

Conflicts of Interest Allowed Opioid Crisis to Grow: FDA Makes Narcan Available Over the Counter

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March 29, 2023, the FDA announced it will soon make naloxone (brand name Narcan) — a drug that reverses the fatal effects of an opioid overdose — available over the counter without a prescription

Instructions on how to use Narcan are provided

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In the video above, Joe Rogan interviews journalist Mariana van Zeller, who in 2009 shone a bright light on the drug abuse epidemic with her online documentary series "The OxyContin Express."^{1,2}

Largely thanks to her reporting, Florida ended up implementing an opioid database so that people can no longer visit multiple doctors and then receive and fill multiple prescriptions. While it has not completely solved the problem, this database has at least reduced the amount of abuse taking place.

Zeller's husband was also the cinematographer for the 2022 documentary "American Pain," which details the rise and fall of Chris and Jeff George, identical twins caught trafficking more than 500 million dollars' worth of opioid pills through a tiny "pill mill" in a Florida strip mall.

No Justice for Victims

While the two brothers ended up serving prison terms, **no pharmaceutical executive has ever been sent to prison for their role in the drug epidemic they intentionally created and promoted.** Meanwhile, as Zeller notes — and has witnessed first-hand — entire communities have been devastated and destroyed by addiction.

PR companies that aided and abetted drug companies in their deception also have yet to pay a price. The Publicis Groupe, for example, is accused of placing illegal advertisements for OxyContin in the electronic medical records of patients and creating training materials for Purdue Pharma sales reps on how to combat doctors' objections to the drugs.

Publicis also developed strategies to counter opioid guidelines issued by the U.S. Centers for Disease Control and Prevention and created "patient stories" to "humanize" the OxyContin brand and counter negative press about addiction risks.

As detailed in "[Dr. Mercola's Attackers Sued for Role in 'Crime of the Century'](#)," Massachusetts attorney general sued Publicis Health in May 2021 for its role in fueling the opioid crisis. The case is still ongoing.

Criminals Let Off the Hook

Purdue Pharma was also sued for their role in creating the opioid epidemic. The company pleaded guilty to criminal charges in October 2020 and reached a settlement with the federal government totaling \$8.3 billion.

But the owners and operators of Purdue, the Sackler family, all got off scot-free, even though they were personally in charge of the company's deadly decisions. In previous articles, I've detailed how Purdue's false advertising spawned the opioid crisis.³

To recap, a single paragraph in a 1980 letter to the editor^{4,5} — NOT a study — in The New England Journal of Medicine, which stated that narcotic addiction in patients with no history of addiction was very rare, became the basis of a fraudulent drug marketing campaign that has since led to the death of hundreds of thousands of people.

Purdue Pharma used this letter to the editor as the basis for its claim that opioid addiction affects less than 1% of patients treated with the drugs. In reality, opioids have a very high rate of addiction and have not been proven effective for long-term use.⁶

Purdue isn't the only opioid maker whose executives have been spared accountability. In July 2021, Johnson & Johnson and three drug distributors — AmerisourceBergen, Cardinal

Health and McKesson — agreed to pay a combined [settlement of \\$26 billion for their roles in the opioid epidemic](#). They too got a sweetheart of a deal, as the \$26 billion settlement amounts to just 4% of the four companies' annual revenue, and none of the decisionmakers went to jail.

Conflicts of Interest Allowed the Opioid Crisis to Grow

Even the American Medical Association (AMA), one of the largest medical lobbying groups in the U.S., has contributed to the opioid crisis by fostering cozy relationships with Big Pharma.

Richard Sackler, who served as the president of Purdue Pharma, was a member of the AMA Foundation's board of directors from 1998 to 2004, and the AMA's pain management training program was developed by a team with close ties to the industry.

Dr. Roneet Lev, chief medical officer to the Office of National Drug Control Policy from 2018 to 2020, who looked through the AMA's training modules, called it "'How to Create an Addict' education." I discussed these and many other details in "[The AMA's Contribution to the Opioid Epidemic](#)."

In 2019, the BMJ^{7,8} also highlighted how conflicts of interest within the National Academies of Sciences, Engineering and Medicine (NASEM) — which advises the U.S. Food and Drug Administration on opioid policies — may have played a role in the opioid crisis. Seven of the 15 academics serving on the NASEM panel that advised the FDA on opioid prescribing guidelines had ties to industry. On top of that, NASEM itself accepted \$14 million from the Sackler family.

FDA Makes Narcan Available Over the Counter

March 29, 2023, the FDA announced it will soon make naloxone (brand name Narcan) — a drug that reverses the fatal effects of an opioid overdose — available over the counter without a prescription. As reported by NPR:⁹

"Today's action paves the way for the life-saving medication to reverse an opioid overdose to be sold directly to consumers in places like drug stores, convenience stores, grocery stores and gas stations, as well as online," the FDA said in a statement.¹⁰

Emergent BioSolutions, the drug company that produces Narcan, said on Wednesday that it hoped to make the nasal spray available on store shelves and at online retailers by late summer ...

The FDA approval comes as the U.S. continues to see a staggering number of opioid-related deaths, driven in large part by the spread of synthetic opioids such as illicit fentanyl."

If anything, this is a testament to just how bad the U.S. drug problem has become. In 2021 alone, 16.95 million doses of Narcan were distributed in the U.S.,¹¹ although it's not known how many of those doses were administered. But whatever that number, it wasn't enough.

According to Centers for Disease Control and Prevention data,¹² there were 81,692 fatal opioid-related overdoses in the 12-month period ending in April 2022, up from 76,383 the

year before. Other statistics show opioids are a factor in 7 out of every 10 overdose deaths.¹³ As noted by The New York Times:¹⁴

“According to reports by the Centers for Disease Control and Prevention, in 2021, bystanders were present at 46% of fatal opioid overdoses. If they had been carrying naloxone and knew how to use it, lives could have been saved.”

How to Use Narcan

Making Narcan more widely available may indeed help save the lives of some of those who have been unlucky enough to get sucked into addiction. In a March 29, 2023, article, The New York Times detailed how to use the drug¹⁵ in case of an opioid (including oxycodone, heroin and fentanyl) overdose. First, you’ll need to determine whether the person has overdosed on opioids. Symptoms of an opioid overdose include:

1. Slowed breathing, gurgling or no breathing
2. Pupils narrowed to a pinpoint
3. Blue or purple lips and/or fingernails
4. Clammy skin
5. Cannot be roused by shaking and shouting

The drug works by displacing opioid molecules from the opioid receptors in the brain, so it won’t work if the person has overdosed on a non-opiate drug. It won’t make matters worse, however, so when in doubt, use it.

The OTC Narcan box contains two nasal sprays with plungers, each containing 4 mg of naloxone. Do not prime the plunger as this will release the contents. Wait until you’re ready to administer the dose.

1. Get the Narcan ready, then tilt the person’s head backward and insert the spray tip into one nostril until both of your fingers are touching the nose. Push the plunger down to administer the dose.
2. Call emergency services (911 in the U.S.) after you’ve given the first dose, as every second counts.
3. Next, roll the person onto their side. Place one of their hands under their head and bend the leg that is on top at the knee to prevent them from rolling over. Narcan can trigger acute withdrawal symptoms, including vomiting, so make sure the airways are kept clear to avoid choking.
4. If the person has not regained consciousness after two to three minutes, repeat the process and administer the second dose into the other nostril.
5. Stay with them until emergency services arrive.

OTC Narcan Does Nothing to Address the Problem

While OTC Narcan may indeed reduce the number of lethal overdoses, it does nothing to address the underlying problem, which is the ease with which people can access opioids. Opioids were initially approved for breakthrough cancer pain only, and there’s a solid argument to be made for banning opioids for all other uses, especially considering they provide no better pain relief than over-the-counter nonsteroidal anti-inflammatory drugs (NSAIDs).¹⁶

According to Cochrane Reviews,¹⁷ a combination of 200 mg of ibuprofen and 500 mg of acetaminophen is one of the strongest pain reliever combos available and is more effective than opioids.

Research¹⁸ published in 2018 also found that opioids (including morphine, Vicodin, oxycodone and fentanyl) fail to control moderate to severe pain any better than over-the-counter drugs such as acetaminophen, ibuprofen and naproxen.

Insurance companies should also stop favoring opioids when it comes to reimbursement. As noted in the American College of Physicians' guideline for acute, subacute and chronic low back pain,¹⁹ heat, massage, acupuncture or chiropractic adjustments should be used as first-line treatments. When drugs are desired, NSAIDs or muscle relaxants should be used.

Alas, while clinical practice guidelines call for nonpharmacological intervention for back pain, most insurance plans don't pay for such treatments. They do pay for opioids, though. Other situations in which opioids are inappropriately prescribed, and massively so, are for tonsillectomies and wisdom teeth extractions. This too needs to stop.

Dentists wrote a staggering 18.1 million prescriptions for opioids in 2017 alone,²⁰ and research has shown that 6.9% of those who received an opioid prescription from their dentist were still using opioids between three and 12 months later.^{21,22} In comparison, among those who did not get an initial opioid prescription, only 0.1% sought an opioid prescription in the 12 months that followed.

Drug Industry Is Again the Primary Beneficiary

It's telling that rather than banning opioids, the FDA instead opts for a route that will benefit the very industry that created the problem. First, they deceived us about opioids' addictiveness and created a market that didn't exist by bribing doctors into prescribing it for all sorts of pain. Then, they created a drug "solution" for the drug problem they intentionally created, and the FDA is A-OK with that. It's an absolute racket.

By making Narcan available over the counter, the FDA is primarily setting drug companies up for even greater profits. Eventually, other naloxone products may become OTC as well.

But even if they don't, what's clear is that the drug industry made billions of dollars creating this drug addiction problem and is also raking in profits from anti-overdose treatments. And they want to be hailed as saviors for doing so to boot. If there were any justice, the companies that sell opioids would be forced to hand out anti-overdose meds for free.

Drug Industry Uses Fear to Extract Greater Profits

Instead, drug companies see anti-overdose medications as another cash cow. Naloxone has been off patent since 1985, so companies are coming up with all sorts of "new and improved" and/or higher-dose versions that can be patented and sold for a premium.

The problem is, few if any of these updated drugs are any better than the original generic one. Many don't realize this, however, which means many schools, police departments and local public health agencies end up wasting their resources on higher-priced drugs.

The drug industry is even cashing in on the fact that government refuses to lift a finger to address the influx of fentanyl over our wide-open border. As reported by STAT News, they're using the fear of fentanyl, which is far stronger than other opioids, to sell higher-priced high-dose versions of naloxone:²³

"At first glance, the race to create stronger, more advanced overdose-reversal tools seems like a win-win: a case study in American pharmaceutical companies saving countless lives and turning a profit along the way.

A new STAT examination, however, captures a far different reality: One in which pharmaceutical companies have used the opioid crisis, and the nation's fear of fentanyl, to aggressively market high-cost naloxone products that divert resources away from cheaper forms of the lifesaving medication.

These expensive new products, according to researchers, harm-reduction groups, doctors, and pharmaceutical industry experts, don't fill a legitimate public health need. Instead, they serve largely as an excuse to charge exorbitant prices for a medication that has been off patent for nearly 40 years ...

[C]ompanies ... have brought to market a glut of high-dose, mechanically complex naloxone products — all of which sell for far higher prices than their generic counterparts. Advocates say there's a simple reason why: No company has held patent exclusivity over naloxone since 1985, and there's little money to be made selling low-cost generic versions ...

The contrast, experts say, highlights a fundamental mismatch between public health needs and profit motives. And it demonstrates, too, how the fear of fentanyl, the ultra-potent synthetic opioid, has allowed companies to push the narrative that standard doses are no longer enough ...

Drug companies' behavior in the naloxone market mirrors a longstanding pharmaceutical industry practice: protecting profit margins by continually offering medications in new — and therefore, patentable — formulations and delivery mechanisms ...

Amid the climate of fentanyl-driven fear, drug companies have worked to advance the narrative that only super-sized naloxone doses can reverse a fentanyl overdose."

No Need for High-Dose Versions in Most Cases

Many drug abuse experts and researchers agree that the standard 4 mg naloxone dose is sufficient for most cases, and using high-dose versions in all instances is a waste of resources. Several studies have also confirmed this.

For example, a 2019 study²⁴ that looked at the amount of naloxone required to reverse opioid overdoses outside of medical practice found no increase in the dosages used between 2013 and 2016, even though the prevalence of fentanyl overdoses increased in that time. A 2020 review²⁵ that analyzed ER admission records from 2017 and 2018 came to the same conclusion, stating:

"Our findings refute the notion that high potency synthetic opioids like illicitly

manufactured fentanyl require increased doses of naloxone to successfully treat an overdose. There were no significant differences in the dose of naloxone required to treat opioid overdose patients with UDS [urine drug screen] evidence of exposure to fentanyl, opiates, or both.”

Giving a larger-than-typical dose also has drawbacks worth considering. Since it displaces the opioid from the opioid receptors in your brain, it will cause very acute withdrawal symptoms, and an excessive dose could make those symptoms far more debilitating than necessary.

As noted by STAT News,²⁶ “withdrawal symptoms can be so agonizing that they are driven to again use illicit substances, like fentanyl, sometimes leading to a repeat overdose.”

OTC Narcan May Result in Higher Prices

STAT News also points out that OTC Narcan may end up costing you more than before, even though affordability is a major part of the availability equation:²⁷

“The FDA’s approval this week of Narcan as an over-the-counter drug is a milestone. But it is not as large a victory as it may seem. For one, naloxone products are already available to most Americans via a loophole known as a ‘standing order’ — in essence, a blanket prescription written by a state or local health official.

Thanks to coupons and discounts, naloxone is often entirely free to individuals who seek it out, especially if they have health insurance. Strangely, the FDA granting over-the-counter status for Narcan may make cost more of a barrier for individual buyers ...

Most insurance plans typically only cover prescription medications — meaning that individuals looking to buy naloxone at a pharmacy may soon be forced to pay dramatically more.”

Struggling With Opioid Addiction? Please Seek Help

Regardless of the brand of opioid, it’s important to realize they are extremely addictive drugs and not meant for long-term use for nonfatal conditions. Chemically, opioids are similar to heroin, so if you wouldn’t consider shooting up heroin for a toothache or backache, seriously reconsider taking an opioid to relieve this type of pain.

If you’ve been on an opioid for more than two months, or if you find yourself taking a higher dosage or taking the drug more often than you initially did, you may be addicted. Resources where you can find help include:

- Your workplace Employee Assistance Program
- The [Substance Abuse Mental Health Service Administration](#)²⁸ can be contacted 24 hours a day at 1-800-622-HELP

Also review “[The Remarkable Benefits of Low-Dose Naltrexone](#),” in which I discuss how micro-doses of LDN, an opioid antagonist, can successfully treat opioid addiction.

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Notes

¹ [The Oxycontin Express](#)

² [NPR March 2, 2011](#)

³ [The Atlantic June 2, 2017](#)

⁴ [NEJM 1980; 302\(2\): 123 \(PDF\)](#)

⁵ [STAT News May 31, 2017](#)

⁶ [Medscape September 28, 2015](#)

⁷ [BMJ 2019;366:l5321](#)

⁸ [BMJ 2019;366:l5273](#)

⁹ [NPR March 29, 2023](#)

¹⁰ [FDA March 29, 2023](#)

¹¹ [Reagan-Udall Foundation for the FDA, Naloxone Economic View March 2023](#)

¹² [CDC Provisional Drug Overdose Deaths 12 Mos Ending April 2022](#)

¹³ [NCDAS Drug Overdose Death Rates](#)

^{14, 15} [The New York Times March 29, 2023 \(Archived\)](#)

¹⁶ [JADA July 2016; 147\(7\): 530-533](#)

¹⁷ [MNDental.org NSAIDs Are Stronger Pain Medications Than Opioids](#)

¹⁸ [JAMA March 6, 2018;319\(9\):872-882](#)

¹⁹ [AAFP.org Low Back Pain Clinical Practice Guideline](#)

²⁰ [ADA.org May 25, 2019](#)

²¹ [JAMA Internal Medicine 2019;179\(2\):145-15](#)

²² [Stanford Medicine December 3, 2018](#)

^{23, 26, 27} [STAT News March 28, 2023](#)

²⁴ [Substance Abuse 2019; 40\(1\): 52-55](#)

²⁵ [Journal of Medical Toxicology January 2020; 16\(1\): 41-48](#)

²⁸ [Substance Abuse Mental Health Service Administration](#)

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