioid-Induced Hyperalgesia (OIH)-2

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- There is no definitive demonstration of a decrease of pain when opioids are tapered or discontinued.
  - Various papers were not definitive, or showed weak evidence (Type 3 or 4)
    - No trials explored clinical outcomes such as effects on opioid consumption (after reviewing 8 trials of “OIH)
    - Another review stated “there is consistent type 3 or 4 evidence that opioid tapering in CPPs reduced pain or maintains the same level of pain- the reviewed studies did actually test for that and had marginal evidence in quality with missing data” controlled studies would be useful- tolerance is not the same as OIH
    - Opioid tapering did not prove the reason for such results from opioid tapering did not prove that the reason was the presence of OIH
    - Of import is the fact that Effective opioid tapering done in a multidisciplinary pain treatment milieu does not seem to enhance or demonstrate OIH as

Schneider J. Correspondence: Opioid-induced hyperalgesia: pain care in older adults. Practical Pain management. January/February 2020 20(1): 11-12. Yang DZ, Sin B, Beckhusen J, et al. Opioid-induced hyperalgesia in the nonsurgical setting: a systematic review. Am J Ther. 2019;26(3):e397-e405. Fishbain DA, Pulikal A. Does opioid tapering in chronic pain patients result in improved pain or same pain vs increased pain at taper completion? Pain Med. 2018 Dec 28. Higgins C, Smith BH, Matthews K. Evidence of opioid-induced hyperalgesia in clinical populations after chronic opioid exposure. Br J Anaesth. 2019;122(6):e114-e126. Davis B, ... Schneider JP, et al. A patient-centered approach to tapering opioids. J Fam Pract. 2019; 68(10):548-556.



# Chronic Pain +

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- The chronic pain patient may have an increased risk for major issues with adverse cardiac and cerebrovascular events (MACCEs) (COVID NOT ON-BOARD)
  - Outcomes included all-cause mortality, stroke, a need for coronary angioplasty, and occurrence of acute myocardial infarction. Participants with chronic pain had a higher prevalence of underlying comorbidities such as hypertension, diabetes, renal diseases, and depression. After adjusting for these comorbidities and others, researchers found that participants with chronic pain had a higher risk for MACCE than those without chronic pain (adjusted hazard ratio [AHR], 1.3; 95% CI, 1.3 -1.4)
  - There was no difference identified in MACCE risk between men and women. However, there was an increased risk of MACCEs in the age subgroup <20 years (AHR, 4.7; 95% CI, 1.9 –11.7). Researchers also found that 5.5% of the participants used opioids, and that nonsteroidal anti-inflammatory drugs were the most common analgesics used among participants with chronic pain (79.7%). Individuals taking opioids had a higher risk for MACCEs than those who did not use opioids (AHR, 1.3; 95% CI, 1.1–1.5)
  - Investigators noted that the possible reasons for increased occurrence of MACCE in patients with chronic pain included “reduced activity, disability, sleep disturbance, fatigue, and mood alterations such as anxiety and depression.”

Chung K-M, MD, Chung-Han H, PhD, Chen Y-C, MS, et al. Chronic pain increases the risk for major adverse cardiac and cerebrovascular events: a nationwide population-based study in Asia. Pain Medicine. doi:10.1093/pm/pnaa107

# Changes in Opioid Use Secondary to Florida Law (5/18/2020)

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- More than 30 states restrict opioid dispensing for acute pain- FL is most stringent allowing 3 days meds, but patients may return to doc for 4-day extension
  - Before the law (July 2018) 5.5 patients per 1,000 enrollees per month began using opioids when decreased after the law to 4.6/1000 enrollees/mo (in a single health plan with 45,000 enrollees)
  - They did not expect the number of opioid users would decrease so significantly-”This indicates that some prescribers have now decided to not even prescribe opioids at all to certain patients in the setting of acute pain
  - This group were younger than the “typical opioid initiator”
  - “We know that pain patients are suffering as a result of some of the policies for the opioid crisis so states should think about both the pain patient and the opioid crisis

Hincapie-Castillo JM, Gooden A, Possinger SC et al. Changes in Opioid Use After Florida’s Restriction Law for Acute Pain Prescriptions. JAMA Netw Open. 2020; 3(2):e200234. doi: 10.1001/jamanetworkopen.2020.0234

# Another Pain Refugee...And Soon Another Wrongful Death (May 30, 2020)

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- From Richard (Red) Lawhern, PhD, Alliance for the Treatment of Intractable Pain
- Note from an opioid refugee:
  - “Is there any way you could advocate for me or find a new pain doc for me? Not a scared one. Someone willing to stand up for their patients, that truly need these medications to survive & have a social life. I'm willing to travel from my hometown. I'll have to drive places right now, since flights are hard to get at the moment. Even a temp situation that can do this medication until I find a permanent doctor with some guts. This is not fair or right. I have been on opioids for over 15 years no problems only help. I'd honestly rather be dead then have to go through this BS. I'm going to give it a month or two to find someone else who is willing to give me a decent dose of pain meds. After that, I'm done. Done with life like this. I can't do it anymore. It's not fair or right.”
- Messages of this type keep coming: the problem obviously persists

# They Fight, Still they Fight (June 2020)

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- California physician Connie Basch declined an offer from the CA medical board to receive probation in exchange for an admittance of guilt in her case involving the overprescription of opioids
- The complaint- she would call five “legacy” patients that came to her several years ago on high doses of opioids and anti-anxiety medication
- The state alleges: even though she tapered them to lower doses, she wasn’t doing it fast enough in adherence with state-mandated schedules
- The FDA noted last year that “no standard opioid tapering schedule exists that is suitable for all patients”

<https://edsinfo.wordpress.com>

# A Good Man: Devastated (March-May 2020)-1

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- Apparently, a woman from Rural New York, whose son died from a heroin overdose, complained to the North Carolina Medical Board about a physician who had tweeted that “Kline claims that only 1 percent of people have the genetic makeup to become addicted to opioids and that the addiction rate has not changed through the years.”
  - This angered Mrs. Julie Roy, who had never had any dealings with Dr. Kline. She wrote a letter of complaint to the NC Medical Board- who promptly demanded Dr. Kline relinquish his DEA license to prescribe, leaving 34 high impact pain patients without a pain management physician
  - As more and more doctors become reluctant to prescribe opioids, some patients have become desperate for pain management. Some have taken their own lives because they couldn’t find relief from their pain.

NC chronic pain doc suspended following tweets - NC Health ...[www.northcarolinahealthnews.org](http://www.northcarolinahealthnews.org) › 2020/03/10

# A Good Man: Devastated (March-May 2020)-2

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- In conversation with the author, Dr. Kline notes that 6 charts are in “play”
- From what he states, it would appear (from the onset- a complaint from a tweet?) that he is being “railroaded”
  - I say that, as he noted to me that the “interventional anesthesiologist who is the state’s expert witness” stated that
  - “Anyone on high dose opiates should have implantable morphine pump or stimulator”
    - This is not either realistic or true, it is not an “unwritten rule”- it is absurd
    - No comments about – appropriateness in an older patient or any specific patient; insurance; patient comorbidities; need for more than one surgery typical; possible AEs including meningitis
      - In a patient who is functional on an appropriate oral dose (which may be higher than the CDC guideline, the guideline that the state of NC has made into their Opioid rule)

Personal Communications

## From the CDC (6/17/2020)

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- The CDC is looking to obtain comments concerning perspective on and experiences with pain and pain management: they are assessing the need for updating or expanding the CDC guideline for Prescribing Opioids for Chronic pain
- They are planning to do a “rewrite” of the initial CDC guidelines from 2016, for 2021, but will not as yet state who is on the team working to re-write the guidelines- which will hopefully have PROP members in the minority

# ER Opioids “out of favor” (June 18, 2020)-1

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- Yes, there are cost arguments (ER meds more expensive); lack of long term (a year or more) studies of ER Opioids (and we all know that opioids don't work long term, right??? WRONG); more addiction? (No)
  - National Institute on Drug Abuse Director Nora Volkow, MD, has written, “Addiction occurs in only a small percentage of people who are exposed to prescription opioids, even among those with preexisting vulnerabilities.” She estimates a less than 5% risk.
  - Another paper showed “What percent of the treated group developed de novo addiction after 90 days?” The answer was 0.72%.”
- “ERs have better adherence, less clock-watching, better sleep, and are less likely to produce euphoria.” (Argoff)
- Less euphoria, lower street value (esp. with TRPs)

Schneider JP. Editorial: Why Are ER Opioids Out of Favor? *Practicle Pain Management*. 20(3): 6-8. Volkow N, McLellan AT. Opioid abuse in chronic pain – misconceptions and mitigation strategies. *NEJM*. 2016;374(13):1253-1263. Schuchat A, Houry D, Guy GP. New Data on Opioid Use and Prescribing in the United States. *JAMA* 2017;318(5):425-426. Argoff C, Silvershien D. A comparison of long- and short-acting opioids for the treatment of chronic noncancer pain. *Mayo Clinic Proc*. 2009;84(7):602-612



# ER Opioids “out of favor” (June 18, 2020)-2

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- Federation of State Medical Boards has advised, “When initiating opioid therapy, the lowest dose possible should be given and titrated to effect. It is generally suggested to begin opioid therapy with a short-acting opioid and rotate to a long-acting/extended-release if indicated.”
- A patient’s pain may consist of acute on chronic pain, or breakthrough pain, making the use of ER opioids with IR opiates to deal with breakthroughs, appropriate
- While most follow the Federation of State Medical Board’s guidance, above, the FDA states it is also appropriate to start to treat pain with some ER opioids (eg, ER morphine, Butrans, Nucynta)
  - This reflects FDA indications such that low doses may be prescribed for chronic pain as an initial prescription without regular use of an IR opioid prior to initiation of the ER product

Schneider JP. Editorial: Why Are ER Opioids Out of Favor? Practical Pain Management. 20(3): 6-8. Federation of State Medical Licensing Board. Model policy for opioids in treatment of chronic pain. 2015.

# The War on Opioids: Digital Dystopia Edition

## (June 17, 2020)

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- Illicitly made fentanyl products sold on the black market comprise more than three quarters of opioid-related overdose deaths, state Prescription Drug Monitoring Programs (PDMPs) keep doctors, pharmacists and patients under constant surveillance.
- Law enforcement raids doctors' offices if they deviate from government-mandated caps on the opioids they prescribe. Pain patients are abandoned by terrorized doctors, and in desperation turn to street drugs and sometimes suicide. Now a vendor offers to take surveillance to the next level.
- California-based Fullpower Technologies and OPOS — are trying to combine the power of the former's "hybrid Edge/Cloud AI, algorithms, big data, predictive analytics" with the latter's opioid patient monitoring expertise to create a round-the-clock digital opioid patient tracking system.

Singer JA, Eddington P. The War on Opioids: Digital Dystopia Edition. Orange County Register. Published June 17, 2020 at 11:29 am (From Cato Institute Department of Health Policy)

# The War on Opioids: Digital Dystopia Edition

## (June 17, 2020)-2

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- The companies are proposing that Americans undergoing chronic opioid therapy for pain management 1) download their app onto their smartphones, 2) allow the companies to “track vitals, function and behavior” via “contactless biosensors” and 3) store and share that data with the treating medical provider.” In other words, the companies want to incentivize participating doctors to convince their patients to give up their health data so the doctors and Fullpower-OPOS can profit.
  - This is the Facebook user digital information-for-profit model applied to the health care sector.
  - One other third party that stands to benefit: local, state, and federal law enforcement.
- This would be terrifying- JUST SAY NO!

Singer JA, Eddington P. The War on Opioids: Digital Dystopia Edition. Orange County Register. Published June 17, 2020 at 11:29 am

# The AMA—Another Country Heard From— only 5 years too late: June 16, 2020-1

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- The AMA, which states it represents American Physicians, but has stood by for 5 years during which thousands/millions of undertreated CPPs, secondary to the weaponization of the CDC Guidelines published in 2016, committed suicide or suffered, unable to obtain appropriate, individualized pain medicine/treatment
- They have emerged from hiding and make some good points; the issue is who will accept them or where/when they have been issued

Madara, James (CEO And Executive Vice President, American Medical Association); letter to Deborah Dowell, CMO of the CDC, June 16, 2020

# The AMA—Another Country Heard From— only 5 years too late: June 16, 2020-2

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## ■ The AMA:

- is urging the Centers for Disease Control and Prevention (CDC) to make significant revisions to its 2016 Guideline for Prescribing Opioids for Chronic Pain.
- called for CDC to remove arbitrary limits or other restrictions on opioid prescribing given the lack of evidence that these limits have improved outcomes for patients with pain.
  - they have increased stigma for patients with pain and have resulted in legitimate pain care being denied to patients.
- “Hard thresholds should never be used. Where such thresholds have been implemented based on the previous CDC Guideline, they should be eliminated”

Madara, James (CEO And Executive Vice President, American Medical Association); letter to Deborah Dowell, CMO of the CDC, June 16, 2020

# The AMA Comes OUT!-1

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- Excerpts from Dr. Madara's letter to the CDC:
  - “a broad-based public health approach is required. This approach must balance patients' needs for comprehensive pain management services, including access to non-opioid pain care as well as opioid analgesics when clinically appropriate, with efforts to promote appropriate prescribing, reduce diversion and misuse, promote an understanding that substance use disorders are chronic conditions that respond well to evidence-based treatment, and expand access to treatment for individuals with substance use disorders.”
  - “The nation no longer has a prescription opioid-driven epidemic.”
  - “We are now facing an unprecedented, multi-factorial and much more dangerous overdose and drug epidemic driven by heroin and illicitly manufactured fentanyl, fentanyl analogs, and stimulants.”

Madara, James (CEO And Executive Vice President, American Medical Association); letter to Deborah Dowell, CMO of the CDC, June 16, 2020

# The AMA Comes OUT!-2

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- “We can no longer afford to view increasing drug-related mortality through a prescription opioid-myopic lens.”
- The nation’s opioid epidemic has never been just about prescription opioids, and we encourage CDC to take a broader view of how to help ensure patients have access to evidence based comprehensive care that includes multidisciplinary, multimodal pain care options
- the AMA urges CDC to work with physicians and patients to ensure that the revisions support patients with pain and the physicians who care for them.
- AMA Pain Care Task Force (PCTF) was formed in 2018. The newly formed PCTF is made up of representatives from 20 health care associations.
- health insurance plans and pharmacy benefit managers have used the 2016 CDC Guidelines to
  - justify inappropriate one-size-fits-all restrictions on opioid analgesics while also
  - maintaining restricted access to other therapies for pain.

Madara, James (CEO And Executive Vice President, American Medical Association); letter to Deborah Dowell, CMO of the CDC, June 16, 2020

# The AMA Comes OUT!-3

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- There is no question that the nation's physicians have reduced opioid analgesic supply—both in volume and dose strength—but there has not been a concomitant increase in access to or affordability of evidence-based non-opioid alternatives.
- The Task Forces further affirm that some patients with acute or chronic pain can benefit from taking prescription opioid analgesics at doses that may be greater than guidelines or thresholds put forward by federal agencies, health insurance plans, pharmacy chains, pharmacy benefit management companies, and other advisory or regulatory bodies.
- The Task Force continues to urge physicians to make judicious and informed prescribing decisions to reduce the risk of opioid-related harms, but acknowledges that for some patients, opioid therapy, including when prescribed at doses greater than recommended by such entities, may be medically necessary and appropriate.
- The AMA urges the CDC Guideline start by recognizing the need for individualized care for patients with pain.

Madara, James (CEO And Executive Vice President, American Medical Association); letter to Deborah Dowell, CMO of the CDC, June 16, 2020



# The AMA Comes OUT!-4

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- It is clear that the CDC Guideline has harmed many patients —so much so that in 2019, the CDC authors, the FDA and HHS issued long-overdue, but greatly appreciated, clarifications that states should not use the CDC Guideline to implement an arbitrary threshold
- The CDC Guideline has been misapplied as a hard policy threshold by states, health plans, pharmacy chains, and PBMs

Madara, James (CEO And Executive Vice President, American Medical Association); letter to Deborah Dowell, CMO of the CDC, June 16, 2020

# The AMA Comes OUT!-5

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- Examples of inappropriate policies with specific limits or policies that misapply the CDC Guideline in different ways and have resulted in specific harm to patients include the following:
  - Walmart’s policy includes a 50MME or 7-day hard threshold for opioid prescribing;
  - CVS Caremark’s policy has multiple restrictions, including a 7-day hard threshold for opioid prescribing;
  - OptumRx’s policy is aligned with 2016 Guidelines
  - Walgreen’s Good Faith Dispensing Policy does not list specific thresholds, but the AMA has received numerous complaints about pharmacists refusing to fill a prescription because of “corporate policy.”
  - Blue Cross-Blue Shield Association 7-day hard threshold;
  - United Healthcare 7-day, 90 MME hard threshold;
  - More than 30 states have enacted laws with opioid prescribing restrictions ranging from 3 to 14 days, including many with MME limits and other restrictions.

Madara, James (CEO And Executive Vice President, American Medical Association); letter to Deborah Dowell, CMO of the CDC, June 16, 2020

# Maximum Opioid Doses: A Pharmacological Abomination (June 22, 2020)

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- An excellent article about opioid use and the fact that “MMEs” are incredibly worthless, based on flawed science and bound to harm patients; this article goes through bioavailability, genetics and human metabolism and the SCIENCE of opioids- not seen in the CDC Guidelines
- RE: Opioid Dosing:
  - Some opioid drugs will be absorbed and pass to the bloodstream very well and some will do so very poorly.
  - Even opioids that appear to be structurally and functionally similar will be metabolized at very different rates.
  - Other drugs can drastically alter the physiological response of a pain patient to a given opioid; the second drug may increase a person's response to the opioid or it may decrease it.
  - Even under ideal conditions - two people taking the same opioid drug at the same dose, at the same interval, and taking no other drug - huge variations of innate metabolism from one individual to another will necessarily result in a wide range in clinical response to that drug.
- The Conclusion:
  - The CDC MME chart, in fact, the entire concept of morphine milligram equivalents may be convenient for bureaucrats but because of differences in the absorption of different drugs into the bloodstream, half-life of different drugs, the impact of one or more other drugs on opioid levels, and large differences of the rate of metabolism caused by genetic factors, is not only devoid of scientific utility, but actually causes far more harm than help by creating "guidelines" that are based upon a false premise. When a policy is based on deeply flawed science, the policy itself will automatically be fatally flawed. It cannot be any other way.

Bloom J. Maximum Opioid Doses: A pharmacological Abomination. American Council on Science and Health. June 22, 2020. <https://www.acsh.org/news/2020/06/22/maximum-opioid-doses-pharmacological-abomination-14858>

# Three Minutes to Change the World-1 (July 4, 2020)

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- The US Agency for Healthcare Research and Quality informs us that there are no profiling instruments that accurately predict risks of opioid dependency, tolerance, or addiction in individuals. However, as they fail to inform us, there never will be.
- Genetic polymorphism in P-450 series liver enzymes that metabolize opioids generates a wide natural range of minimum effective dose. Case reports indicate some patients are helped by as little as 20 MMEDD, while others benefit from over 2000 MMEDD — without significant side effects, sometimes for periods of years.

Lawhern, RA. Three Minutes to Change the World. Published in Dr. Lynn Webster's Blog, <https://www.lynnwebstermd.com/2020/07/04/three-minutes-to-change-the-world/>.

# Three Minutes to Change the World

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- Over-prescribing did not create our US opioid “crisis.” Dr Nora Volkow, Director of NIDA, tells us “addiction is not a predictable outcome of opioid prescribing.” Risk of addiction to medically managed opioids is less than 1%. Overdose mortality is three to six times higher in youth under age 24 than in seniors over age 62. But prescribing in seniors is three to six times higher than in youth. U.S. states with higher prescribing rates have overdose mortality rates below the national average.
- The American Medical Association has repudiated MMED as a measure of risk or benefit and characterized “high prescriber” letters as a blacklisting of doctors and their patients, violating legal due process. Denial of pain care when it is available constitutes patient abuse and desertion.

Lawhern, RA. Three Minutes to Change the World. Published in Dr. Lynn Webster's Blog, <https://www.lynnwebstermd.com/2020/07/04/three-minutes-to-change-the-world/>.

# Three Minutes to Change the World-3

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- “It is time to admit publicly that the 2016 CDC guidelines were not only misapplied, but wrong on facts, science, and medical ethics. Contrary to the narratives of fringe element anti-opioid zealots and their insurance company sponsors, medically managed opioid analgesics are safe, effective and indispensable. For millions of pain patients, no effective alternative treatments exist.”

Richard A. Lawhern, PhD

Presentation to the Board of Scientific Counselors  
of the CDC National Center for Injury Prevention and Control

*Presented on July 22, 2020*

Lawhern, RA. Three Minutes to Change the World. Published in Dr. Lynn Webster's Blog, <https://www.lynnwebstermd.com/2020/07/04/three-minutes-to-change-the-world/>.

# Opioids May Be Appropriate for Chronic Pain (June, 2020)

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- “Patients living with chronic pain require appropriate access to opioid therapy along with improved access to pain care and additional therapeutic options”
- Medically Reasonable and Ethical to consider opioid therapy as a treatment option

Christo PJ. Opioids May Be Appropriate for Chronic Pain. J Law Med Ethics. 2020; Jun, 48(2):241-248.

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## **Treating Pain/Headache during the Pandemic**



# Practicing Pain/Headache Medicine during the Pandemic: May/June 2020

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- Telemedicine are us!
  - Video/Virtual visits (Doximity/ Epic/ Web-ex)
  - Phone Visits (Doximity)
  - There are here now, and I believe they will stay
    - Patients who must drive hours to see me in Chapel Hill- why not do a Video/Virtual visit (after initial eval)
- Doing an abridged neurological examination
- Maintaining the practice with patients glad to participate!

Jay, GW. How the COVID-19 Pandemic Is transforming Pain Care. Practical Pain Management. May/June 2020; 20(3):36-39

# The Good News (March 2020)

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- During the COVID-19 Pandemic, the DEA has allowed prescribing of controlled substances based on a telemedicine visit (must be Video, not phone)- must be via an “audio-visual, real-time, two-way interactive communication system”-Telephone only communications are not allowed as part of the DEA exceptions
  - For patients who have had a monthly in-person medical evaluation- until the crisis is over
  - If the physician has seen the patient in person previously – after a follow-up evaluation by a method (in person, via telehealth, telephone or email, the physician may issue a any needed prescriptions directly to the patient or pharmacy
  - If the patient was never seen before in person (in DEA facility)- the same
  - The DEA will allow up to 15 days for a written prescription to reach a pharmacy after an oral prescription- if needed may use fax or scan

Center to advance Palliative Care. Outpatient opioid prescribing during Covid-19. <https://www.capc.org/covid-19/outpatient-opioid-prescribing-during-covid-19/> Assessed 7.11.2020. DEA's response to COVID-19. <https://www.dea.gov/press-releases/2020/03/20/deas-response-covid-19> Assessed 7/11/2020. McDermott W. Letter to Practitioner Registrants and Pharmacists. March 27, 2020. [https://www.deadiversion.usdoj.gov/GDP/\(DEA-DC-017\)\(DEA065\)%20Early%20RX%20Refill%20-%20OMB%203-20-20%202200%20DAA%20approved.pdf](https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-017)(DEA065)%20Early%20RX%20Refill%20-%20OMB%203-20-20%202200%20DAA%20approved.pdf). MCDERMOTT W, [https://www.deadiversion.usdoj.gov/GDP/\(DEA-DC-021\)\(DEA073\)%20Oral%20CII%20for%20regular%20CII%20scirpt%20\(Final\)%20+Esign%20a.pdf](https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-021)(DEA073)%20Oral%20CII%20for%20regular%20CII%20scirpt%20(Final)%20+Esign%20a.pdf). How to Prescribe Controlled Substances to Patients During the COVID-19 Public Health Emergency. [https://www.deadiversion.usdoj.gov/GDP/\(DEA-DC-023\)\(DEA075\)Decision\\_Tree\\_\(Final\)\\_33120\\_2007.pdf](https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-023)(DEA075)Decision_Tree_(Final)_33120_2007.pdf).

# The Bad News (February 2020)

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- People with increased risk for experiencing severe symptoms and possibly dying of COVID-19, are seniors and those with chronic illness
- This includes patients with chronic pain who are in both risk groups
- People with chronic pain may be more susceptible to viruses in general, because chronic pain can diminish the immune systems efficacy
  - At McGill University, it was found that chronic pain changes the DNA in T-cells, white cells essential for immunity
  - Researchers were surprised by the number of genes affected by chronic pain

Webster L. Are you at higher risk for Coronavirus? Pain News Network, February 15, 2020. <https://www.painnewsnetwork.org/stories/2020/2/15/are-you-at-higher-risk-for-coronavirus> Assessed July 11, 2020.

## A Good Read (March 27, 2020)

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- The American Society of Regional Anesthesia and Pain Medicine:
  - “Recommendations on Chronic Pain Practice during the COVID-19 Pandemic”:
    - Joint statement by American Society of Regional Anesthesia and Pain Medicine (ASRA) and European Society of Regional Anesthesia and Pain Therapy (ESRA)
  - Reasonable recommendations

# Increasing Overdose Deaths 7/2/2020

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- Overdose deaths have increased during the pandemic
  - Also increased demand for addiction services
- Suicidality, physical limitation in function as well as emotional suffering, typically ever-present in chronic pain patients, increase during the pandemic with its loss of vital pain services
  - Rural >> Urban
  - Ability to obtain PPE
- Treatment needed to keep the CPP out of the hospital ED and maintain hospital ability to deal with COVID-19 and other significant medical problems

Ehley B. Pandemic unleashes a spike in overdose deaths. Politico. 7.2.2020. <https://www.politico.com/news/2020/06/29/pandemic-unleashes-a-spike-in-overdose-deaths-345183>. Assessed 7.11.2020. Choo J. When life is unsettled: Pain Management During a Pandemic. June 15, 2020. <https://www.painmedicineneeds.com/Commentary/Article/06-20/When-Life-Is-Unsettled-Pain-Management-During-a-Pandemic/58562> Assessed 7.11.2020

# More Deaths: July 1, 2020

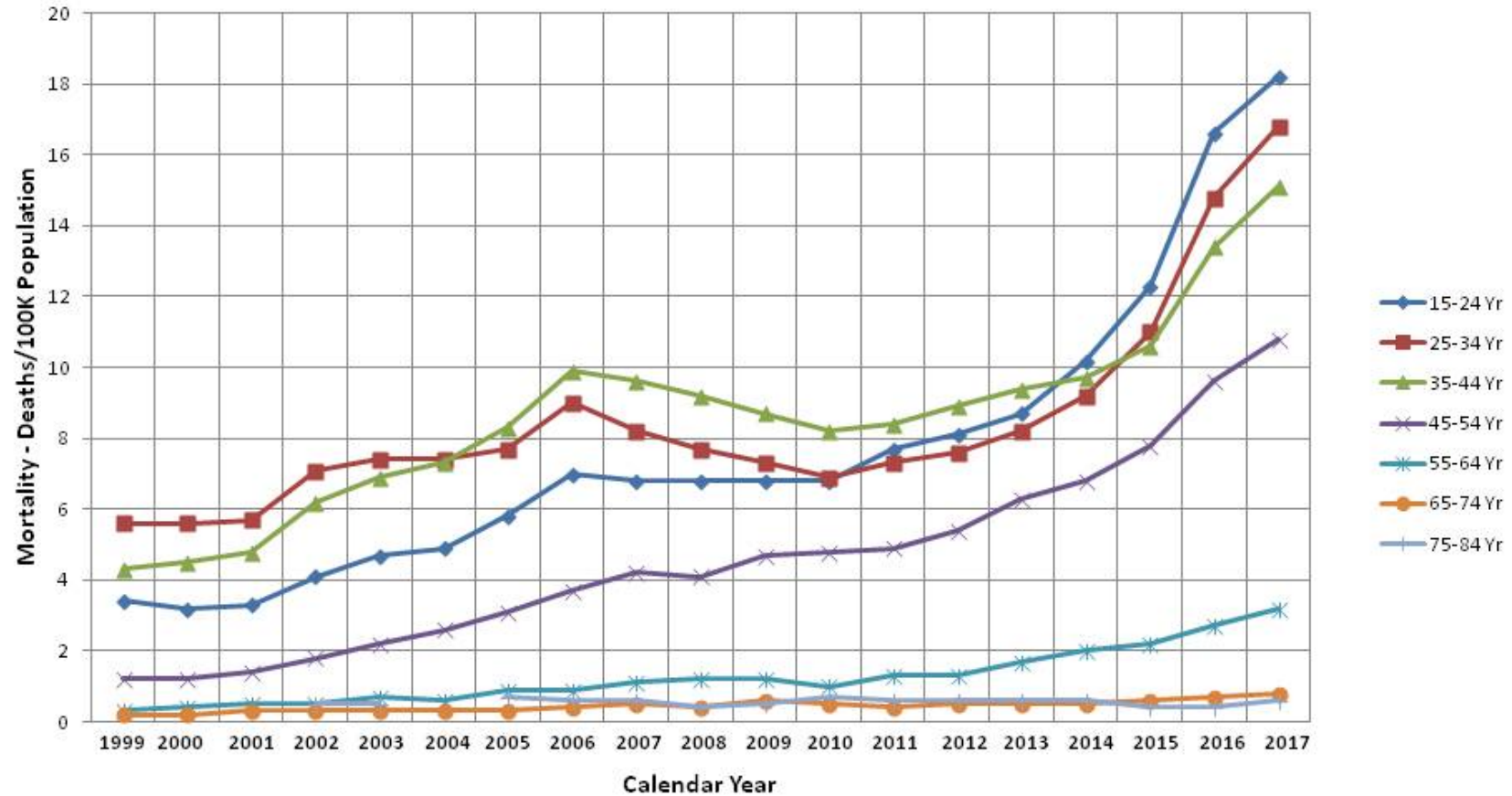
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- The White House Drug Czar, Jim Carroll, attributed much of the increase in overdose rate to anxiety, social isolation and depression secondary to the COVID-19 pandemic
  - He also noted the overdose death rate from methamphetamine related deaths have been surging the last few years
  - However, evidence shows there is no correlation between prescription volume and the non-medical opioid use or opioid use disorder
  - Isolation, loneliness, and the anxiety and depression associated with quarantines, lockdowns, and the resultant economic dislocations are the opposite of what people suffering from addiction require.
  - many chronic pain patients have been unable to follow up with their physicians, whose offices have been closed (or office hours restricted) in order to reduce the spread of COVID-19. And many elective procedures to treat or eliminate these painful conditions have been postponed or cancelled because of blanket bans on elective procedures.
  - the driving force behind overdose deaths has always been drug prohibition. And so it will remain, until it is repealed.

Singer JA. The “Drug Czar” says Overdose Deaths were already rising before Pandemic and are spiking- the ultimate blame belongs to prohibition. Cato At Liberty. July 1, 2020. <https://www.cato.org/blog/drug-czar-says-overdose-deaths-were-already-rising-pandemic-now-are-spiking-ultimate-blame> Assessed July 11, 2020

## Age Adjusted Opioid-Overdose Related Mortality by Year and Age Group

(CDC Wonder Database Apr 2, 2019)

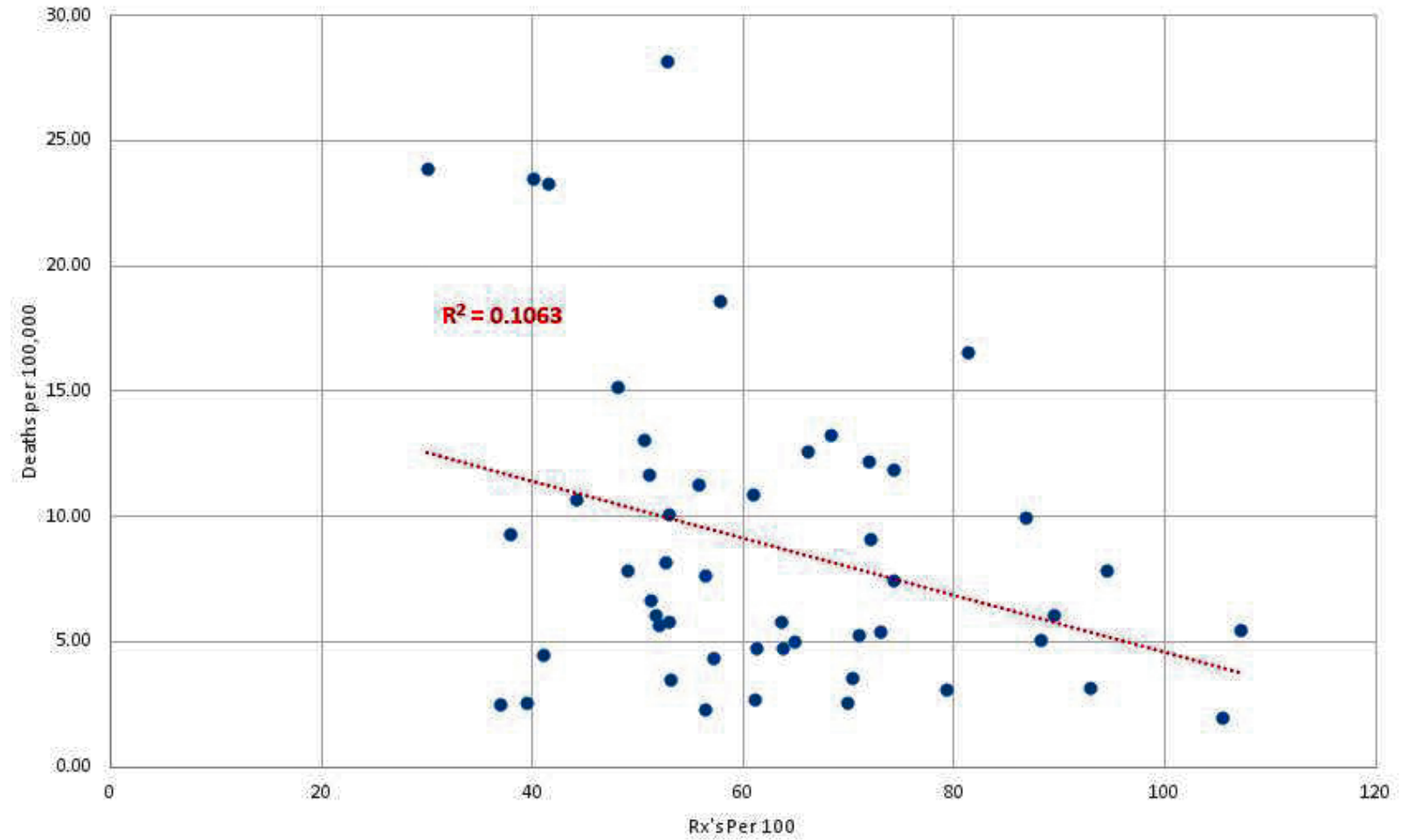


Dataset: Multiple Cause of Death, 1999-2017

Narcotics Related (T40.0-T40.6) Accidental and Intentional Drug Overdose Deaths (X42, X62)

Richard A Lawhern PhD., "Over Prescribing Did Not Cause America's Opioid Crisis" Understanding Chronic Pain –  
Online Blog of Lynn Webster MD, April 5, 2019 <http://www.lynnwebstermd.com/over-prescribing/>

Rxing Rate vs Deaths per 100,000 By State, 2017



Richard A Lawhern PhD., "Over Prescribing Did Not Cause America's Opioid Crisis" Understanding Chronic Pain – Online Blog of Lynn Webster MD, April 5, 2019 <http://www.lynnwebstermd.com/over-prescribing/>



# Not so Good News: July 10, 2020

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- The 2016 were supposed to exclude cancer pain care, but NO, it didn't
  - the opioid crisis “has enhanced fear — fear of addiction in particular” among both patients and doctors;” per Dr. Judy Paice, director of the Cancer Pain Program at Northwestern University
  - Many primary care doctors no longer prescribe opioids. Oncologists are still prescribing these medications, but in many cases they’re somewhat anxious about doing so. That has led some patients to have trouble even obtaining a prescription for pain medication,”
  - In 2019, the Cancer Action Network said there has been “a significant increase in cancer patients and survivors being unable to access their opioid prescriptions.” One out of four said a pharmacy had refused to fill their opioid prescription and nearly a third reported their insurance refused to pay for their opioid medication
  - Also in 2019: That same year, CDC issued a long-awaited clarification noting the “misapplication” of the guideline to patients it was never intended for, including “patients with pain associated with cancer.” BUT THAT DIDN'T STOP THE PROBLEM

Chriss R. The CDC, Opioids and Cancer Care. Pain News Network. July 10, 2020 <https://www.painnewsnetwork.org/stories/2020/7/10/the-cdc-opioids-and-cancer-care> Assessed July 11, 2020

## To Be Continued Next Year

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- We will see what happens during the next year, as the CDC guidelines are to be “updated” but no one knows by whom
- The pandemic will hopefully be over early next year, if a vaccine can be approved and people use it
- Will insurers, PBMs, state government, medical boards, et al, ad nauseum get the message?
  - It is now being broadcast by more people and medical groups- not to mention the FDA
- There are some reasons for hope but WE SHALL SEE!

Extra Slides

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## **AMA RECOMMENDATIONS TO THE CDC**

# AMA Recommendations-1

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- 1. Non-pharmacologic therapy and non-opioid pharmacologic therapy are preferred for patients with pain. Providers should consider using opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy, as appropriate. In order to achieve this goal, public and private payer policies must be fundamentally altered and aligned to support payment for nonpharmacologic treatments and multimodal, multidisciplinary pain care. In addition, more evidence must be developed to inform clinical decision-making on the use of nonpharmacologic approaches, and more clinicians need to be trained in their effective use.

Madara, James (CEO And Executive Vice President, American Medical Association); letter to Deborah Dowell, CMO of the CDC, June 16, 2020

# AMA Recommendations-2

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- 2. Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function and should consider how therapy will be adjusted, including the potential for tapering and/or discontinuation, if benefits do not outweigh risks. Clinicians should continue opioid therapy only if there is clinically meaningful benefit in achieving treatment goals for improving or maintaining levels of pain and function that outweighs risks to patient safety

Madara, James (CEO And Executive Vice President, American Medical Association); letter to Deborah Dowell, CMO of the CDC, June 16, 2020

## AMA Recommendations-3, 4

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- 3. Clinicians are encouraged to have open and honest discussions with their patients so as to avoid stigmatizing the decision to start, continue, or discontinue opioids or non-opioid therapy. This discussion also must account for the treatment options accessible to the patient based on their health condition, social determinants of health (e.g. transportation, employment, childcare responsibilities, race, gender, age) and insurance coverage.
- 4. (Statement)The AMA strongly supports a pharmacist carrying out his or her corresponding responsibility under state and federal law, but the past few years are rife with examples of patients facing what amounts to interrogations at the pharmacy counter as well as denials of legitimate medication. The AMA urges CDC to provide strong guidance and support for physicians and pharmacists to work together rather than jump to conclusions about a patient's PDMP report.

Madara, James (CEO And Executive Vice President, American Medical Association); letter to Deborah Dowell, CMO of the CDC, June 16, 2020

# AMA Recommendations-5

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- 5. Before starting long-term opioid therapy, and at periodic intervals thereafter, physicians should establish and review treatment goals with all patients, including shared goals for pain and function. Physicians should initiate opioid therapy with the lowest effective dose. Continued opioid therapy and/or dose escalation should occur only if there is clinically meaningful improvement or maintenance in treatment goals for pain and function that outweighs risks to patient safety. Hard thresholds should never be used.

Madara, James (CEO And Executive Vice President, American Medical Association); letter to Deborah Dowell, CMO of the CDC, June 16, 2020

# AMA Recommendations- 6, 7

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- 6. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids in a quantity needed only for the expected duration of pain severe enough to require opioids. Hard thresholds should never be used. Where such thresholds have been implemented based on the previous CDC Guideline, they should be eliminated.
- 7. Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy at appropriate clinical intervals determined by the clinician. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other available and affordable therapies and, if necessary, discuss with patients a shared plan to carefully and gradually lower dosages, or discontinue opioids.

Madara, James (CEO And Executive Vice President, American Medical Association); letter to Deborah Dowell, CMO of the CDC, June 16, 2020



## AMA Recommendations-8

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- 8. Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid-related overdose, such as history of overdose, history of substance use disorder, or higher opioid dosages, or concurrent benzodiazepine use, are present. Risk factors should be discussed with the patient, but no single risk factor should be used as a determining factor in decisions to discontinue or deny care.

Madara, James (CEO And Executive Vice President, American Medical Association); letter to Deborah Dowell, CMO of the CDC, June 16, 2020

# AMA Recommendations-9, 10

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- 9. Clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to help inform the provider's clinical decision making . Clinicians should continue to review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy at clinically appropriate intervals. PDMP reports raising questions should be carefully examined but not used, by themselves, as reasons to discontinue or deny care to the patient.
- 10. When prescribing opioids for chronic pain, clinicians' potential use of urine drug testing should be made in consultation with the patient, including discussion of the limitations of such testing and assurances that test results are only one factor in ongoing treatment decisions. Urine drug testing should not, by itself, be a determining factor in whether to discontinue or deny care to a patient.

Madara, James (CEO And Executive Vice President, American Medical Association); letter to Deborah Dowell, CMO of the CDC, June 16, 2020

# AMA Recommendations-11, 12, 13

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- 11. Clinicians should avoid prescribing opioid medication and benzodiazepines concurrently whenever possible, unless it is clinically indicated and required for optimal patient management.
- 12. Clinicians should offer or arrange evidence-based treatment, including medications used to treat opioid use disorder in combination with behavioral therapies, where available) for patients with opioid use disorder.
- New recommendation for patients with pain who may have a history of an opioid use disorder:
  - Patients with a current or history of an opioid use disorder should receive effective pain care, including opioid therapy when clinically indicated and in consideration of known risks and benefits.

Madara, James (CEO And Executive Vice President, American Medical Association); letter to Deborah Dowell, CMO of the CDC, June 16, 2020