The Opioid Epidemic: How the Medical Industry Created a Public Health Crisis

Chris Johnson, MD

HCMC Emergency Medicine, 2003

Chair, Dept. of Human Services Opioid Prescribing Workgroup

Board member, Physicians for Responsible Opioid Prescribing

Board member, Steve Rummler Hope Foundation

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Goals for talk –

1. **The problem** – What are opioids and what is the crisis facing the U.S. today by the numbers – which are terrible.

2. **Why it happened?** – Not an accident. Arose from deliberate action of those with financial interest in expanded prescribing, taking advantage of a medical community that was vulnerable to exploitation and compromise of its scientific principles.

3. **Why it persists?** - Incentives in the health care industry poorly suited to stopping this alone. Many not interested in stopping crisis if that will mean financial loss or liability.

3. **What can we do to solve?** – Steps prescribers can take. But A SOCIETAL RESPONSE IS NEEDED. If health care providers alone could fix this they would have done so by now.

4. **Take Home Points** – All Opiates are Heroin.
The Problem

What are Opioids and Why Are We Talking About Them?
A Brief History of Opioids and their Use...

Use as analgesic dates to the ancient civilizations of Sumer, Assyria, Egypt, Greece and Persia.

In other words, as old as written civilization itself...

Papaver somniferum, the opium poppy. (From Roman mythology, Somnus was the god of sleep)

Somnus from Ovid’s “Metamorphoses”, 15 volumes, history of the word from the beginning to Julius Caesar. Pub AD 8.
A Brief History of Opioids and their Use...

Dried extract of Opium contains active ingredients Morphine plus Codeine.

Raw opium (shown left) contains about 12% morphine.

Morphine – named after the Greek god Morpheus, ‘the god of dreams’
Morphine works predominantly by being metabolized in the body to morphine.
How Opiates Help Treat Pain...2 Primary Pathways

Pathway 1 – Inhibit Nociception. Opiates block pain receptors in the dorsal horn of the spinal cord, blocking neurotransmitter release (substance P, glutamate)
Opiates bind mu (mu1) receptors in the brains ‘reward’ center. Inhibits GABA (gamma amino-butyric acid) release resulting in increased dopamine release.
FASCINATING ...
SO WHAT'S THE PROBLEM?
Bind $mu$ ($mu2$) receptors in the respiratory center of the brain mainstem, causing slowed respirations and, in high enough doses, DEATH by respiratory failure.
So Opiates, like other medicines, have use but also risk.
“The United States contains 5% of the World’s Population and consumes 80% of the World’s Opioids.”

2009 National Survey on Drug Use and Health
The United States stands alone vs. the rest of the world in its extensive use of opiates. Rates are more than 5x that of Western Europe.
That looks crazy.
Has it always been like this?
No. It hasn’t.

Opioid Prescriptions have tripled in last 20 years. We are now over 220 million per year in U.S.

(VONA – Vector One NAational. A service to provide prescription data).
Accidental Rx Overdose Deaths –
2000 – 4,400    2014 – 18,893 (>300% increase)
To put the 18,893 death toll for 2014 in perspective...
2014 – 6 World Trade Centers... and then another 900.
That was just one year.

From 2000-2014, over 189,000 Americans died from accidental opiate prescription overdose (Center for Disease Control).

To put *that* number into perspective...
That is greater than the total number of U.S. soldiers lost in the European theater in World War II.

(188,588. Statistical and Accounting Branch Office of the Adjutant General)
But prescription opiates are only part of the problem.

We have another opiate now to worry about...
Mirroring the rise in prescription abuse and overdose deaths has been heroin.

75% of current heroin users start with prescriptions. (Drug and Alcohol Dependence, 2015)
2001 - < 2000 heroin deaths, 2014 more than 10,000

(National Institute on Drug Abuse)
THE ICEBERG OF MISERY

For every 1 opioid overdose death in 2010 there were...

- 15 abuse treatment admissions
- 26 emergency room visits
- 115 who abuse/are dependent
- 733 nonmedical users
- $4,350,000 in healthcare-related costs

Deaths are just the tip.
So How and Why Did This Happen??
What has changed in America that has led to this crisis is the **power and influence of the pharmaceutical industry**.
Multi-pronged approach to gain influence over the marketplace and change the culture to increase sales of prescribed opiates:

1. **Recruit “thought leaders”** at leading academic institutions to spread your message

2. **Market directly to primary care doctors**, offer gifts and incentives

1. **Influence government and regulatory bodies** to approve products and mandate pain control requirements

1. **Blur the line** between “academic” societies, “patient advocacy” groups and marketing.
Tactic #1 – Recruit Pain Specialists at Leading Academic Institutions to Be Your Advocates. (Sometimes these individuals are called “thought leaders”)

Goal – Convince the medical community that opiates are not so dangerous as previously believed.
Dr. Russell Portenoy


Sought to rehabilitate the medical community of ‘opiophobics’. Did help pioneer the field of palliative care for cancer patients.
Dr. Portenoy was President of the American Pain Society in 1995. Originated and championed the “Pain is the 5th Vital Sign” movement.

Reported pain “levels” were to be taken as relevant as blood pressure, temperature or heart rate as an indicator of patient health.
1996 – co-authored a position statement published in the Clinical Journal of Pain de-emphasizing risk of addiction of opioids. *Cited the risk of addiction was “less than 1%”.*

WHERE DID THAT “LESS THAN ONE PERCENT” STATISTIC COME FROM?
It came from a “study” that appeared in the New England Journal of Medicine in 1980 vol. 302 by Jane Porter and Hershel Jick. Known simply now as “Porter and Jick”.

Really? Less than 1% become addicted?

What was in this study?

Here it is. Get ready.
To the Editor: Recently we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients with no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients, percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.
This was not a study. It was a “tweet”.

But if it said anything, what did it say?
It said absolutely NOTHING about risks and benefits of putting patients on opiates indefinitely in an outpatient setting for CHRONIC PAIN.

This paragraph was transformed over the years to mean “OPIATES ARE NOT ADDICTIVE” for any patient with pain. Ignored the fact that the exposure was brief and acute.
This was a great failure of the medical ethics and scientific prudence and skepticism.

Porter and Jick’s paragraph was an OBSERVATIONAL STUDY!
This was never done with opiates.

NIH Pathways to Prevention Program. October, 2014. Dr. Erin Krebs, U of MN. No study for use of opiates for chronic pain lasted longer than 12 weeks.
In a taped interview in 2010 – “I gave innumerable lectures in the late 1980s and 90s about addiction that weren’t true.”

“Clearly, if I had an inkling of what I know now then, I wouldn’t have spoken the way I spoke.”
Tactic #2 – Market Relentlessly to the Primary Care Doctors.

This was new. Prior to the late 1990s, pain relievers, especially extended release pain relievers, were only marketed to the pain and cancer specialists.

But then it all changed in 1996...
OxyContin, Purdue Pharma, 1996, continuous release preparation of oxycodone.

(Conceived in 1980s when Purdue saw its patent on MS Contin expiring.)
Why target Primary Care Physicians specifically?

Because they see everyone. Largest market opportunity. (Can’t make billions on hospice pts)
Sales materials including the video “I Got My Life Back” distributed to patients and clinics.

Video shows 7 people with their personal stories of how OxyContin was the answer to suffering.
Strategies Used –

• Between 1996 – 2001 over 40 conferences for providers in resorts, all expenses paid, over 5000 attendees (doctors, pharmacists, nurses)

• Targeting of PRIMARY CARE PHYSICIANS! NOT JUST PAIN SPECIALISTS. DIRECT CONTACT VISITS AND GIFTS.
Strategies Used –

Starter coupon program. First Rx for OxyContin was free. 34,000 used the program before it was canceled.
They even released their own CD as gifts – “Get in the Swing with OxyContin!”
Tactic #3 – Influence Governmental and Regulatory Bodies.

Rules about pain control to favor more aggressive drug prescribing and administration.
1992 passage of the Prescription Drug User Fee Act, 50% of the FDA’s budget came from the drug industry.

FDA increasingly pressured to approve new drugs quickly or risk loss of funding from pharma.
In late 1990s approved opiates for long term use for chronic pain at insistence of pain specialists and advocacy groups stating pain is “undertreated.”
Joint Commission Statement, 2001. Mandated that hospitals measure pain scores and tied their performance evaluation to those scores.

Joint Commission published a guide which was sponsored by Purdue Pharma. Guide stated that risks of addiction had been exaggerated.
Tactic #4 – Increase market penetration by “blurring” the line between advertising and advocacy.

Message that pain is “undertreated epidemic” more effective when coming from “patient” or “academic” groups, than directly by the companies.
Look closely at who is behind patient advocacy groups.

Who could be against that?

Look at the bottom of the page. This is entirely a Purdue Pharma entity. Started in 1993 as an “unbranded” form of outreach.
Dr. Lynn Webster, Past President, American Academy of Pain Management

“We have an epidemic on our hands. And the status quo is failing us.”
Curious thing about that “academy”...they have a “Corporate Council”. Here are some members...

- **Purdue Pharma** – Oxycontin (oxycodone)
- **Endo Pharmaceuticals** – Opana (oxymorphone), Percocet
- **Pfizer** – Avinza (extended release morphine), Embeda (morphine plus narcan)
- **Janssen** – Duragesic (fentanyl), Ultram
- **Mallinckrodt** – Exalgo (hydromorphone, aka dilaudid), Roxicodone (oxycodone), Methadone

Double check yourself: http://www.aapainmanage.org/about/corporate-council/
Non-biased patient Advocacy?

American Pain Foundation - shuts down May 2012 amid senate probe of ties to pharmaceutical industry, 90% of funding.

https://www.propublica.org/article/senate-panel-investigates-drug-company-ties-to-pain-groups
With these tactics, the pharmaceutical industry has been enormously successful. We have bought notion that:

1. chronic pain is “an undertreated epidemic” and
2. the opiates are “safe and effective” at helping people reclaim their lives.
But is it really accurate to say this is an “epidemic”?

And have people really “reclaimed their lives”?
Joint inflammation is one of the most common causes of chronic pain. Is there an “arthritis epidemic”? 
This is NO *epidemic* of chronic pain.

When the incidence of something is high and stays there. That is not an epidemic. That is called **LIFE**.
What about the claim that these medicines would help those in chronic pain “reclaim” their lives?

So did they?
You could not conclude that by looking at employment data!

Disability has only increased!

1990 – 4 million on disability

2014 – 11 million, record high, 200% increase in 20 years
The top causes of disability remain back and joint pain, something opiates should be able to treat.
And whatever happened to those 7 patients featured in the Purdue Pharma video?

Two of them, John Sullivan (top left) and Ira Pitchal (bottom right) died while in active addiction. Sullivan fell asleep behind the wheel due to opiates, 2008. Pitchal was found unresponsive in his home, age 62.

Lauren (top right) became addicted but weaned herself.

So Why Are We Still Doing This?!
Answer: Medicine in America is Big Business.
From my own year-end performance review – “Chris, we are all so proud of the work you are doing with chronic pain. But it’s such a fine line between increasing risk of opiate addiction and HCAHPS scores.”
Since its inception in 2008, HCAHPS as an indicator of hospital performance has become mandatory.

CMS has tied Medicare (the largest health care payer) reimbursement to hospitals on their performance on these surveys.

Hospitals have ENORMOUS INCENTIVE TO PERFORM WELL ON THESE SURVEYS!
'During this hospital stay, did you need medicine for pain?'

“During this hospital stay, how often was your pain well-controlled?”

“During this hospital stay, did the hospital staff DO EVERYTHING THEY COULD to help you with your pain?”
And doctors increasingly have precious little time to generate this favorable “patient experience.”

Must answer to their clinic directors who in turn answer to health system executives about “throughput” and “relative value units per hour”
Q: What do you think happens to prescribing when overworked physicians strive to meet these unrelenting, even conflicting, demands?

A: Exactly what you would expect. The path of least resistance.
Study of almost 2900 patients in Boston area, 9 out of 10 patients who had a serious opiate overdose (ER visit or admission) continued to get opiate prescriptions afterwards.

In 70% of cases, from the same physician who prescribed them before the overdose.
It is Time For A Change. For Our Patients. For Ourselves.
As far as the human brain is concerned...

All Opiates Are HEROIN!!!

Diacetylmorphine
Heroin not originally a “street drug”

“Heroin”, Bayer Pharmaceuticals, 1898-1910
German “heroisch” = heroic, strong
AND HERION IS JUST ANOTHER OPIATE. THEY BIND THE SAME BRAIN RECEPTORS

- Morphine
- Diacetylmorphine/‘heroin’
- Oxycodone
- Acetyl group
- Hydromorphone / Dilaudid
- Hydrocodone
Heroin (diacetylmorphine) is used in the United Kingdom every day for acute, painful injuries. Again, referred to as Diamorph. (We use Dilaudid/hydromorphone.)
To Our Community of Providers

PREVENTION IS FAR MORE EFFECTIVE THAN TREATING OPIOID USE DISORDER once it has developed!

So STOP STARTING PATIENTS WITH RECURRING PAIN SYNDROMES ON OPIOIDS!
April 20, 2017
Hser, Mooney, and Saxon

465 deaths of 2576 patients with Opioid Use Disorder over a 9 year period.

ALMOST 1 IN 5 DEAD IN LESS THAN 10 YEARS ONCE O.U.D. DEVELOPS!!!

That is 10 times the annual death rate of the unaffected population!

Some activities with similar annual fatality risk...
Even taking them for 2 Months is associated with complications.

- 34% of patients taking opioids for two months or longer became dependent or addicted
- 57% of long term users think opioids improved their health
- Family members of long term users more likely to report addiction and poor health response

SPACE Trial – Strategies for Prescribing Analgesics
Comparative Effectiveness. May 2017

240 Patients with back, neck and joint pain. 120 received opioids and 120 treated with non-opioids. 12 month study

RESULT – NO DIFFERENCE IN PAIN LEVELS BUT HIGHER COMPLICATIONS FOR OPIOID GROUP!

(note - $1.4 million research grant, taxpayer dollars)
To Our Political Leaders

Major Overhaul Needed in Health Care!
• Reform the FDA – fund it publically, not by industry
• Reward and incentivize outcomes, not process of care
• Increased access to chemical dependency tx
To Everyone, Can WE PLEASE STOP WITH THE MORALIZING LANGUAGE ABOUT ADDICTION?! No place for such talk in modern medicine.

Or was it an amazing coincidence that as sales went up we had a corresponding increase in “immoral” people in the United States?

We are not here to punish or judge anyone.

This crisis has brought misery to millions.

We are trying to restore HOPE!
Thanks!

Questions?

chrisj442@gmail.com