

A Nation In Pain Appeals to Our Legislators: Stop the Anti-Opioid Madness!

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Briefing to Legislative Staff

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A Nation in Pain ^[1]

- 100 million+ US citizens have pain every year
 - Pain is the number one reason why people visit a doctor
- ~40 million have “high impact” pain
 - Compromised quality of life
- ~20 million treated with opioid pain relievers
 - ~3 million longer than 90 days ^[2]
 - <1% post surgical pts continue on opioids >90 days ^[3]
 - <0.6% later diagnosed with substance abuse disorder ^[4]

[1] US National Academies of Science

[2]

<https://medium.com/@stmartin/neat-plausible-and-generally-wrong-a-response-to-the-cdc-recommendations-for-chronic-opioid-use-5c9d9d319f71#wzchd1kkl>

[3] <http://www.bmj.com/content/360/bmj.j5790.long>

[4] <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2532789>

A Nation Denied Pain Relief

- #1 Cause: 2016 and 2022 revised CDC Opioid “Guidelines” for adults with chronic pain
 - Originally written for General Practitioners and new patients
 - Not intended as mandatory or retroactive practice standards
 - **BUT:** 36 States passed legislation limiting opioid dose or duration
 - Thousands of hospitals and practices forcibly tapering legacy patients below minimum effective levels; patients often cut off without taper
 - Patients discharged, deserted without referral ☐ medical collapse, sometimes suicide from overwhelming pain
 - For many patients, there are no effective alternatives to opioids
 - Millions of patients can no longer find a doctor to treat pain
- 2016 Veterans Health Administration “Opioid Safety Initiative”
 - Similar results with veterans denied pain care

A Nation Denied Pain Relief -2

- CDC Guidelines used by DEA and State drug agencies as an excuse for raids on doctor offices
 - Armed SWAT teams intimidating doctors and patients
 - Patient records seized, employees coerced by threats of prosecution
 - Healthcare provider civil assets seized in some cases
 - Prominent announcements of investigations ☐ ruin doctor practices
 - Months-long delays before court proceedings; many cases dropped
- Prosecutions cast long shadows, create hostile climate
 - Many healthcare providers leaving pain management or refusing opioid treatment
 - Even to post-surgical patients or terminal cancer patients in hospice!
 - Many providers fear financial and professional ruin even when they've done nothing wrong
- June 2022 Supreme Court Decision in Ruan Vs. United States will require complete revision of grand jury and court instructions in prosecution of doctors for inappropriate prescribing

CDC Guidelines Are Fatally Flawed

- Political agendas were driven by writers' anti-opioid bias
- Strong conclusions drawn from weak evidence or NO evidence
 - Inconsistent research quality standards
 - Cherry-picked research and one-size-fits-all thinking
 - Widespread use of junk science in Morphine Milligram Equivalent Daily Dose (MMEDD) [5]
 - No community pain management specialists or patient advocates in writers group
- Shortage of long-term trials conflated with lack of effectiveness
 - Non-opioid and behavioral pain therapies have no better trials record
 - Short term opioid trials demonstrate positive benefit in >70% of patients
- Ignored wide variations of individual opioid metabolism
 - Six key liver enzymes are governed by genetics
 - Some patients absorb opioids poorly, others very rapidly
 - Minimum effective opioid dose range ~ 50 to >2000 MMED

CDC Guidelines Have Been Repudiated

- American Medical Association Resolution 235 (Nov 2018)
 - Some pts benefit from higher opioid doses than CDC recommended
 - MMED is not useful as more than general guidance
- AMA Board of Directors Study 22 (Jun 2019)
 - “High prescriber” letters deny due process and place doctors and patients on arbitrary black lists
- American Academy of Family Physicians + 4 other organizations
 - “Frontline Physicians Call on Politicians to End Political Interference in the Delivery of Evidence Based Medicine” (March 2019)
 - Representing over 650,000 physicians and medical students
- CDC and FDA published April 2019 “clarifications” disclaiming intent to force tapers on legacy patients, and warning of harms to patients
- AMA and many others recommended major revisions
 - Repeal all State and Federal laws and regulations setting hard limits on opioid doses

What Does AMA Resolution 235 Say?

...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 ... such care may be medically necessary and appropriate...

AMA [will] 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...

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.

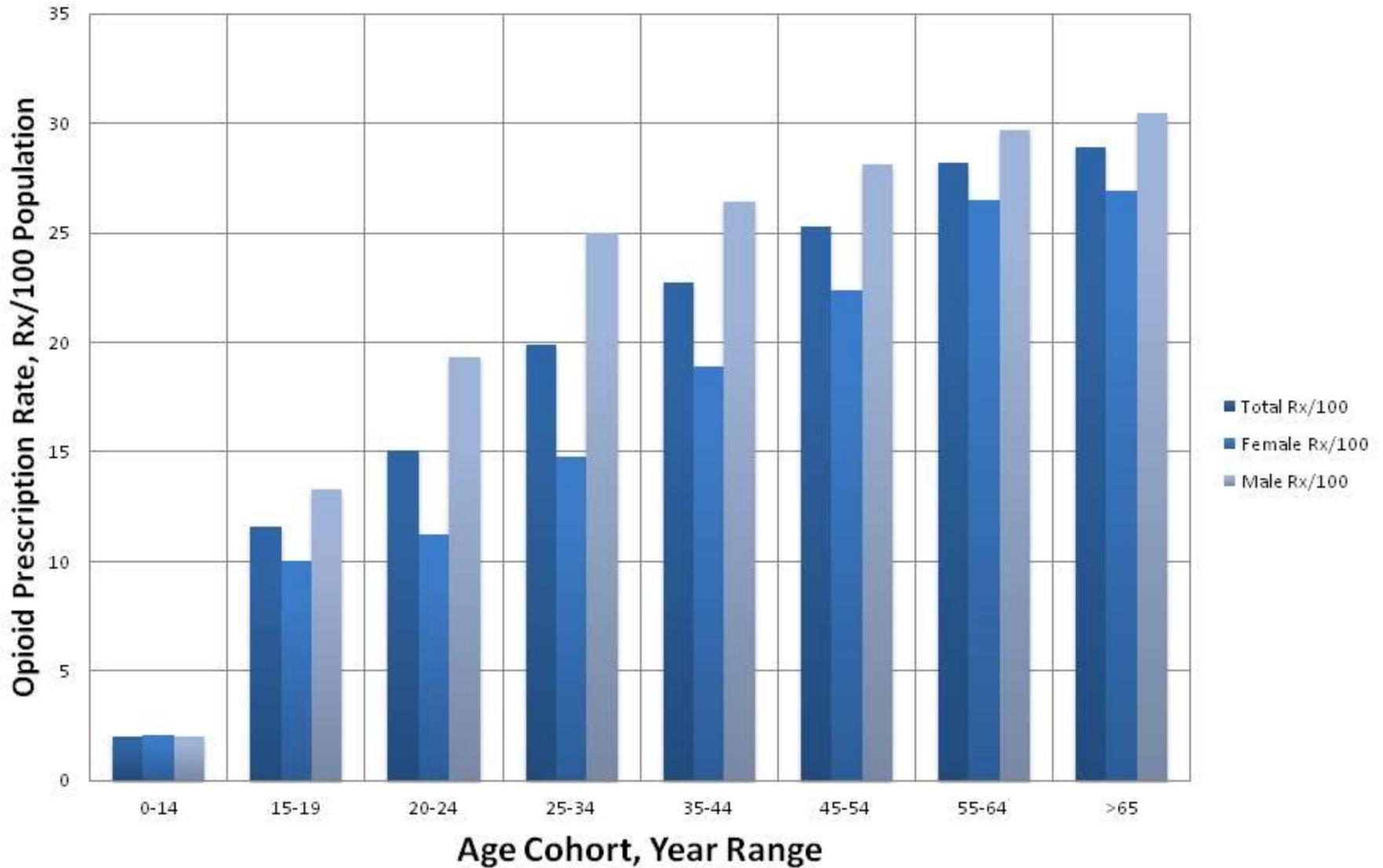
Fundamental Realities of the “Opioid Crisis”

[“The Opioid Crisis in Three Charts”]

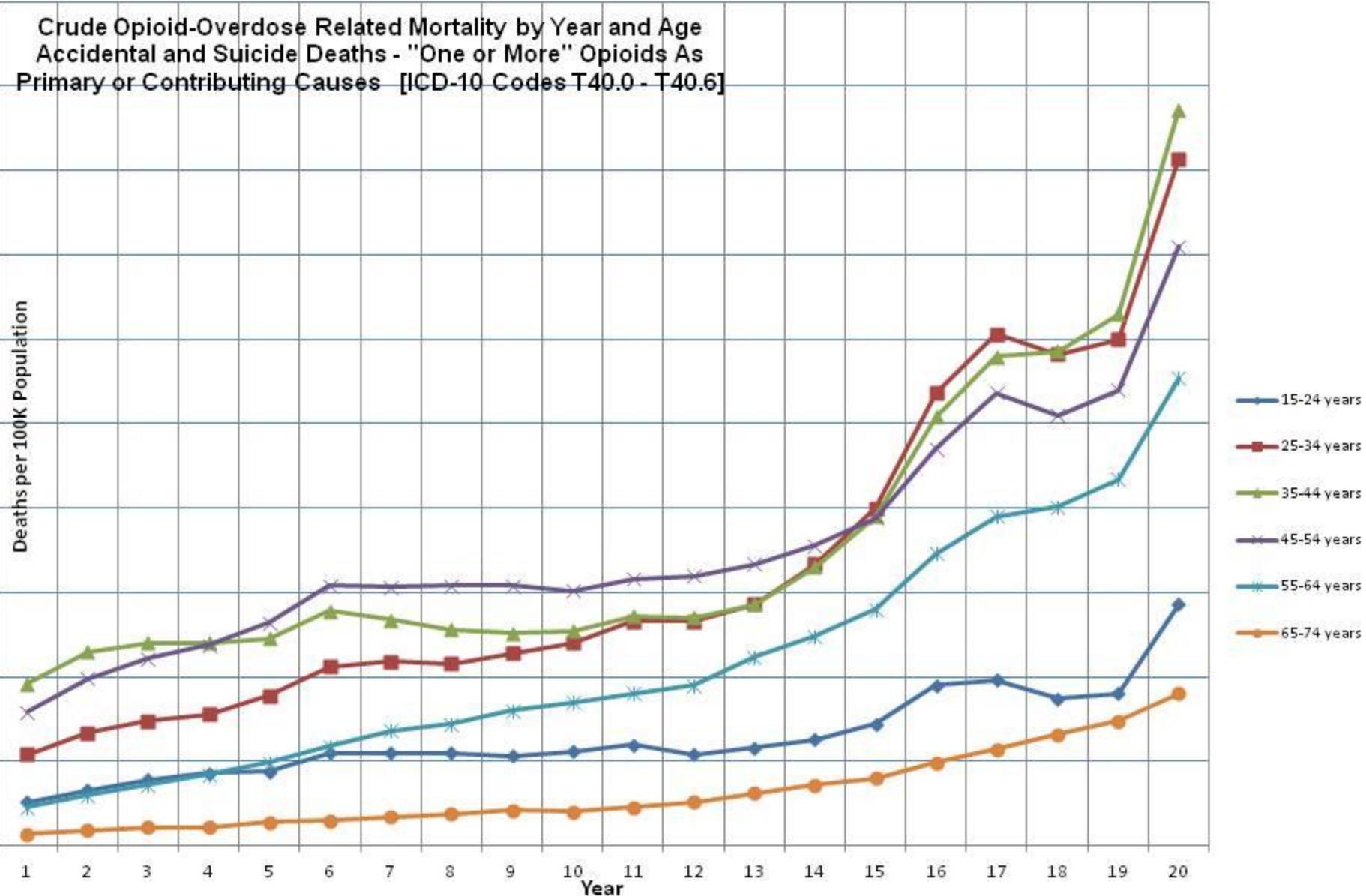
- America has a public health crisis in addiction and overdose deaths
 - dominated by illegal street fentanyl and heroin
- Opioid crisis caused by economic stagnation, hopelessness and aggressive cartel marketing – not by doctors “over-prescribing” opioids to their patients
- There is no cause and effect relationship between doctor prescribing vs rates of overdose mortality or hospital admissions [6]
- Demographics of prescribing and overdose are contradictory
 - Seniors are prescribed opioids for pain 50% more often than young adults 25-34
 - But seniors have lowest rate of overdose deaths of any age group
 - Mortality in young adults is four times higher than in seniors over 64, and has skyrocketed over 20 years.
- “The Problem” is not prescriptions!

[6] Aubry and Carr, “Overdose, opioid treatment admissions and prescription opioid pain reliever relationships: United States, 2010–2019” *Frontiers in Pain Research*, August 4, 2022

Prescribing Rates per 100 Population by Age Range, 2016



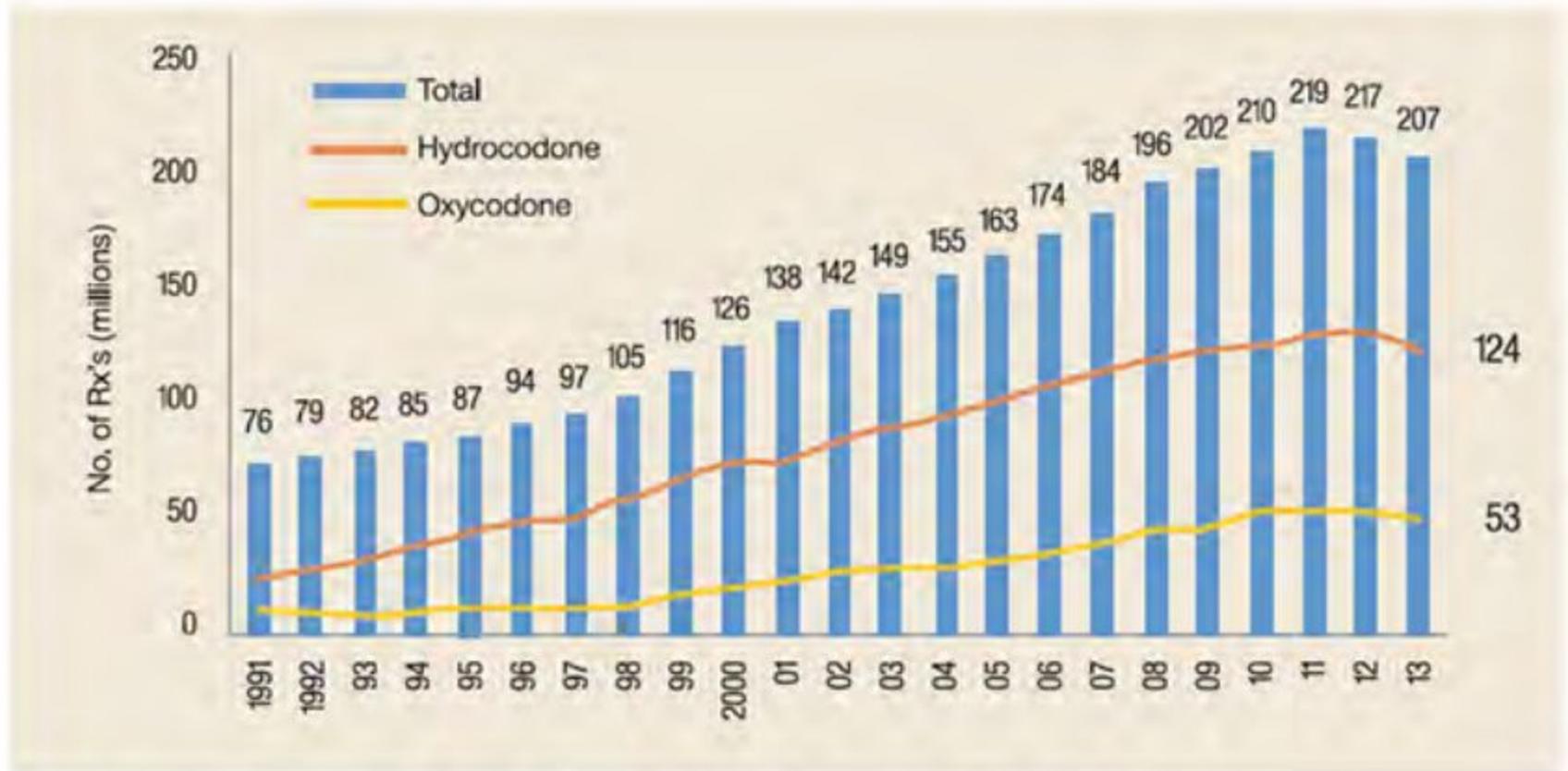
**Crude Opioid-Overdose Related Mortality by Year and Age
Accidental and Suicide Deaths - "One or More" Opioids As
Primary or Contributing Causes [ICD-10 Codes T40.0 - T40.6]**



Age Adjusted Opioid Overdose Related Mortality by Year and Age Group

[Data Plotted from US CDC National Cause of Death Database]

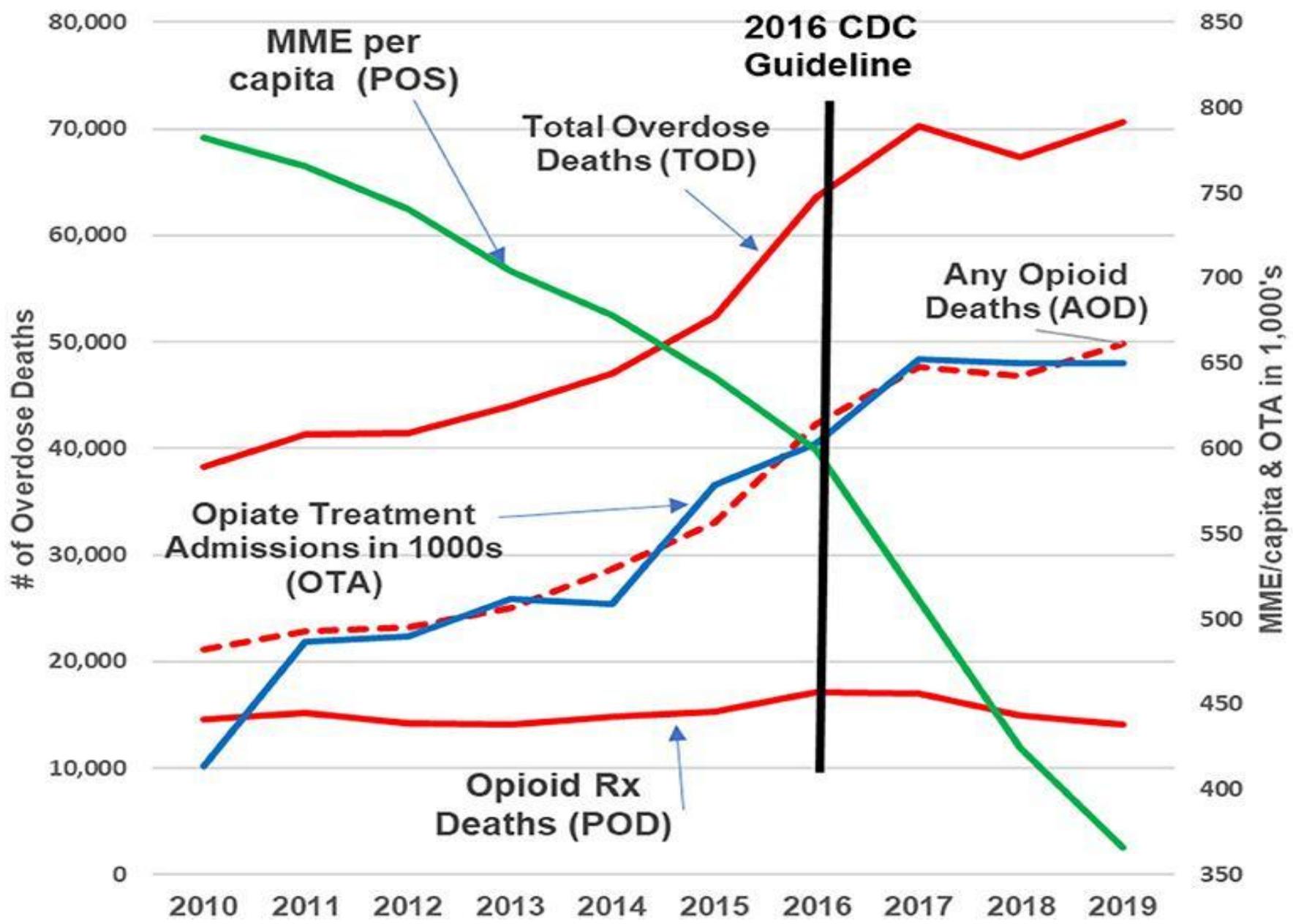
US Prescribing Trends – 1991 to 2012



Opioid Prescriptions Dispensed by US Retail Pharmacies IMS Health, Vector One: National, years 1991-1996, Data Extracted 2011. IMS Health, National Prescription Audit, years 1997-2013, Data Extracted 2014.

Source: "Common Myths About the Joint Commission pain standards"

<https://www.jointcommission.org/-/media/enterprise/tjc/imported-resource-assets/documents/pain-myths-poster11x17pdf.pdf?db=web&hash=B1C5EE65FAB0921BB5509DC46F70902B&hash=B1C5EE65FAB0921BB5509DC46F70902B>



[7] Ibid, Aubry and Carr

Conclusions

- The public narrative driving opioid regulatory policy is based on mythology
 - Doctors over-prescribing to pain patients did not cause the opioid crisis and aren't sustaining it
 - Abuse risk among medically managed patients is likely under 0.6% -- too low to measure accurately [4, 8]
- National policy on opioid regulation must change
 - Stop the exodus of practitioners from pain management
 - Free doctors to practice evidence-based medicine without fear
 - Reclaim the lives of patients denied safe and effective treatment for pain.
- Legislation is needed to halt Federal and State regulatory over-reach
 - Immediately change policy at CDC, CMS, DEA and DoJ
 - Then change State-level drug enforcement and Medical Board policy

“A Bill to Deter Departure of Providers from Pain Management” [9]

- Mandate AMA Resolution 235 as US policy for CDC, FDA, NIH, and HHS Centers for Medicare and Medicaid Services (CMS)
- Rewrite 2016 and 2022 CDC Guidelines to recognize indispensable role of opioids – or withdraw outright
- Repeal Section 131 of the “Veterans Administration Mission Act”, and rewrite VHA pain practice guidelines to track AMA Resolution 235
- HHS/CMS withdraw rule changes authorizing Medicare Part D insurers to deny patient refills subject to “safety edits” of prescriptions above 100 MMED

- State legislation also needed to require a court warrant that a crime has likely been committed, before law enforcement may access to Prescription Drug Monitoring Program data
- Remove all State references to CDC guidelines in their public health regulations and laws

[9] <http://face-facts.org/lawhern/congress-clean-up-this-mess/>