Regulatory response to America’s Opioid Crisis

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Rates of Opioid Sales, OD Deaths, and Treatment, 1999–2010

CDC. MMWR 2011
How the opioid lobby frames the problem

Source: Slide presented by Lynn R. Webster MD at FDA meeting on hydrocodone upscheduling, January 25th, 2013.

This is a false dichotomy

63% admitted to using opioids for purposes other than pain

35% met DSM V criteria for addiction

92% of opioid OD decedents were prescribed opioids for chronic pain.


Non-medical use (abuse) of painkillers declining since 2002

Figure 3
First-time nonmedical use of pain relievers. Source: 64, 70.


Non-medical Opioid Users

(a) Past month nonmedical OPR use by age

Opioid Overdose Decedents

(b) OPR-related unintentional overdose deaths by age

Death rates from overdoses of heroin or prescription opioid pain relievers (OPRs), by age group


Opioid Related Overdose Deaths
United States, 1999-2013

Heroin admissions, by age group & race/ethnicity: 2001-2011

Figure 21: Heroin admissions aged 12 and older, by age group and race/ethnicity; 2001-2011

[Graph showing trends in heroin admissions by age group and race/ethnicity from 2001 to 2011]

Source: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 10/10/11.

Primary non-heroine opiates/synthetics admission rates, by State (per 100,000 population aged 12 and over)

[Map of the United States indicating admission rates by state for 1999]

1999 (range 1 - 50)

- < 8
- 8 - 14
- 15 - 18
- 19 - 44
- 45 or more
- Incomplete data

Source: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 11/03/10.
Primary non-heroin opiates/synthetics admission rates, by State
(per 100,000 population aged 12 and over)

2005
(range 0 – 214)

< 8  
8 - 14  
15 - 18  
19 - 44  
45 or more  
Incomplete data

SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 11.03.10.

Primary non-heroin opiates/synthetics admission rates, by State
(per 100,000 population aged 12 and over)

2007
(range 1 – 340)

< 8  
8 - 14  
15 - 18  
19 - 44  
45 or more  
Incomplete data

SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 11.03.10.
Re-framing the U.S. opioid crisis as an epidemic of addiction

- Opioid OD deaths are common in people suffering from opioid addiction

- From 1997 to 2011 the prevalence of opioid addiction increased by 900%

- Opioid OD deaths increased mostly because prevalence of opioid addiction increased
Controlling the epidemic:  
*A Three-pronged Approach*

- **Prevent** new cases of opioid addiction
- **Treatment** for people who are already addicted
- **Supply control** to reduce over-prescribing and black-market availability

**Interventions**

- Up-scheduling hydrocodone combos
- Opioid label changes
- Mandatory prescriber education
- Abuse deterrent formulations
- PDMP-based interventions
- Expanding access to naloxone
- Expanding access to addiction treatment
Hydrocodone combos recently moved to Schedule II

Extended-release hydrocodone approved by FDA over objection of expert panel
Doctors Petition for Limits on Painkillers

A group of doctors and public health officials urged the Food and Drug Administration on Wednesday to curtail the overuse and abuse of prescription painkillers by changing labeling directions on how and when physicians should prescribe them.

The request came in a so-called citizens petition sent Wednesday to the F.D.A. by some 35 physicians, including Dr. Thomas A. Farley, the commissioner of the Department of Health in New York City, and Dr. Nirav R. Shah, the commissioner of the New York State Department of Health.

PROP’s proposed label changes:

1. Strike the term “moderate” from the indication for non-cancer pain.

2. Add a suggested maximum daily dose, equivalent to 100 milligrams of morphine for non-cancer pain.

3. Add a suggested maximum duration of 90-days for continuous (daily) use for non-cancer pain.
WASHINGTON — The Food and Drug Administration on Tuesday announced changes to the labeling requirements for long-acting painkillers, in a further effort to curb prescription drug abuse, which has been on the rise in recent years.

Agency officials said the labeling changes, set to take effect by the end of the year, would “help improve the thoughtful prescribing of these medicines,” which include OxyContin, a highly addictive opioid that has figured prominently in the abuse epidemic. Morphine and fentanyl are other examples.

The agency is also requiring producers of such drugs to conduct studies on the long-term risks of taking them. Researchers applauded the move, saying that a lack of such data was a major problem in determining safe prescribing practices.

Mandatory Prescriber Education
Risk/Benefit of Opioids for Chronic Non-Cancer Pain

Source: Franklin; Neurology; Sept 2014-Position paper of the AAN
Demonstration of so-called “abuse-deterrent” formulation

Original Tablet

Reformulated Tablet

Source: Cone et al. Alcohol Drug Addiction 2013

Status of Prescription Drug Monitoring Programs as of June 2012

Operational PCMPs
Enacted PCMP legislation, but program not yet operational
Legislation pending
Naloxone

In parts of the U.S. naloxone is now available to:

- Police and other first responders
- Drug users (to rescue peers)
- Family members of drug users and pain patients
- Drug treatment providers

Comparison of Mortality Data from AIDS Case Reports and Death Certificates in Which HIV Disease Was Selected as the Underlying Cause of Death, United States, 1987–2006
Summary

• The United States is in the midst of the worst drug epidemic in its history.

• Key driver of morbidity and mortality is opioid addiction

• Controlling epidemic requires primary, secondary and tertiary opioid addiction prevention strategies