Who Is Behind the Pain Killer Epidemic? Big Pharma, Of Course

The FDA approved Zohydro, with five to 10 times the abuse potential as its predecessor, OxyContin.

By Martha Rosenberg / AlterNet

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There is good news and bad news when it comes to the nation's decade-long opioid/heroin addiction epidemic. The good news is the government has cracked down on pill mills, strengthened warnings on pill labels and approved an injectable form of naloxone which reverses heroin overdoses and will reduce deaths in the hands of caregivers and police.

The bad news is on the same day the FDA announced plans to tighten restrictions on hydrocodone combination products like Vicodin, it approved the long-acting drug Zohydro made from hydrocodone bitartrate which has five to 10 times the abuse potential of the infamous OxyContin. The FDA did so over the objections of many medical and public health groups and its own advisory committee. And even as public health professionals are outraged by the FDA's tin ear and refusal to learn from the opioid addiction epidemic, a pill that combines oxycodone with morphine is also inching its way toward approval.
Many of the current addicts started out on narcotic painkillers and turned to cheaper and more available heroin when their supply became cut off or got too expensive. This risky switch from pills to street drugs was abetted by the creation of a "deterrent-proof" version of OxyContin that people could no longer crush and snort. (The reason OxyContin had been king on the street was all 80 milligrams could be ingested at once if the pill was crushed, a rush described by users as better than cocaine.)

But why were millions of Americans on narcotic painkillers, once limited to terminal and cancer pain, surgery and accidents, to begin with? Because Big Pharma paid doctors in advisory positions to institute looser guidelines, reports the Milwaukee Wisconsin Journal-Sentinel — and quickly discovered that the medical establishment and patients neither remembered or cared why narcotic painkillers had been the most restricted of all drugs.

One example of the pay-to-play is the American Geriatrics Society, which changed its guidelines in 2009 to recommend "that over-the-counter pain relievers, such as ibuprofen and naproxen, be used rarely and that doctors instead consider prescribing opioids for all patients with moderate to severe pain," writes medical reporter John Fauber. To recommend narcotic painkillers over over-the-counter painkillers is outrageous enough. But half the panel's experts "had financial ties to opioid companies, as paid speakers, consultants or advisers at the time the guidelines were issued," Fauber reports. The University of Wisconsin's Pain & Policy Studies Group also took $2.5 million from opioid makers even as it pushed for looser use of narcotic painkillers, he reports.

Thanks to the "second look" inspired by Pharma money, narcotic painkillers soon were prescribed for back injuries, headaches, arthritis, fibromyalgia, toothaches and mental issues like depression. They were even prescribed for "unemployment" and "withdrawal symptoms" from opioids, said Businessweek. While pill mills did a brisk business, employers were paying an extra $39,000 for a work injury case when short-acting opioids like Percocet were added and an extra $117,000 when long-acting opioids like OxyConti were added to the case. Ka-ching!
And there was another, more insidious way that Pharma got the medical establishment and prescribers to reconsider narcotic painkillers. Federal regulators and executives of Pharma companies that make pain drugs have held private meetings at expensive hotels at least once a year since 2002. The meetings are under the auspices of IMMPACT, an organization funded by 11 drug companies including makers of narcotic painkillers.

As early as 2003, Raymond Dionne, a National Institutes of Health (NIH) official, questioned the ethics of the schmoozing of federal officials and industry in closed meetings and suggested open meetings on the NIH campus. Federal officials should not be accepting expensive dinners at the Four Seasons Hotel, he wrote in correspondence to IMMPACT. Robert Dworkin, an IMMPACT co-founder, actually found the ethical concerns amusing. If you want, we will buy you and other government officials "inexpensive sandwiches" he wrote back in an email, adding, "The rest of us undoubtedly will feel guilty, but we will probably resist the temptation to have tuna fish in respect for your plight." Dworkin is a professor and pain expert at the University of Rochester Medical Center in Rochester, NY.

IMMPACT has a clear and stated goal of "improving the design, execution, and interpretation of clinical trials of treatments for pain." One "improved design" federal officials admit grew out of the clandestine meetings is called "enriched enrollment." It is a new system that allows Pharma companies to eliminate people who respond poorly to a drug or don't tolerate the drug at all before the clinical trial begins. This fait accompli system is like drawing a bull's eye around an arrow after it been shot into a wall (or "reaching the person to whom I am speaking," as Lilly Tomlin used to spoof). The sleazy science increases the chance of a drug being approved, how quickly it is approved and of course lowers Pharma's costs. Both Purdue Pharma, who makes OxyContin, and Janssen, which makes Duragesic and Nucynta, have acknowledged the value of IMMPACT's efforts to improve clinical trial procedures.

And there is more bad science associated with opioids. When it comes to long-term as opposed to short-term relief of pain, there is scant scientific
evidence of narcotic painkillers' effectiveness despite Pharma's promotion of their long-term use. The drugs even paradoxically make pain worse when used for more than a short period of time. Patients risk developing opioid-induced hypersensitivity (OIH) which is an increased pain sensitivity that makes it even harder to quit the already addictive drugs. Last year, Johnson & Johnson, Janssen's parent company, was investigated by the city of Chicago for deceptive marketing of narcotic painkillers to city employees. The city claims Janssen improperly marketed the opioids for long-term treatment of chronic pain, such as back pain and arthritis. Janssen maintains the opioids are safe and effective over an extended period of time.

Thanks to Pharma, we are now seeing the reason for narcotic painkillers' traditional tight control. In addition to their addiction and abuse potential and overdoses, opioids are linked to respiratory suppression, sleep apnea, bowel obstruction, constipation, serious cognitive problems, depression, apathy, hormonal changes (decrease in testosterone), a decrease in immune responses and an increased risk of falls and fractures, especially in the elderly. Thanks to Pharma's narcotics party, more than 17,000 people are dying in the U.S. every year from opioid overdoses and emergency room admissions for non-heroin opioids have leapt from 299,000 in 2001 to 885,000 in 2011. Poisonings from legal and illegal drugs now exceed car accidents in injury deaths.

But despite a near consensus among doctors and medical groups and public officials that narcotic painkillers are becoming a health catastrophe, the damage is not likely to end soon with Zohydro ER inexplicably approved this year and likely to become OxyContin 2.0.

Explaining the FDA's apparent nose-thumbing to patients and medical professionals in favor of Pharma, FDA spokesperson Morgan Liscinsky said, "Prescribers now have a hydrocodone option for patients who require an extended-release opioid." Most would say we do not need another opioid "option."

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