

How we got here: A history of the opiate epidemic



By: Claude Solnik November 7, 2017 0 (image: Bruce Goldman)

Pain is a perpetual problem, difficult to measure or defeat and sometimes chronic. But back in the 1990s, the fight to defeat pain shifted into gear with opiates as the main weapon.

"The use of narcotic medications to treat pain became prevalent," Bruce Goldman, director of substance abuse services at Zucker Hillside Hospital, said. "A lot of people were assigned large doses with very little restrictions or concerns."

Much of the opiate epidemic, in other words, came out of not a war on drugs, but a war on pain. The problem was born from doctors' prescriptions as much as out drug dealers' business. While heroin remained illegal, the marketing and prescription of legal opiates caught on.

"It's the biggest [epidemic] and one that began within the healthcare system," said Jon Morgenstern, director of addiction services for Northwell Health's Center for Addiction Services and Psychotherapy Intervention Research. "That's never happened."

There was a concerted effort to tame pain: In the 1990s the federal government even rated hospitals from one to five smiley faces to evaluate how they handled pain.

"Pain is subjective," Linda Ventura, founder of Thomas' Hope Foundation, said. "Pain medication was overprescribed."

Morgenstern also believes the Joint Commission's decision to evaluate hospitals based on how pain was handled, while well intentioned, opened a Pandora's box.

"They made one of those criteria pain," he said of the federal government's evaluation of hospitals. "To ensure that hospitals and physicians adequately address pain. That was a really problematic rule. Pain is subjective."

Morgenstern says physicians were instructed to prescribe opiates as the prevailing standard of care. If you didn't prescribe pills, which generated huge profits for pharmaceutical companies, you declined at your own risk.

"Physicians were told they needed to make sure their patients, if in pain, were given medication," he said. "That medication was opiates. I have a lot of colleagues who are primary care physicians who were told this. They said they knew this would create problems."

Opiates were being dispensed in larger and larger amounts by physicians and hospitals, who Morgenstern said were, "The criteria for accreditation and patient satisfaction, which you're graded on, was if a patient comes in and is in pain, you give him this medication," he said.

While some physicians expressed concerns, those were drowned out by arguments that opiates, far from addicting America, were lessening its pain.

Pharmaceutical representatives educated physicians, insisting that opioids weren't addictive, assuring them there was no reason for that concern.

"I know people who were talking about this in the 1990s," Ventura said. "They were sold a bill of goods from a pharmaceutical company. I still blame them. They should know better."

The Food and Drug Administration approved a procession of opiates, fueling a new epidemic that would flood the market.

Much the way some argue people's decisions, not guns, kill, the argument developed over whether addiction or simply abuse was the problem. But the priority, at least in the 1990s, was fighting pain, even if it meant the proliferation of pills.

"Some of that was driven by the government stepping in, saying everyone should be pain free," Dr. Jay Enden, regional medical director for Northwell Health, said of the prevalence of pain medication. "If you don't make people pain-free, you're not doing a good job."

Morgenstern said there was some truth to the need for more focus on pain, but this was soon seized on as a massive medical marketing opportunity.

"The concern was that pain was undertreated," Morgenstern said. "There was an opportunity that the pharmaceutical industry exploited and lied about."

Pharmaceutical companies looked for data to fuel drug sales, reaching out to academia, but sometimes with strings attached. Purdue Pharma, Morgenstern said, sought to have research done at Columbia University regarding oxycodone. But the firm, he said, sought to have the right to review results.

"They really wanted to sell a lot of oxycodone," Morgenstern said of Purdue in the 1990s. "When I was at Columbia, they came to us. They were worried even then that there might be issues related to oxycodone. They wanted to give us money to do research. We refused it. They weren't going to let us do an independent study. They wanted to review."

Pain accompanied so many things from surgery to cancer, car accidents to wisdom tooth revival that opiate sales soared. They were being prescribed with abandon, as they became the darling of drug companies, swelling earnings and letting doctors dispense pills to dismiss discomfort.

"There was a great partnership, let me put it that way," Ventura said. "Doctors were overprescribing for happy faces. They were given research that these drugs were not addictive." Meanwhile, doctors who wanted good grades from patients were happy to prescribe large amounts of pain killers, just in case people needed them. People weren't given minimal, but rather larger, amounts.

"What that did was move people in the medical profession to overprescribe," Enden continued of the climate of the time, noting that the government eventually ended the grading of pain treatment as a prime measure of hospitals. "The government pulled that out of the patient satisfaction scorecards. They realized a secondary effect was more opiates in the system."

The backlash began as concerns began to change the discussion to one over the dangers and damages of approving opiates.

A Food and Drug Administration advisory committee recommended against approving Xohydro, which the FDA promptly approved.

"That's the lobbyists," Ventura said. "You think your congressman and senator are not being bothered every day."

But as the death toll, and cost for government through Medicaid and Medicare grew, pharmaceutical companies came under fire.

Purdue Pharma settled suits in various states. But physicians continued to use various opiates as the go-to treatment for nearly every type of pain.

Lately, the FDA has been taking a second look at whether some of these drugs do more damage than good.

The FDA's Drug Safety Risk Management and Anesthetic and Analgesic Drug Products Advisory Committees in May concluded that the benefits of opioid pain medication Opana ER (oxymorphone hydrochloride extended release) did not outweigh public health risks.

The pain these painkillers cause, more than the profit and benefit they provide, was in the spotlight. Against the backdrop of an opiate epidemic, the FDA took action.

The agency in June ordered Endo International to remove the drug from the market due to opioid abuse. Endo International in July stopped selling Opana ER.

Endo expects to incur a \$20 million pre-tax impairment charge in the second quarter of 2017 to write-off the remaining book value of this drug. Sales of the drug were \$158.9 million for 2016 and \$35.7 million for the first quarter of 2017.

But the costs for opiate makers could be far higher, as states and counties look toward litigation to make up for massive medical costs from drug abuse – that may be linked to improper drug marketing and the downplaying of addiction.

Forty-one attorneys general have demanded information and documents from opiate manufacturers to see whether the firms broke laws in marketing and distributing prescription opioids.

"Too often, prescription opioids are the on-ramp to addiction for millions of Americans," Attorney General Eric Schneiderman said. "We're committed to getting to the bottom of a broken system that has fueled the epidemic."

The attorneys general served subpoenas on pharmaceutical firms Endo International, Janssen Pharmaceuticals, Teva Pharmaceutical Industries and Allergan. They also demanded documents from distributors such as AmerisourceBergen, Cardinal Health and McKesson.

Opioid distributors make nearly \$500 billion a year in revenue, according to Schneiderman. Pain had gone from a problem to an industry.

Many counties in New York State, including Nassau and Suffolk, are suing opiate makers, blaming them for massive medical costs.

The suits, being consolidated, charge that the makers used deceptive marketing practices to essentially hook millions of people on pain medications.

"We know this will be a long battle, but we look forward to fighting for the residents of our state," Salvatore Badala, an attorney at Napoli Shkolnik in Melville, filing suits on behalf of Nassau, Suffolk and many other counties, said.

Paul Napoli, co-counsel at Napoli Shkolnik, said the counties are joining to "fight the epidemic against the manufacturers."

"The staggering number in that is that three out of four new heroin users start with prescription opiates," Enden said. "From a medical standpoint, we must reduce the degree to which we prescribe opiates."

There's now a call for physicians to prescribe medications that are not opiates, recognizing and relying more on other options.

"We need better alternatives for pain than we have available," Morgenstern said. "Physicians need to be better educated about how to make that balance between pain and whether and how much opiate prescriptions they need and other alternatives."

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