

# Virginia declares opioid addiction a public health emergency

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29 November 2016

Virginia's health commissioner declared last week that opioid addiction in the state is a public health emergency. She issued a standing order allowing any resident of the state to access naloxone, which can reverse the effects of an opioid overdose.

According to Virginia Health Commissioner Marissa J. Levine, three people die every day in the state from opioid overdoses, while 12 people are treated in the emergency room. The number of heroin overdoses in Virginia in the first 9 months of this year has increased 89 percent compared to the previous year.

In 2014, for the first time more Virginians died from opioid overdoses (728) than from car accidents (700).

According to the Virginia Hospital and Healthcare Association, between 2007 and 2015 there were 4,036 deaths in the state related to prescription opioid overdoses. Between 2011 and 2014, more than 1,300 babies in Virginia were born with neonatal abstinence syndrome due to the mother's drug use.

The declaration follows the release of a surgeon general's report that found one in seven Americans face substance addiction, but only 10 percent ever receive any assistance. According to the report, last year over 27 million people in the United States used illicit drugs or misused prescription drugs.

According to the Centers for Disease Control and Prevention, 61 percent of the 47,055 drug overdoses in 2014 were due to opioid use. That translates to an average of 78 opioid overdose deaths in the United States every day. This number has nearly quadrupled since 1999.

The number of overdoses and resulting deaths has worsened due to the use of stronger opioids, such as fentanyl and carfentanil.

Fentanyl, a synthetic opioid, is estimated to be 50 to 100 times as potent as morphine, according to the National Institute on Drug Abuse. The fast-acting nature of fentanyl increases the likelihood and lethality of overdoses compared to heroin or other prescription drugs.

Carfentanil, an analog of fentanyl, is a tranquilizer used for elephants and other large animals. It is 10,000 times as potent as morphine. The drug has never been tested on humans in clinical trials, so there is little known about the drug, including the lethal dose range. Drug users often mistake carfentanil for heroin or heroin mixed with fentanyl because of their similarity in appearance, heightening the danger of the drug.

Carfentanil-related incidents have been concentrated in the states of Indiana, Ohio, Pennsylvania, Kentucky and West Virginia, but also further south in Georgia and Florida. Incidents have also emerged in Virginia, according to the state's health commissioner.

The potency of these stronger opioids means that overdose victims typically require multiple doses of naloxone to be revived. They have

been at the root of the recent spate of overdoses in cities such as Huntington, West Virginia in August and Akron, Ohio in September.

A driving factor in the rise in opioid addiction and deaths from overdoses in the past 15 years is the increase in the number of prescriptions for opioid painkillers, such as oxycodone, hydrocodone and fentanyl—marketed as OxyContin, Percocet, Vicodin, Subsys, etc. Aggressive marketing by drugmakers has magnified the opioid epidemic, while at the same time enriching pharmaceutical companies.

Purdue Pharma, for example, encouraged doctors to prescribe OxyContin for all types of aches and pains, not just those associated with terminal illnesses. In order to distinguish the drug from cheaper, generic opioid painkillers, the company marketed the drug as providing 12-hour relief. When patients complained that the medication lost its effectiveness prematurely, Purdue encouraged doctors to prescribe higher doses for the same time interval—increasing the risk of addiction and overdose.

The drug became a blockbuster and placed the owners of Purdue, the Sackler family, onto Forbes' list of the 20 wealthiest families with a personal wealth of \$14 billion. The company, now based in Stamford, Connecticut, has opposed any attempts to place restrictions on prescribing OxyContin, while showering politicians with campaign cash.

Insys Pharmaceuticals, based in Chandler, Arizona, is the manufacturer of a rapid-acting version of fentanyl marketed as Subsys. The company is currently under investigation in more than 15 regions by state attorneys general, federal prosecutors and regulators over its business practices and marketing of Subsys.

In a 22-count criminal indictment filed in Mobile, Alabama against two doctors prescribing vast quantities of opioid painkillers, federal prosecutors allege that Insys effectively bribed doctors by rewarding them for writing large numbers of prescriptions for Subsys, prescribing a combined \$4.9 million worth of the drug, according to a recent article in the *Wall Street Journal*. An analysis of federal data by the *Journal* found that the top 20 prescribers of Subsys for Medicare patients in 2014 were also the largest recipients of consulting and other fees from Insys. Dr. Gavin Awerbuch, for example, a Michigan neurologist who recently pled guilty to prescribing Subsys for no legitimate medical purpose, wrote \$10.1 million worth of Subsys prescriptions for Medicare patients between 2013 and 2014, and received \$90,000 in fees from Insys from August 2013 through 2015.

Insys is run by billionaire John N. Kapoor. Prior to co-founding Insys in 2002, Kapoor gained control of LyphoMedi in 1987 through a \$50,000 investment. He quadrupled the price of the company's decades-old drug that was being used to treat AIDS, before selling the company in 1990, a sale that made him more than \$100 million.

Subsys, approved by the Food and Drug Administration (FDA) in 2012, was the company's first new product. The drug now captures half of the prescriptions for rapid-acting fentanyl. Since 2013, the company's revenue has tripled, while its profits grew by 45 percent to \$58.5 million.

"The drug's success," notes the *Journal*, "was underpinned by tactics that Dr. Kapoor used to great effect at his previous companies, charging high prices and employing a low-salaried, highly motivated sales force."

Since the launch of Subsys four years ago, Insys has more than doubled the price of the drug.

The company's 250 sales representatives focus on doctors who are the highest prescribers of fast-acting fentanyl. Sales reps are paid a low base salary, but have financial incentives to push doctors to prescribe the largest number of prescriptions, at the highest doses possible, through sales commissions.

According to the *Journal*, staff from the company's reimbursement center would often call up and lie to pharmacy benefits managers—for example, pretending to be from the office of the doctor that wrote the prescription, or lying that the patient had cancer—to ensure that Subsys would be covered by insurance, which generally limits coverage to cancer patients or requires patients to seek out a lower-cost alternative first.

And while some drugmakers have profited handsomely while contributing to the opioid epidemic, others pharmaceutical companies are intent on profiting from the crisis by jacking up the price of the drug used to treat opioid overdoses, naloxone.

Naloxone binds to the opioid receptors in the central nervous system, and is considered to be an "antidote" to opioid overdose. Discovered in the early 1960s and approved by the FDA in 1971, naloxone has few side effects and is included in most emergency responder kits. It is administered either through intravenous injection or a nasal spray.

"For people who regularly take opioids, including those who take the drugs as prescribed by the doctor for pain, having naloxone on hand can mean the difference between life and death," Phillip Coffin, M.D., the director of the Substance Use Research Unit at the San Francisco Department of Public Health, told *Consumer Reports* in September.

This past May, Politico broke the story on the dramatic price hikes on naloxone formulations. Drugmakers are increasing the price of a drug that has long been available at a low price, similar to the widely publicized price hikes of EpiPen by Mylan and Daraprim by Turning Pharmaceuticals. There are currently five different formulations on the market. The most common formulation of naloxone is made by Amphastar Pharmaceuticals, which in October 2014 raised the list price of its 10 pre-filled, 2-milliliter syringes from \$120 to \$330.

Likewise, Kaleo Pharma raised the list price for its two single-dose Evzio injectors from \$575 two years ago to \$3,750. Between 2005 and 2014, Hospira, now owned by Pfizer, jacked the price for two vials of its generic version from \$1.84 to \$31.66.

Mylan released an additional generic version in 2014, while Adapt Pharma's Narcan nasal spray was approved in 2015. The competition between multiple formulations, however, has done nothing to bring down the price.

Kaleo, for example, has used its price increases to help cover patient copays, which encourages patients to purchase more expensive branded drugs and ultimately drives up insurance rates. The only change made to the company's latest auto injector is the packaging,

which now includes voice-activated instructions.

The price hikes, moreover, have nothing to do with actual cost of manufacturing the drug.

"We're not talking about a limited commodity," Dan Bigg, the executive director of the Chicago Recovery Alliance, told *Business Insider* in August. "Naloxone is a medicine that is almost as cheap as sterile sodium chloride—salt water."

"This is an older generic drug on the World Health Organization's list of essential medicines. It costs pennies in other countries," Baltimore Health Commissioner Leana Wen, told *Consumer Reports*. "It's completely inappropriate and, frankly, shameful that we are faced with these rising prices in the midst of an opioid epidemic. No one should be dying because we can't afford this drug."

The price hikes are "not conscionable," Wen told *Politico*. "We have not been able to understand what is motivating them except for profit."

"One concern is that money for naloxone is coming out of the same pot as money for treatment and prevention," Alison Knopf, editor of *Alcoholism & Drug Abuse Weekly*, told *Stat News* this past summer. "The costlier it is, the less money for treatment and prevention."

While price hikes for pharmaceuticals are often cushioned through insurance coverage, the story is different with naloxone.

"In the case of naloxone," Daniel Raymond, policy director of the Harm Reduction Coalition, told CNBC in September, "when it's purchased directly by health departments, or community organizations or police departments, there's no buffer, they pay the whole cost, so any increase in price erodes their purchasing power, and they're either able to purchase fewer or they're gonna need to find additional dollars to keep pace with the demand."

The source of the drive by pharmaceutical companies to aggressively market prescription painkillers while at the same time hiking the price of the antidote to opioid overdoses, is the same one that lies at the root of the immense social crisis that is ultimately responsible for the epidemic of opioid addiction and overdoses, and the completely inadequate response to address these social problems: the profit system.

The complex interaction between personal and social problems, between brain chemistry and social conditions, the sense of desperation and hopelessness, the lack of social support and connection, all of the factors that come together to produce substance abuse, addiction and drug overdoses, in the final analysis, have their basis within a social system in which every decision is based upon the profit needs of corporations and where the vast majority of the population faces stagnant or declining wages, crushing debt and unrelenting economic uncertainty and austerity.



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