# Recommendations of the HHS Pain Management Task Force

*A Response by Medical Professionals and Patient Advocates*

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*This paper offers a response by medical professionals and patient advocates to the May 2019 final draft report recommendations of the HHS Inter-Agency Task Force on Pain Management. The authors propose that urgent changes in public policy on pain management are needed to repair the widespread damage done to pain patients, healthcare providers, and other stakeholders by the 2016 CDC Guideline on Prescribing Opioids for Chronic Pain, and by the related "Opioid Safety Initiative" of the Veterans Health Administration (VHA). An interim US policy on prescription of opioids is offered for the period during which detailed practice standards will be developed by professional medical associations, as envisioned by the Task Force report and enabling legislation.*

## Introduction

On May 9 to 10, 2019, the HHS Pain Management Inter-Agency Task Force met to vote on extensive recommendations for changes to prevailing US practice guidelines for the treatment of acute and chronic pain.[1] This response to the HHS Task Force is intended to amplify and help focus the findings of the Task Force as they will be applied in further policy deliberations envisioned by the enabling legislation (Comprehensive Addiction Recovery Act, July 2016).

We find much to applaud in the recommendations of the Task Force. Particularly meaningful is the advocacy for patient-centered, multidisciplinary treatment teams that integrate a range of evidence-based options tailored to the individual patient's medical and support needs. Also constructive is the strong emphasis on the need for expansions to medical school and post-doctoral training in pain treatment and funding for related research into mechanisms and treatment protocols.

As many patients and physicians have already been severely affected by the 2016 CDC guideline and the adverse impact of the guideline continues to grow, we believe that there is great urgency for corrective actions by the HHS. Neither patients nor their doctors can afford to wait further years for definitive and corrective guidance on pain treatment. Doctors fearful of sanctions by healthcare provider organizations and federal and state drug enforcement authorities are continuing to leave pain management practice, deserting their patients to agony, disability, and, increasingly, suicide from overwhelming pain. Significant and immediate changes in public policy are needed to correct this trend and to save patient lives.

## Ongoing Centrality of Opioids in Pain Treatment

A core understanding that we believe to be under-emphasized in the Task Force report is that opioid analgesics will likely remain centrally important in pain management for many years to come. There is simply no near-term prospect for the rapid emergence of safe, effective, and affordable alternatives, nor can many of the therapies discussed by the Task Force be seriously embraced as mandated "replacements."[2]

Although the Task Force report represents progress toward patient-centered and multidisciplinary practice, it may also be seen as a missed opportunity to correct long-standing and highly destructive mythologies in public policy regarding addiction in the context of pain treatment. We urge the Task Force and legislators who will implement its recommendations to consider the scientific evidence detailed below.

Ample published data demonstrate that the US public health crisis with regard to opioid addiction and overdose mortality has not been created, nor sustained, by physicians "over-prescribing" opioids to their patients. Today's pain patient is rarely tomorrow's addict.[3] Extensive CDC data are available on the rates of opioid prescriptions by geographic area and demographics of overdose mortality. Some of these data were reviewed in public meetings of the Task Force, followed by extensive comments in its December 2018 draft report.

It is clear from CDC state by state data that there is no relationship between rates of opioid prescribing and rates of overdose mortality. These geographic data are complemented by epidemiologic data. Individuals over age 55 are prescribed opioids three times more often than younger adults, but their overdose-related mortality has remained stable and is the lowest of any age group. By contrast, overdose-related mortality has skyrocketed in people under age 25 over the past 20 years to levels six times higher than in people over age 55 (see Figures 1 and 2, on next page).

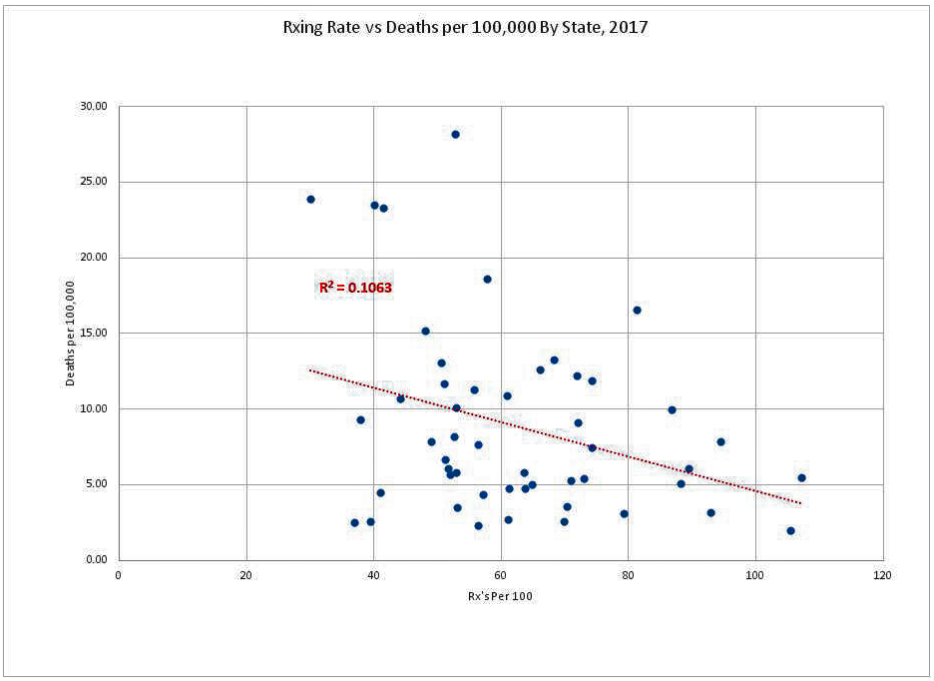


**Figure 1.** Opioid-related mortality vs prescribing rates, 2017.

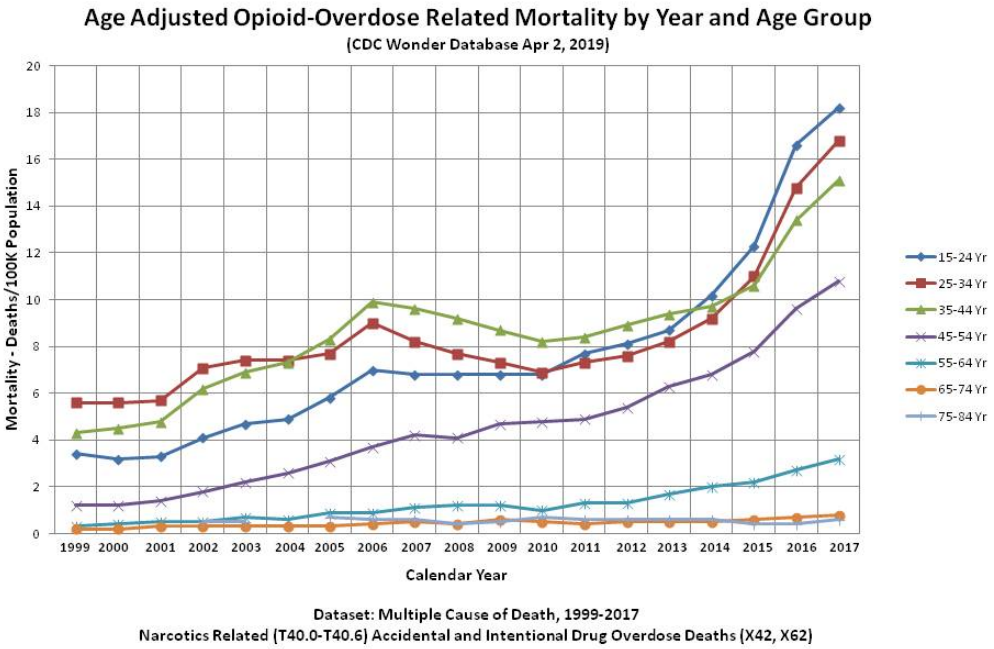


**Figure 2.** Age-adjusted opioid-overdose related mortality by year and age.

Contrary to current US policy on drug addiction and chronic pain, the data in these figures directly contradict any claimed cause and effect relationship between prescribing and mortality. Moreover, the direction of trend lines is remarkable. In nine US states where opioid prescribing rates were highest for 2017, the average rates of overdose-related mortality were lower than the average across the US.

Many factors likely contribute to this outcome. However, a plausible interpretation of this trend is that restrictions on prescribing may actually be increasing mortality by driving deserted patients into unsafe street markets or medical collapse and suicide due to overwhelming pain. This trend first emerged in 2016; trend lines prior to that year were flat, with similarly low correlation.[4,5]

**Issues Surrounding 2016 CDC Guideline**

Considerable discussion is devoted in the Task Force's recommendations to issues surrounding the 2016 CDC guideline on opioid prescribing for chronic pain. There is widespread evidence in public comments to the Task Force that the guidelines have significantly damaged both patients and their doctors by prompting over 30 states and thousands of hospitals and medical practices to restrict use of opioid analgesics, even in patients for whom they have been shown to be effective and safe.

The CDC has recently issued a "clarification" of the guideline that asserts it was never intended to be used as a mandate for limiting the availability of opioids to legacy patients.[6] This clarification was reinforced by an FDA safety warning that rapidly-forced tapers or unsupported cessation of opioid therapy is actively dangerous to patient's health.[7]

Also pertinent is a letter from several prominent pain management professionals to Oregon Gov. Kate Brown, arguing against the mandated tapering of the state's Medicaid patients maintained on opioids, as proposed by the Oregon Health Evidence Review Commission.[8] There are presently no documented trials demonstrating the beneficial outcomes from mandated tapers of legacy patients; indeed, there is a concern that coercing patients otherwise may contribute to medical and emotional collapse, with significant risk of suicide.

Despite expressing criticisms of the CDC guideline, the Task Force report falls short of calling for an outright retraction of this document, or the related "Opioid Safety Initiative" of the VHA. These two documents have prompted widespread denial of appropriate pain treatment to veterans and non-veterans alike. As medical professionals and patient advocates, the authors counsel decisive correction of this oversight.

By virtue of the authority of the CDC, its guideline document has had profound political ramifications, even if unintended, reflected in actions by healthcare provider organizations, state legislatures, the Drug Enforcement Agency (DEA), health insurance companies, and pharmacies. This political juggernaut is not likely to be halted by anything short of withdrawal of the guideline document.

**Opioid Analgesics are Effective and Safe for the Great Majority of Patients**

There is ample published evidence that opioid analgesic therapy is effective and safe for the great majority of patients who present with moderate to severe pain. In the very few randomized controlled trials in which opioid dosage was adequately titrated, over 70% of patients rated their experience as good or excellent.[9,10] Multiple studies have shown that the annual case fatality rate associated with "high dose" opioid regimens (> 100 morphine milligram equivalent doses [MMED]) is 0.25%. This low rate is identical to the annual risk of fatal hemorrhage associated with anticoagulation for stroke prevention in patients with atrial fibrillation.

Assessments of the risks of opioid treatment often conflate dependence (a common and easily managed pharmacodynamic effect of opioids), tolerance (an uncommon and readily managed consequence of chronic opioid therapy), and addiction (a rare but serious medical problem of complex origin). As noted by Nora Volkow, MD, and Thomas A. McMillan, PhD, of the National Institute on Drug Abuse (NIDA):[11]

> *"Unlike tolerance and physical dependence, addiction is not a predictable result of opioid prescribing. Addiction occurs in only a small percentage of persons who are exposed to opioids—even among those with preexisting vulnerabilities...Older medical texts and several versions of the Diagnostic and Statistical Manual of Mental Disorders (DSM) either overemphasized the role of tolerance and physical dependence in the definition of addiction or equated these processes (DSM-III and DSM-IV). However, more recent studies have shown that the molecular mechanisms underlying addiction are distinct from those responsible for tolerance and physical dependence, in that they evolve much more slowly, last much longer, and disrupt multiple brain processes."*

Assessments of the risks of opioid treatment have been heavily influenced by the perception—unsupported by scientific evidence—that even very brief treatment is associated with a high probability of long-term use, abuse, and addiction. Large US-based studies of the incidence of opioid use disorder (OUD) or chronic opioid prescribing in post-operative patients have now made it very clear that the risk of any long-term use of opioids, let alone abuse or addiction, is very low (< 1%).[12,13] Neither of these highly pertinent studies is referenced in the Task Force report, though both were identified in public comments in the December 2018 draft.

Brat, et al,[10] investigated medical insurance records of more than 586,000 patients prescribed opioids for the first time after surgery. Less than 1% continued renewing their prescriptions longer than 13 weeks; 0.6% were later diagnosed with OUD during follow-up periods averaging 2.6 years between 2008 and 2016. It is likely that many recorded diagnoses of OUD in these patients were incorrect. Many doctors who diagnose patients with abuse are general practitioners who lack deep training in addiction and have little experience evaluating the behaviors that actually define addiction. Likewise, some physicians confuse patient reports of continuing pain—caused by failed surgery—for potential opioid abuse. Thus, many patients who commented on the Task Force

report had been discharged as “drug seekers” with minimal or no factual justification by practitioners.

This study substantially contradicts findings of a reference quoted in the Task Force report:[14]

> *"As one large study illustrated, among a population of opioid-naive patients who were given a course of opioids to treat pain following surgery, about 6% became new chronic users. Patients who were at higher risk for becoming chronic opioid users were those with a history of tobacco use, alcohol and substance abuse disorders, anxiety, depression, other pain disorders, and comorbid conditions.”*

Unfortunately, the authors of the study referenced in the Task Force report defined any patient who received at least one prescription within 90 to 180 days after surgery as “chronic opioid users.” However, this metric is not "chronic" in any sense that most practitioners would recognize from common medical practice. It substantially overstates actual incidence of extended prescribing. More usefully, this paper also reinforces the well-established evidence that depression and anxiety are important contributors to suffering related to pain. It also stands to reason that if a surgical procedure was not directed at the source of pain, the pain is likely to persist after surgery.

Sun, et al,[11] tracked long-term opioid prescriptions in non-surgical patients and compared prescription rates to 642,000 patients who received one of eleven common types of surgery. Opioid prescriptions were defined as “chronic” when 10 or more scripts were written in one year, or a prescription was renewed continuously for more than 120 days. The rate for chronic prescriptions of opioid analgesics among millions of non-surgical patients was estimated at 0.136%. For 4 of the 11 surgical procedures studied, the same rate of prescriptions occurred after surgery as before. For the seven remaining procedures, long-term opioid prescriptions rose to 0.174% for caesarean delivery, and 0.69% for total knee replacement—a procedure known to cause lingering pain. It is thus likely that many ongoing prescriptions after knee replacement reflected chronic post-surgical pain, rather than issues of opioid misuse.

Also of concern is a Task Force reference to the SPACE randomized clinical trial of 2018:[15]

> *“A recent study demonstrated that treatment with opioids alone was not superior to treatment with trials of various combinations of non-opioid medications for improving pain-related function over 12 months; the authors concluded that the results do not support initiation of opioid therapy alone for moderate to severe chronic back pain or hip or knee osteoarthritis pain.”*

This trial involved 240 patients treated for chronic pain in US Department of Veteran Affairs (VA) hospitals. It has been widely represented as proof that opioids are no more effective than non-opioid treatments for chronic pain. However, a review of the supplementary material from this study reveals that the mean dose of opioid was 21 MMED, and only 12.6% of patients randomized to the opioid group were taking > 50

MMED, itself a low dose. Furthermore, antidepressants were among the treatment options in the non-opioid group. Thus, results of this trial may best be construed to one of three points:

1) patients whose pain is not sufficiently severe to warrant opioid treatment do not particularly benefit from opioids
2) opioids are not of benefit to patients with moderate to severe chronic pain when opioid dosage is not sufficiently titrated
3) optional use of antidepressants in the non-opioid group substantially mitigated the inadequacy of other non-opioid therapy.

A troubling aspect of the 2016 guideline, repeated in Task Force recommendations, is the assertion that further evidence is needed for the effectiveness of opioids in long-term use. As noted by Tayebb, et al, such evidence is no less needed for the effectiveness of all other therapy models in chronic pain.[16]

**What Must Be Done in the Near Term?**

The HHS Task Force's final recommendations will entail the development of evidence-based or evidence-informed best practice guidelines for a wide range of medical conditions and patient populations. However, as the Task Force process itself demonstrates, such developments may take several years. Patients in pain and physicians already removed or considering a departure from pain management practice cannot wait that long. However, a way forward is suggested in the published repudiation of CDC guideline by the American Medical Association (AMA):[17]

> *"RESOLVED, that our AMA affirms that some patients with acute or chronic pain can benefit from taking opioid pain medications at doses greater than generally recommended in the CDC Guideline for Prescribing Opioids for Chronic Pain and that such care may be medically necessary and appropriate, and be it further*
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> *RESOLVED, that our AMA advocate against misapplication of the CDC Guideline for Prescribing Opioids by pharmacists, health insurers, pharmacy benefit managers, legislatures, and governmental and private regulatory bodies in ways that prevent or limit patients' medical access to opioid analgesia, and be it further*
>
> *RESOLVED, that our AMA advocate that 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."*

The authors of this paper call on the HHS Task Force to explicitly recommend to Congress that the third paragraph of the AMA House of Delegates Resolution 235 be immediately enacted as a legally binding direction on all US healthcare agencies, the HHS Centers for Medicare and Medicaid Services, FDA, NIDA, DEA, and the Department of Justice. This step is a necessary emergency intervention to encourage the return and retention of healthcare providers in pain management practice, pending publication of detailed practice guidelines in all medical specialties. Likewise, we call for immediate dissemination of this policy to all federal and state law enforcement and regulatory bodies.

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## References


1. HHS. Pain Management Best Practices Inter-Agency Task Force Third Meeting. May 9-10, 2019. Available at: www.hhs.gov/ash/advisory-committees/pain/meetings/2019-05-09/index.htm. Accessed June 6, 2019.
2. Lawhern RA, Nadeau SE. Behind the AHRQ report. *Pract Pain Manag*. 2018;18(7):35-37.
3. Singer JA, Sullum JZ, Schatman ME. Today's nonmedical opioid users are not yesterday's patients; implications of data indicating stable rates of nonmedical use and pain reliever use disorder. *J Pain Res*. 2019;12:617-620.
4. Lawhern RA. Over Prescribing Did Not Cause the Opioid Crisis. *Blog of Dr. Lynn Webster*. Last updated April 5, 2019. Available at: www.lynnwebstermd.com/over-prescribing/. Accessed June 6, 2019.
5. Lawhern RA, Tucker JA. Analysis of US Opioid Mortality and ER Visit Data. Last updated April 2019. Available at: face-facts.org/atip/analysis-of-us-opioid-mortality-and-er-visit-data-v15-april-2019/. Accessed June 6, 2019.
6. CDC. Press Release: CDC Advises Against Misapplication of the Guidelines for Prescribing Opioids for Chronic Pain. April 24, 2019. Available at: www.cdc.gov/media/releases/2019/s0424-advises-misapplication-guideline-prescribing-opioids.html. Accessed June 6, 2019.
7. FDA. Press Release: FDA identifies harm reported from sudden discontinuation of opioid pain medicines and requires label changes to guide prescribers on gradual, individualized tapering. April 9, 2019. Available at: www.fda.gov/drugs/drug-safety-and-availability/fda-identifies-harm-reported-sudden-discontinuation-opioid-pain-medicines-and-requires-label-changes. Accessed June 6, 2019.
8. Alliance for the Treatment of Intractable Pain. Stanford Letter to the Oregon Chronic Pain Task Force. December 4, 2018. Available at: face-facts.org/atip/. Accessed June 6, 2019.
9. Moore RA, Wiffen PJ, Eccleston C, et al. Systematic review of enriched enrolment, randomised withdrawal trial designs in chronic pain: a new framework for design and reporting. *Pain*. 2015;156(8):1382-1395.
10. Meske DS, Lawal OD, Elder H, et al. Efficacy of opioids versus placebo in chronic pain: a systematic review and meta-analysis of enriched enrollment randomized withdrawal trials. *J Pain Res*. 2018;11:923-934.
11. Volkow ND, McLellan AT. Opioid abuse in chronic pain—misconceptions and mitigation strategies. *N Engl J Med*. 2016;374(13):1253-1263.
12. Brat GA, Agniel D, Beam A, et al. Postsurgical prescriptions for opioid naive patients and association with overdose and misuse: retrospective cohort study. *BMJ*. 2018;360:j5790.

13. Sun EC, Darnall BD, Baker LC, Mackey S. Incidence of and risk factors for chronic opioid use among opioid-naive patients in the postoperative period. *JAMA Intern Med*. 2016;176(9):1286-1293.
14. Brummett CM, Waljee JF, Goesling J, et al. New persistent opioid use after minor and major surgical procedures in US adults. *JAMA Surg*. 2017;152(6):e170504.
15. Krebs EE, Gravely A, Nugent S, et al. Effect of opioid vs nonopioid medications on pain-related function in patients with chronic back pain or hip or knee osteoarthritis pain: the SPACE randomized clinical trial. *JAMA*. 2018;319(9):872-882.
16. Tayeb BO, Barreiro AE, Bradshaw YS, Chui KK, Carr DB. Durations of opioid, nonopioid drug, and behavioral clinical trials for chronic pain: adequate or inadequate? *Pain Med*. 2016;17(11):2036-2046.
17. American Medical Association House of Delegates Report of Reference Committee B. Resolution 235 – Inappropriate Use of CDC Guidelines for Prescribing Opioids. November 2018. Available at: www.ama-assn.org/system/files/2018-11/i18-refcomm-b-annotated.pdf. Accessed June 6, 2019.