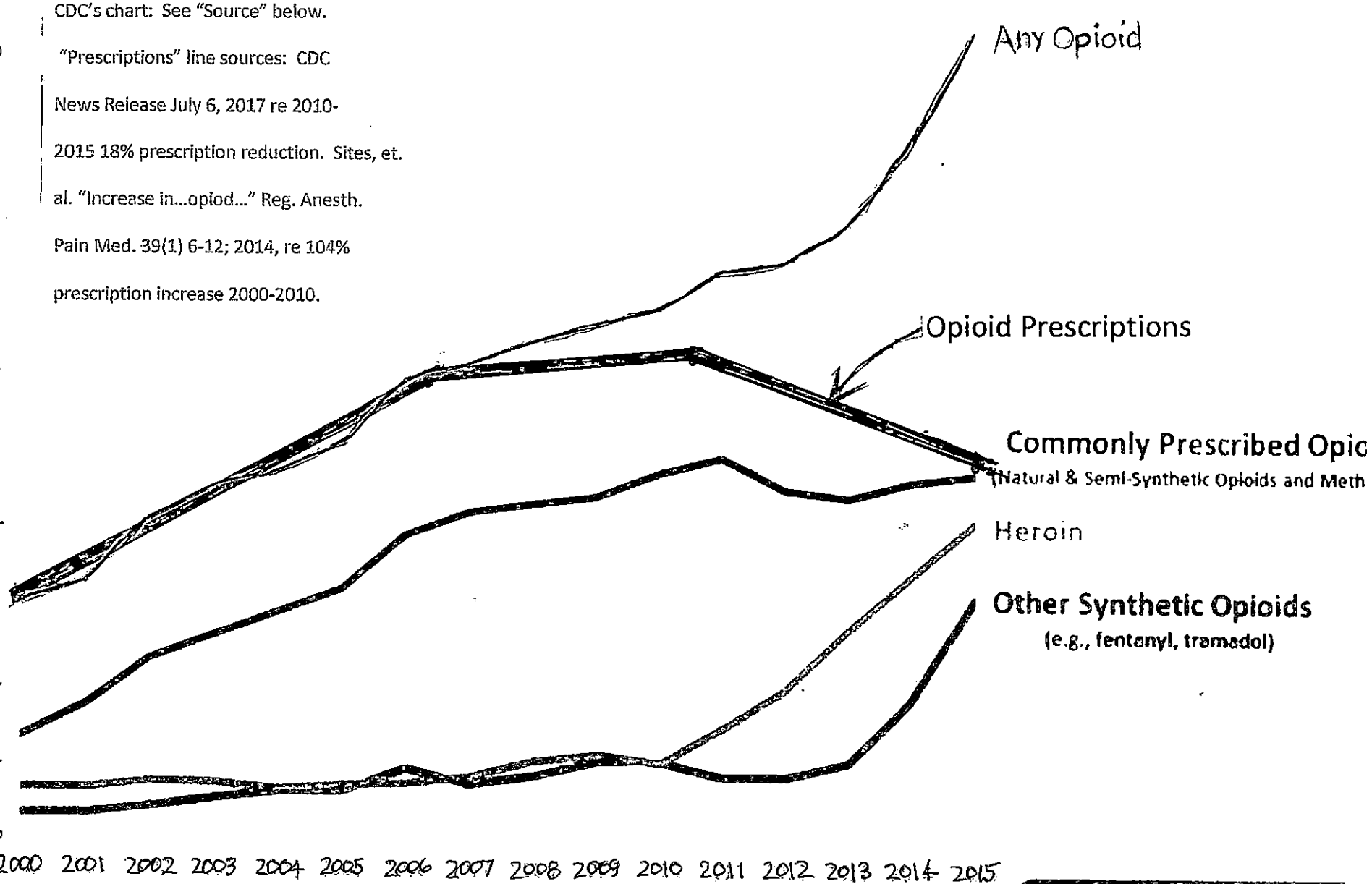
Overdose Deaths Involving Opioids, United States, 2000-2015

"Deaths" lines are direct copies of CDC's chart: See "Source" below.

"Prescriptions" line sources: CDC News Release July 6, 2017 re 2010-2015 18% prescription reduction. Sites, et. al. "Increase in...opiod..." Reg. Anesth. Pain Med. 39(1) 6-12; 2014, re 104% prescription increase 2000-2010.



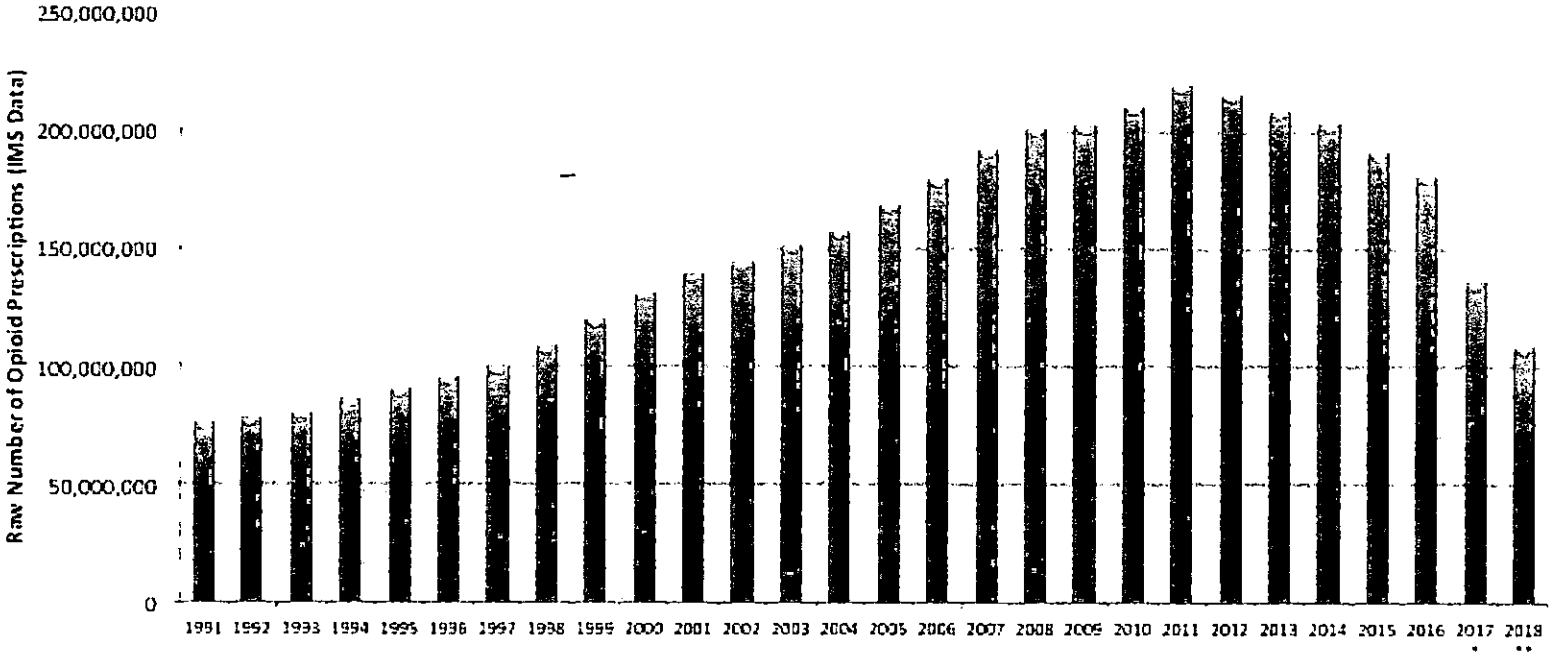
SOURCE: CDC/NCHS, National Vital Statistics System, Mortality. CDC WONDER. Atlanta, GA: US Department of Health and Human Services, CDC; 2016. https://wonder.cdc.gov/.

www.cdc.g

Attachment C

Opioid Prescriptions (IMS Data)
Impact of DEA Production Cuts

Opioid Prescriptions could hit 20 year low in 2018



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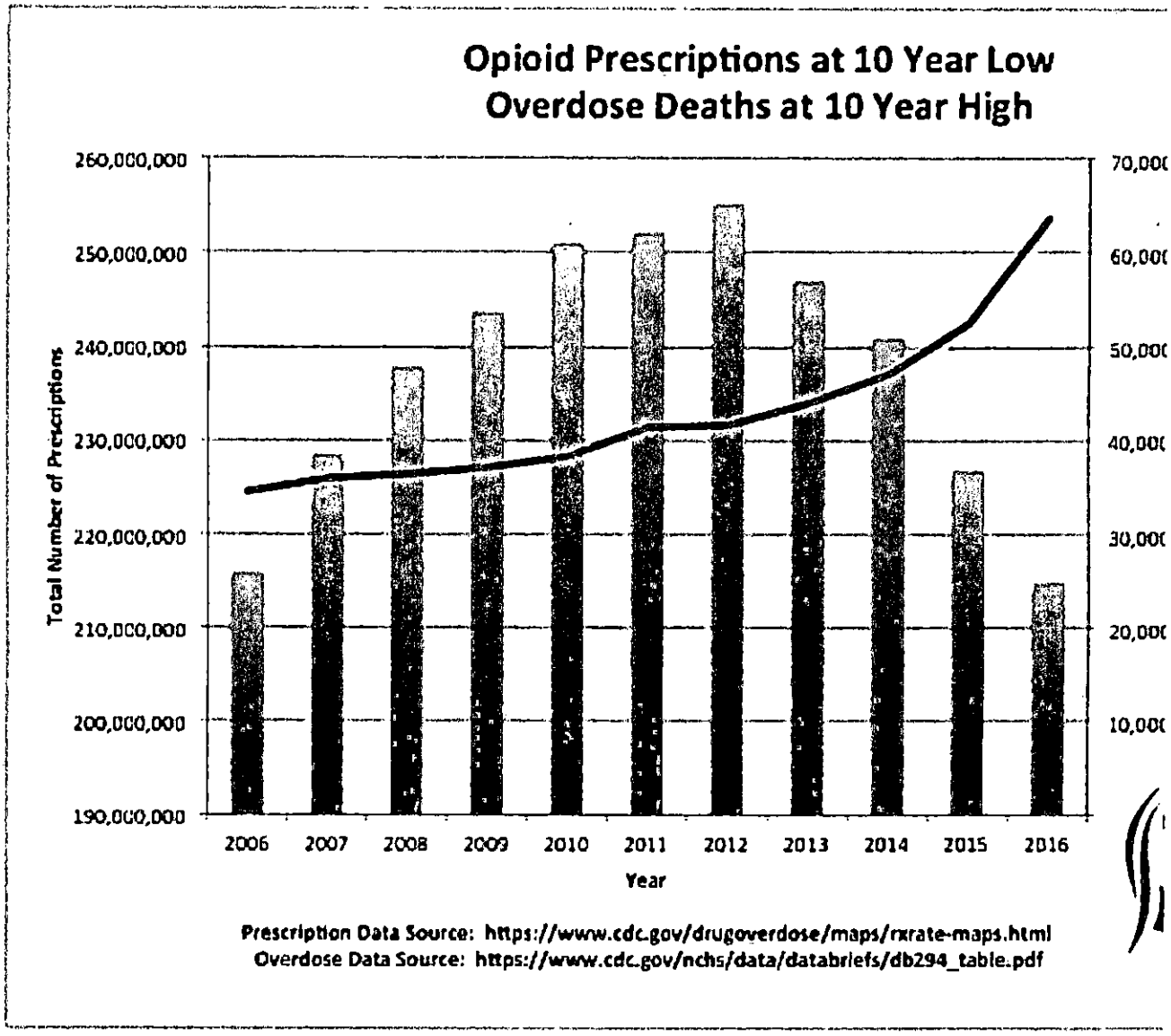
* Assumes 25% DEA cut in production results in 25% reduction in prescriptions
** Assumes 20% DEA cut in production results in 20% reduction in prescriptions

Data Sources
https://acd.od.nih.gov/documents/presentations/12152017Volkow.pdf
https://www.medscape.com/viewarticle/884055
https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html



VERT=#OD DEATHS (10K=70K)

Tell Medicare to Stop

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A White Paper

Prescription Opioids and Chronic Pain

Richard A. Lawhern, Ph.D.

The Alliance for the Treatment of Intractable Pain

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ABSTRACT

The March 2016 "CDC Guidelines for Prescribing Opioids for Chronic Pain" for adult, non-cancer chronic pain must be withdrawn and rewritten. CDC and all government agencies must recognize both the indispensable role that opioids play in chronic pain management, and the central role of physicians to assess and prescribe medications, as patients require.

1. Main Points

1.1. There are over 116 million chronic pain patients in the US (Institute of Medicine)

Chronic pain is defined as pain lasting longer than 90 days or otherwise exceeding medically expected recovery times. Once diagnosed, many chronic pain patients will have debilitating severe pain for the rest of their lives. For many, pain is resistant (refractory) to a wide range of therapies.

For millions of people, management of severe pain has for years included prescription opioid medications as a key element. Opioid medications frequently make a life-or-death difference in quality of life. However, at present, patients with severe pain are being made scapegoats for a perceived – and largely false – "epidemic" of opioid addiction and overdose deaths, which have been misattributed to prescription analgesics.[1 2 3 4]

There are presently no reliable replacements for opioids.[5] Due to under-funding of research on treatments for pain, there are no legitimate prospects for new treatments in the foreseeable future.

1.2. March 2016 CDC Chronic Pain Guidelines

In March 2016, the Centers for Disease Control released updated guidelines for prescription of opioids in adult, non-cancer chronic pain. Outcomes of these guidelines have been horrific for millions of patients. The CDC guidelines[6] recommended that general practitioners should perform an analysis of risks and benefits before prescribing more than 90 Morphine Milligram Equivalent Daily Dose (MMEDD). Although originally phrased as voluntary, the Guidelines became a statutory requirement on the Department of Veterans Affairs, three months before CDC published its final guideline. Non-VA Hospitals and doctors across America quickly interpreted the Guidelines on safety review as a mandatory maximum dose standard.[7 8]

Fearing sanctions by the US Drug Enforcement Agency or State authorities if they prescribe opioids to people who need them, doctors are leaving pain management practice in droves.[9] Availability of pain management specialists is dropping in most areas of the US and Canada. Pharmacies are limiting inventories of opioid medications, and challenging doctor's prescriptions on grounds of corporate policy. Patients with legitimate prescriptions are being turned away.[10]

The US Centers for Medicare and Medicaid estimate that approximately 1.6 million older citizens are presently maintained on opioid doses at levels above 90 MMED.[11] US CDC has estimated that over 19 million prescriptions were written in 2016 for "high dose" (over 90 MMED)

death. Such stories are tragedies for the families that actually experience them.

Families grieve. They demand that government "do something." Their stories are very influential in our public conversation about substance abuse and overdose deaths. It is small wonder that government policy has focused centrally on reducing the availability of medical opioids.

2.2. Focus on Prescription Reduction

Is the present focus on reduction of medical supply appropriate? Almost certainly not! No matter how tragic these stories are, they are neither typical nor representative. As noted by Dr. Nora Volkow and Thomas A. McMillan, Ph.D., of the National Institutes of Drug Abuse,

*"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.**" (Emphasis - ATIP)*[32]

Even the statistics of the CDC itself have proven to be faulty, over-magnifying what has been called a "prescription opioid crisis". CDC has acknowledged that it has reported as "prescription opioid overdoses", deaths that were in fact due to illegally imported fentanyl and its analogs. They called the prescription opioid overdose rate "significantly inflated."[33]

2.3. Large Scale Medical Studies

We also know from recently published, large-scale studies of surgical patients treated with opioids after discharge, that opioid addiction emerging from managed medical exposure is rare among patients who are profiled carefully before surgery. Millions of patients have such exposures every year.

A 2018 study investigated more than 586,000 patients prescribed opioids for the first time after surgery.[34] Less than 1% continued renewing their prescriptions longer than 13 weeks. 0.6% were later diagnosed with Opioid Abuse Disorder during follow-up periods averaging 2.6 years between 2008 and 2016. Likelihood of diagnosis increased with the length of prescriptions, but rose only modestly with higher dose levels. It is quite possible -- even likely -- that the diagnosis of Opioid Abuse Disorder in many of these patients was incorrect. The diagnosis of is typically made by treating physicians without recourse to accepted definitions of the disorder such as the American Psychiatric Association Diagnostic and Statistical Manual, 5th edition. Many doctors who diagnose patients with abuse are general practitioners who lack sufficient training in addiction and have little experience evaluating the behaviors that actually define drug addiction. Likewise, some physicians confuse patient reports of continuing pain – caused by failed surgery – for potential opioid abuse.

During the period of the study, doctors increasingly became concerned with being sanctioned by law enforcement authorities for their use of opioid doses high enough to reliably manage pain. Thus they may have diagnosed drug abuse to protect themselves – not their patients, who were summarily discharged.

A 2016 study[35] 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.

In this study, the rate for chronic prescriptions of opioid analgesics among millions of non-surgical patients was estimated at 0.136 percent. (Parenthetically, this finding strongly implies that "doctor shopping" is not a significant source of opioids abused by people with addiction.) For 4 of the 11 surgical procedures studied, the same rate of prescriptions occurred after surgery as before. For the 7 remaining procedures, long-term opioid prescriptions rose by factors varying from 1.28 (0.174%) for caesarean delivery, up to 5.07 (0.69%) for total knee replacement.

The highest rate of post-surgical chronic prescriptions occurred for total knee replacement – a procedure known to cause lingering pain in many who undergo it.[36,37] It is likely that many on going prescriptions after knee replacement reflected chronic post-surgical pain, rather than issues of opioid misuse. This may also be true of other procedures where long-term prescribing was observed.

These studies demonstrate beyond any reasonable contradiction that managed medical exposure doesn't of itself significantly raise risks of opioid abuse in surgical patients who are properly screened for previous opioid exposure. This outcome directly contradicts the false claim that addiction may start with just a few pain pills.

3. Addiction Risks

It may well be asked, what are the risks of opioid involvement and addiction among patients who have already experimented with drugs before they see a doctor? The CDC does not publish definitive statistics on this issue. But well-established demographics can offer general guidance. In the great majority of cases, the typical beginning addict and the typical chronic pain patient are different people.[38]

3.1. Demographics of Addiction

We now know that the most common beginning opioid abuser is an adolescent or early-20's male who has a history of family trauma, prolonged unemployment, and often mental health issues. This population is generally medically under-served. It is unusual for young males in economically distressed regions of the US to be seen by a doctor. When they are seen, it is unusual for them to be prescribed pain relievers for more than a few days. As noted by Volkow and McMillan, a few days are insufficient to cause drug dependency, much less addiction.

By contrast, the typical chronic pain patient (by a ratio of 60/40 or higher compared to men) is a woman in her 40s or older who has a history of traumatic injury, failed back surgery, neuropathic pain, fibromyalgia, or

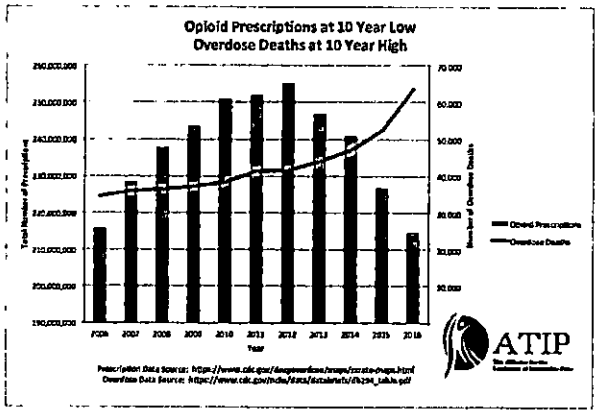

Figure 1

5.1. Review of CDC Data

It is also becoming clear that further restrictions on medical opioid supply will do nothing to moderate the trends revealed in Figure 1. There is evidence that restrictions may indeed be contributing to increased deaths, by driving chronic pain patients into the streets for pain relief - or otherwise - into decline, disability, and suicide.[45]

5.2. A necessary first step

A necessary first step in correcting the horrid outcomes of the 2016 CDC Guidelines must be their formal withdrawal for a major re-write to correct multiple biases, errors and omissions. Board-Certified Pain Management physicians experienced in community-based, long-term treatment of chronic pain patients should lead such an effort.

This rewriting must be supported by a wide range of stakeholders, including providers from hospice, palliative care, cancer treatment, and patients or their advocates as voting members. Guideline development must be conducted using publicly transparent process and supported by sufficient staff to process, analyze, and integrate external input.

5.3. Recommendations

Recommendations must be evidence-based, and guiding principles must include the following:
There is no one-size-fits-all patient or therapy. Medical professionals, in response to the to the needs of the patient, must tailor all pain treatment.

1. There can be no generalized single threshold of risk for Opioid Use Disorder versus opioid dose level or duration. Doctors must be able to trial their patients on different medications and dose regimes, perhaps combined with ancillary non-pharmaceutical therapies.

2. Medically managed exposure to opioid analgesics may create physical dependence without symptoms of addiction in patients treated long-term. Dependence, when it occurs, is an acceptable and physiologically expected outcome of effective pain treatment. Withdrawal symptoms can be managed with appropriately gradual tapering if change or reduction of medication is medically indicated.

3. There is no medical evidence of benefit and ample evidence of needless harms in forced reductions of dose for patients who are medically stable and who benefit from existing dose regimes.

4. Risk of opioid abuse or protracted opioid prescription in properly screened, opioid-naïve post-surgical patients is significantly less than 1%. Doctors need training to distinguish between patients in whom prolonged need for opioid prescription is an indicator for development of chronic pain versus an indicator of opioid misuse.

5. Patient screening for opioids should be oriented to identifying patients who have previous or present non-medical opioid exposure, in order to apply enhanced management protocols and make referral for addiction treatment where appropriate. The costs of urine testing are now outrageously high. False positives of urine testing are replete, and must be substantially reduced through better education and understanding of their results as they are often misused as grounds for dismissal.[46]

6. Best available medical evidence indicates that patients who "doctor shop" or "pharmacy shop" comprise less than 1% of all patients treated with opioid analgesics. Care must be taken to avoid patient stigmatization and false alarms in applying data from Prescription Drug Management Programs. Patient treatment contracts must recognize conditions and limitations of patient daily life before mandating arbitrary discharge or otherwise damaging the patient. A single deviation from an opioid management contract – however minor – is all too often viewed as adequate reason to discharge a chronic pain patient from care.

7. No physician who treats verifiable chronic pain should be subjected to disciplinary action or government sanction solely because of the gross volume of opioids that he or she prescribes. Without reference to the medical conditions and numbers of patients treated, volume of prescriptions is not a reliable indicator for drug diversion to opioid abusers or street markets.

A related step in avoiding further harms must be immediate direction from the US Congress to the Department of Veterans Affairs to cease enforcement of the existing VHA no-opioids policy. It is now well established that such policy is causing significant numbers of patient

suicides in Veteran and non-Veteran populations.

Finally, pending issuance of a new CDC prescription guideline, all US States must stand down from efforts to impose further limitations on opioid prescribing for acute, chronic, or terminal pain. Enforcement of existing State limitations on dose level or duration should be suspended. If and when re-considered, such limitations must be grounded on published medical evidence of benefit and qualified by exceptions for chronic, intractable, or terminal pain conditions.

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