The Real Facts Behind the "Opioid Crisis" and the Abandonment of Pain Patients:

TIMELINE: 2012 - 2018

2012 - **Dr. Andrew Kolodny and Physicians for Responsible Opioid Prescribing - a/k/a PROP** (addiction specialists with no experience treating pain) petitioned the FDA in 2012 to change opioid manufacturing guidelines for patients with non-cancer pain, asking FDA to limit dosing to 100 MED and limit treatment to 90 days.

2013 - The FDA **denied this request in 2013** due to a **lack of scientific evidence** to support limiting usage or dosage and no evidence to suggest cancer pain is different from non-cancer pain. Most patients treated with opioids on higher doses and long term treatment do well and live productive lives without addiction or death.

2014 - **Illicit fentanyl** was added to other illicitly manufactured drugs such as heroin, hydrocodone, xanax, etc. Addicts buy their drug of choice on the street not realizing it has been laced with fentanyl. Carfentanil, Fentanyl, and its analogs are 50-10,000 times stronger than morphine. **Overdoses began in mass quantities** catching the attention of the media and the government.

2015 - The **DEA stepped up enforcement** by targeting and surveilling **doctors and pharmacies.** State Medical Boards and County Law Enforcement agencies began **threatening and prosecuting** doctors for "**over prescribing**" opioids to pain patients.

2015 - CDC **contracted** with members from the **anti-drug lobbying group PROP** to help **draft CDC guidelines for opioid prescribing** geared towards primary care physicians.

2016 - The **CDC published the 2016** opioid death report/statistics which falsely claimed pain patients were addicted and dying in massive numbers even though historically pain patients are rarely addicted or involved in opioid-related deaths.

2016 - The **CDC Guidelines were implemented by states & medical boards across the country** as **rule** rather than **suggestions** for primary care physicians as originally intended. This **forced hundreds of doctors to cut pain patients** off their medication or to a lower, non-therapeutic dosage. This was done in spite of CDC **having no prescription or regulatory power** and FDA already telling PROP there is no scientific evidence to suggest these limitations are necessary or useful.

2017 - Pharmacies and insurance companies **began limiting opioid quantities and/or refusing to fill opioid prescriptions** based on perceived addiction bias against patients with pain from all causes due to media/government misinformation, namely the original 2016 CDC opioid death report and guidelines.

2017 - Federal government **cut production of opioids** creating **shortages** and leaving many hospitals, cancer patients, and pain patients without medication to treat pain.

2018 - The CDC finally issued a **correction** for the erroneous 2016 opioid death report **admitting that the majority of the deaths were from illicit fentanyl and heroin, not legal prescription pain medication.** CDC and National Institute on Drug Abuse (NIDA) **concede** pain patients are almost never involved in opioid-related deaths. According to SAMHSA 2016 and similar studies the addiction rate for pain patients is .8%. **That means 99.2% do not get addicted.**

- Government regulators **ignore CDC and NIDA statements**, continue threatening and targeting doctors. This resulted in many doctors **turning their backs on their patients,** early retirement, or closing their practice out of fear of losing their license or being prosecuted. Many pain patients are **left with no meds, no doctor, and no treatment**, leaving them to **suffer in agony** with few options.
- Enter the "**SUBOXONE or BUPE**" suggestion to the rescue. Many patients fall for this alternative but do not realize that in order for a doctor to prescribe & justify these meds, the patient's diagnosis code must be changed from "chronic intractable pain" to "OUD/SUD"
- NIH, FDA, DEA, CMS, Medical Boards, States **abandoned pain patients** based on CDC's initial report and guidelines implemented as rule because of the false ideology CDC created. The majority of drug abusers will continue to access **ILLEGAL** drugs from the street and will continue to **OVERDOSE** with no help. Pain patients and doctors

continue to take the blame for **illicit fentanyl and heroin addiction/overdoses** and are the **scapegoats** being left behind to needlessly suffer.

- Production of opioids are **cut again by 25%** which created more **shortages** for hospitals.

- Beginning in January of 2019, CMS is **scheduled to implement the CDC guidelines** as a **hard limit** for Medicare and Medicaid patients and will not cover or approve prescriptions above the **90 MME limit.**
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  Production of opioids are **scheduled to be cut again in 2019** which will create even more shortages for hospitals and the patients who are still able to receive pain medication.

●***September 2018:***

Once the opioid legislation package is enacted, it will authorize & distribute millions in grants to aid every state for outpatient addiction programs, inpatient rehabilitation centers, addiction treatments for SUD/OUD, including (MAT) Medication Assisted Treatments which includes Suboxone/Buprenorphine.

Many doctors are now pushing pain patients to switch to **Suboxone/Buprenorphine** and are being told that since it's an opioid it is an effective drug to treat chronic pain.

Incidentally, **Suboxone is the same medication** Dr. Andrew Kolodny has championed and **openly advocated for** over the last decade. PROP stands to gain millions in federal grants for addiction treatment and medication assisted treatment (MAT).

This seems to be a monopoly playing out in plain sight.

Dr. Andrew Kolodny is notorious for taunting pain patients on Twitter and then blocks anyone who challenges him. This behavior is cruel, sick, and twisted, especially coming from a professional psychiatrist.

IMPORTANT LINKS:

FDA Refuses PROP's Request To Limit Opioid Dosage and Usage
http://paindr.com/wp-content/uploads/2013/09/FDA_CDER_Response_to_Physicians_for_Responsible_Opioid_Prescribing_Partial_Petition_Approval_and_Denial.pdf
https://www.huffingtonpost.ca/marvin-ross/doctors-evidence-pain-patients_a_23371118/

PROP Involved in Drafting CDC Guidelines
https://www.painnewsnetwork.org/stories/2015/9/21/prop-helped-draft-cdc-opioid-guidelines

http://nationalpainreport.com/cdc-opioid-prescribing-guideline-unintentional-consequences-88
36710.html

Illicit Fentanyl on the Rise
https://www.cdc.gov/drugoverdose/images/pbss/CDC-Fentanyl-overdoses-rise.pdf
https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates

CDC Admits Death Data Inaccurate
https://ajph.aphapublications.org/doi/10.2105/AJPH.2017.304265
http://www.clinicalpainadvisor.com/opioid-addiction/the-issues-with-the-cdc-guidelines-on-opi
oids-for-chronic-pain/article/524976/

Pain Reliever Use Disorder - SAMHSA
https://www.samhsa.gov/data/sites/default/files/NSDUH-FFR1-2016/NSDUH-FFR1-2016.htm#o
pioid4

Cochran Report - Rate of Addiction Rare
https://www.cochrane.org/CD006605/SYMPT_opioids-long-term-treatment-noncancer-pain

Living with CDC Opioid Guidelines
https://www.practicalpainmanagement.com/treatments/pharmacological/opioids/living-cdc-opi
oid-guidelines

https://www.practicalpainmanagement.com/treatments/pharmacological/opioids/inhumane-da
ngerous-game-forced-opioid-reduction

The Myth That Prescriptions Caused The Opioid Crisis
https://amp-newsobserver-com.cdn.ampproject.org/c/amp.newsobserver.com/opinion/op-ed/art
icle145348794.html

An Opioid Crisis?

The True Culprit:

ILLICIT Fentanyl mixed with illegal drugs. The videos below depict the scourge of people who are addicted to this DEADLY substance.
https://www.bbc.com/news/video_and_audio/must_see/45968955/on-america-s-trail-of-destruction

https://www.bbc.com/news/av/health-42899283/are-we-missing-the-real-opioid-drug-crisis

A Crisis?:

Sensational story lines sell newspapers and generate hits on websites. Currently, the pharmaceutical industry—which manufactures and distributes medicine that for many provide vital relief from chronic, agonizing pain—is being cast by the media, and litigants, as the cause of a national crisis. But the causes of the Opioid Epidemic are complex which is reflected in the science. There may not even be an "epidemic".
https://www.cnn.com/2017/10/26/politics/opioid-crisis-companies-liable-joe-manchin-the-lead/index.html

The Science:

Most people who are prescribed opioids use their medication **without incident**. In fact, data from the National Survey on Drug Use and Health shows that **only 1 to 2 percent** of the **98 million prescription opioid users** are likely to become addicted in any one year. A fraction of those may die from overdose. Other data suggests overdoses involve **combinations** of drugs (over 90% of overdoses in New York).
https://www1.nyc.gov/assets/doh/downloads/pdf/epi/databrief50.pdf

The DEA & DOJ Attack on Legitimate Doctors and Pain Patients:

Thousands of doctors are being threatened by the DEA and forced to reduce or discontinue prescribing opioid pain medication for their patients. Many are retiring early or abandoning their patients without notice out of fear of prosecution against them. Our government does not belong in our doctors office and should never interfere with the sacred doctor patient relationship!

The Drug Enforcement Administration has been **sifting through thousands of supposedly private medical files,** looking for Texas doctors and patients to prosecute without the use of warrants.

"Literally, they let the DEA just go wandering through people's medical records just to make sure laws aren't being broken. Really? Are you serious?" former Virginia Attorney General Ken Cuccinelli said.

“I think that the public, we’re at a moment now where the public is becoming more aware of and alarmed at privacy violations by the government,” Nate Wessler, staff attorney with the American Civil Liberties Union added. “I don’t think there’s a whole lot of awareness about how administrative subpoenas operate or certainly about the vast scale of their use.”

https://dailycaller.com/2015/07/22/furor-grows-over-feds-issuing-warrant-less-subpoenas/

LITTLE KNOWN FACTS:
WHY ISN'T THE MAINSTREAM MEDIA DIVULGING THESE STATISTICS?

CONVENIENT CLAIM:

■ About 11.5 million adults "misused" prescription pain relievers at least once in 2015. The most common reason for their last misuse of the drugs was to relieve physical pain (63.4%).

Defining misuse:

As defined in the NSDUH, misuse of prescription drugs includes use in any way that a physician did not direct the patient to use the medication. This includes use without a prescription of the patient's own or use in greater amounts, more often, or longer than the patient was told to take them. The data shows that many people misused prescription drugs for the very reason that the substance was being prescribed.

THE INCONVENIENT CONCLUSION:

Example: IF YOUR DOCTOR PRESCRIBES ANY MEDICATION TO BE TAKEN EVERY 6 HOURS, BUT YOU TAKE IT A LITTLE BIT EARLIER TO RELIEVE YOUR PAIN PRIOR TO WAITING THE FULL 6 HOURS, YOU ARE CONSIDERED TO BE MISUSING OR ABUSING YOUR PRESCRIPTION! THIS IS THE REASON THEIR STATISTICS COME ACROSS TO BE SO ALARMING.

CONVENIENT CLAIM: **Are Prescription Opioids Driving the Opioid Crisis?**
Mark Edmund Rose, BS, MA
Pain Medicine, Volume 19, Issue 4, 1 April 2018, Pages 793 -807.
https://doi.org/10.1093/pm/pnx048

THE INCONVENIENT CONCLUSION:

Many current assumptions about opioid analgesics are ill-founded.
Illicit fentanyl and heroin, not opioid prescribing, now fuel the current opioid overdose epidemic. National discussion has often neglected the potentially devastating effects of uncontrolled chronic pain. Opioid analgesic prescribing and related overdoses are in decline, at great cost to patients with pain who have benefited or may benefit from, but cannot access, opioid analgesic therapy.
https://academic.oup.com/painmedicine/article/19/4/793/3583229

CONVENIENT CLAIM: **Heroin addicts 1st became addicted by abusing prescription pain medication.**

THE INCONVENIENT CONCLUSION:

One of the studies that was used in creating guidelines and subsequent state laws. Only pieces of this study are used, the rest are well hidden. The biggest reason is that the first line of the conclusions say that out of

100,000 patients, 5906 were later identified as having substance abuse disorder. Less than 0.6% abused their medications. Typical addiction rate in the US is 2-5%.

https://www.bmj.com/content/360/bmj.j5790

UNINTENDED CONSEQUENCES ON LEGITIMATE PAIN PATIENTS

THE UNTREATED & UNDERTREATED PAIN CRISIS vs. THE ADDICTION & OVERDOSE CRISIS:
These Two Very Different Issues Must be Separated in Order to be Treated Appropriately

THE CHRONIC PAIN EPIDEMIC:

More than 100 million Americans live with some form of chronic pain.

Nearly 40 million Americans report severe levels of pain

More than 25 million live with persistent, daily pain

Chronic pain falls under a large category spanning from acute to intractable and from mild to severe, ALL of which stem from a broad range of illnesses, causes, and conditions.

For some pain patients, non-opioid treatment might be effective. However, there are a significant number of complex patients who have already tried and exhausted all other forms of non pharmacological, surgical, and other invasive treatments, leaving their last and only option to be a multimodal pain management treatment plan which includes the use of opioid therapy.

CAUSE & EFFECT

As a result of recent regulatory efforts to reduce opioid prescribing, several thousands of pain patients are being faced with forced opioid tapering or discontinuation against their will. This has resulted in patients with previously well-managed pain facing agonizing pain levels and intense withdrawal symptoms.

Patients who have experienced sudden dose tapering or discontinuation have reported increased depression, anxiety, alienation, fear, worthlessness, hopelessness, and increased suicidality. Unfortunately, these events have been attributed to a recent spike in a high number of suicides due to untreated or undertreated pain. (1)

SUBSTANCE ABUSE EPIDEMIC:

Approximately two and a half million Americans have substance use disorders related to opioids, both illicit and prescription (2). This number accounts for 2 percent of our population and this number HAS NOT CHANGED in the last 60 years.

National studies on drug abuse have found that over 75% of people who report misuse of prescription opioids DID NOT receive them from a doctor and were NOT prescribed to them. (3)

According to CDC research, between 0.7 and 8% of people with chronic pain who receive opioids may go on to develop an opioid use disorder (4)

Citations:

1. Kline, T. (2018). #OpioidCrisis Pain Related SUICIDES associated with forced tapers. Medium.

2. Volkow, N.D. (2014). America's Addiction to Opioids: Heroin and Prescription Drug Abuse.

3. U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration. (2014). National Survey on Drug Use and Health.

4. Edlund M. J., Martin B. C., Russo J. E., DeVries A., Braden J. B., & Sullivan M. D. (2014). The role of opioid prescription in incident opioid abuse and dependence among individuals with chronic noncancer pain: the role of opioid prescription. Clinical Journal of Pain, 30, 557–64.

Requiring unnecessarily frequent doctor visits can be both physically and financially burdensome for people with chronic pain due to a variety of factors including the cost of frequent co-pays, limited time off allowed by employers, barriers to accessible and affordable transportation, limited mobility due to pain or physical barriers, and others.

Links to Resources:

Opioid laws hit physicians, patients in unintended ways - Modern Healthcare
http://www.modernhealthcare.com/article/20180730/NEWS/180739995

The drive to taper opioids: mind the evidence, and the ethics | Spinal Cord Series and Cases
https://www.nature.com/articles/s41394-018-0092-5.epdf?author_access_token=kWh1gbuVjg-vE_P1uTBO-9RgN0jAjWeI9jnR3ZoTv0N595hNdqXCaMyZLdQjiLhsmmPDXD9_hEomUaJHPkT8FDuy2LTIdrfDOJyzWcOZouwN1rR08tIU_b4eODE0DIlbRSjegM468m5VHfiXjywxxQ%3D%3D

CDC Guidelines Refuted with Scientific Evidence – EDS and Chronic Pain News & Info
https://edsinfo.wordpress.com/2016/09/08/cdc-guidelines-refuted-with-scientific-evidence/amp/

Stopping prescribing opiates in 2014: indicted for “distribution of controlled substances” involving opioids | PHARMACIST STEVE
http://www.pharmaciststeve.com/?p=26648

The Silent Warrior – The Secret Life Of A Pain Patient – Chronic Pain Journal
https://chronicpainjournal.wordpress.com/2013/04/07/the-silent-warrior-the-secret-life-of-a-pain-patient/amp/?__twitter_impression=true

Pharmacy Refusals 101 - NWLC
https://nwlc.org/resources/pharmacy-refusals-101/

CDC Admits Rx Opioid Deaths ‘Significantly Inflated’ — Pain News Network
https://www.painnewsnetwork.org/stories/2018/3/21/cdc-admits-rx-opioid-deaths-significantly-inflated

A ‘civil war’ over painkillers rips apart the medical community | PBS NewsHour
https://www.pbs.org/newshour/amp/health/painkillers-controversy-doctors?__twitter_impression=true

The Changing Opioid Epidemic: Not from Rx – EDS and Chronic Pain News & Info
https://edsinfo.wordpress.com/2016/11/22/the-changing-opioid-epidemic-not-from-rx/amp/?__twitter_impression=true

Journal of Pain Management and Medicine- Open Access Journals
https://www.omicsonline.org/pain-management-medicine.php
https://www.scientificamerican.com/article/a-medical-madoff-anesthestesiologist-faked-data/
https://www.scientificamerican.com/article/a-medical-madoff-anesthestesiologist-faked-data/

My patients' quality of life is not worth risking my practice or my license over | PHARMACIST STEVE
http://www.pharmaciststeve.com/?p=26637

Doctors of Courage | The Truth Behind Government Attacks on Doctors
http://doctorsofcourage.org/

Pain management, prescription opioid mortality, and the CDC: is the de | JPR (link:
https://www.dovepress.com/pain-management-prescription-opioid-mortality-and-the-cdc-is-the-devil-peer-reviewed-article-JPR

CDC's new opioid guidelines will be used by plaintiffs bar, WLF says | Legal Newsline
https://legalnewsline.com/stories/510704148-cdc-s-new-opioid

Professionals Call on the CDC to Address Misapplication of its Guideline on Opioids for Chronic Pain through Public Clarification and Impact Evaluation

Authors: Health Professionals for Patients in Pain (HP3)
Date: September 25, 2018

*Any **professional who cares for patients**, including physical therapists, pharmacists, nurses, psychologists and social workers, is invited to sign this letter at the bottom, as are health professional societies that wish to endorse formally.*

*The **HP3 Supporters' page** is available for:*

- *Persons lacking a health professional degree or who lost a license*
- *Persons wishing to list their diagnoses*
- *Leaving comments about pain and care experiences*

I. In 2016, the Centers for Disease Control and Prevention, CDC, issued a Guideline for Prescribing Opioids for Chronic Pain for primary care physicians. Its laudable goals were to improve communication between clinicians and patients about the risks and benefits of opioid therapy for chronic pain, improve the safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy. The Guideline reflected the work of appointed experts who achieved consensus on the matter of opioid use in chronic pain.

Among its recommendations are that opioids should rarely be a first option for chronic pain, that clinicians must carefully weigh the risks and benefits of maintaining opioids in patients already on them, and that established or transferring patients should be offered the opportunity to re-evaluate their continued use at high dosages (i.e., > 90 MME, morphine milligram equivalents).

In light of evidence that prescribed dose may pose risks for adverse patient events, clinicians and patients may choose to consider dose reductions, when they can be accomplished without adverse effect, and with possible benefit, according to some trial data.

Nonetheless, it is imperative that healthcare professionals and administrators realize that the Guideline does not endorse mandated involuntary dose reduction or discontinuation, as data to support the efficacy and safety of this practice are lacking.

II. Within a year of Guideline publication, there was evidence of widespread misapplication of some of the Guideline recommendations. Notably, many doctors and regulators incorrectly believed that the CDC established a threshold of 90 MME as a de facto daily dose limit. Soon, clinicians prescribing higher doses, pharmacists dispensing them, and patients taking them came under suspicion.

Actions that followed included payer-imposed payment barriers, pharmacy chain demands for the medical chart, or explicit taper plans as a precondition for filling prescriptions, high-stakes metrics imposed by quality agencies, and legal or professional risks for physicians, often based on invocation of the CDC's authority. Taken in combination, these actions have led many health care providers to perceive a significant category of vulnerable patients as institutional and professional liabilities to be contained or eliminated, rather than as people needing care.

III. Adverse experiences for these patients are documented predominantly in anecdotal form, but they are concerning. Patients with chronic pain, who are stable and, arguably, benefiting from long-term opioids, face draconian and often rapid involuntary dose reductions. Often, alternative pain care options are not offered, not covered by insurers, or not accessible. Others are pushed to undergo addiction treatment or invasive procedures (such as spinal injections), regardless of whether clinically appropriate.

Consequently, patients have endured not only unnecessary suffering, but some have turned to suicide or illicit substance use. Others have experienced preventable hospitalizations or medical deterioration in part because insurers, regulators and other parties have deployed the 90 MME threshold as a both a professional standard and a threshold for professional suspicion. Under such pressure, care decisions are not always based on the best interests of the patient.

IV. Action is Required: The 2016 Guideline specifically states, "the CDC is committed to evaluating the guideline to identify the impact of the recommendations on clinician and patient outcomes, both intended and unintended, and revising the recommendations in future updates when warranted". The CDC has a moral imperative to uphold its avowed goals and to protect patients.

Therefore, we call upon the CDC to take action:

- We urge the CDC to follow through with its commitment to evaluate the impact by consulting directly with a wide range of patients and caregivers, and by engaging epidemiologic experts to investigate reported suicides, increases in illicit opioid use and, to the extent possible, expressions of suicidal ideation following involuntary opioid taper or discontinuation.

- We urge the CDC to issue a bold clarification about the 2016 Guideline – what it says and what it does not say, particularly on the matters of opioid taper and discontinuation.

Signatories here represent their own views, and do not purport to reflect formal positions of their employing agencies, governmental or otherwise. *For questions regarding the letter please contact Stefan G. Kertesz, MD, Professor of Medicine at University of Alabama at Birmingham School of Medicine (skertesz@uabmc.edu)*