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Are prescription opioids increasing the addictive behavior and death rate in the United

States over the last 20 years?

By

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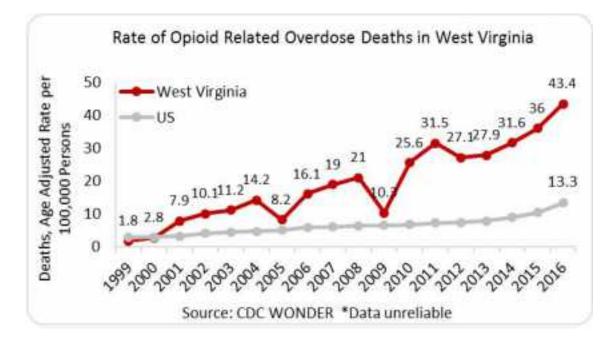
MASTER OF PHYSICIAN ASSISTANT STUDIES

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INTRODUCTION

The United States is in an opioid crisis. Of all the opioids that are marketed in the United States the most popular is Oxycontin, containing the active ingredient oxycodone, the chemical equivalent of heroin which is more powerful than morphine.¹ Along with heroin and fentanyl, Oxycontin has become one of the great killers of this era. It is estimated that in 2016 there were over 20,000 overdose deaths related to prescription pain relievers, as opposed to 12,990 overdose deaths related to heroin in 2015.² The state of West Virginia has been the one that has suffered the most. The rate of opioid-related overdose deaths in West Virginia, the state worst afflicted, has gone from 1.8 deaths per 100,000 in 1999 to 43.4 deaths per 100,000 in 2016. ^{3.} For the sake of mathematical exactitude this is a rise of 2400% in the incidence of opioid-related death in a single state, while the rest of the country's death rate has 'only' risen by 700%.³

This chart, compiled by drugabuse.gov in the state of West Virginia compares the numbers of



deaths in West Virginia to the overall average in the United States.

The population of West Virginia is just over 1.8 million. The people of West Virginia have suffered the greatest increase in opioid-related deaths. As long ago as 2004 Purdue Pharmaceuticals, which is the major producer of Oxycontin, agreed to pay the state of West Virginia \$3.5 million dollars to mitigate the effects of its aggressive marketing of the drug. That appears to have been a mild slap on the wrist for the company, which three years later agreed to pay over \$600 million in fines. These fines were assessed because the corporation's top officers were all found to have knowingly lied when they claimed that Oxycontin was less addictive than narcot-ics.⁴ Meanwhile, the Sackler family, which owns Purdue Pharma privately, is one of the wealthiest families in America, listed by Forbes magazine as the 19th-largest fortune in the United States at over \$13 billion. A fine of a few hundred million would hardly deter them from continuing the sale of Oxycontin, which accounts for billions of dollars in profits every year for Purdue Pharma.⁵

The people of West Virginia continue to suffer from this drug, and in disproportionate numbers. Just two small-town pharmacies in West Virginia were found to have been responsible for receiving and distributing over 20 million pills of Oxycontin over a 10-year period.⁶ This would seem to indicate that these two pharmacies were responsible for diverting the pills, since the local communities could not have supported that kind of volume of prescriptions. This would seem to beg the question: where are the regulators? This kind of dramatic rise in numbers, accompanied by a dramatic rise in overdoses would seem to indicate that opioids should be controlled much more carefully, at the very least.

But pharmacies do not dispense opioids without prescriptions. That means that these drugs are being prescribed at abnormally high rates. Taking into account that many doctors and companies were very aggressive in certifying that this entire new class of opioids, including Oxycontin, Oxycodone, and others, were not addictive. By the time the regulators got to them and demanded some restitution, it was too late. The manufacturers of these drugs, along with the complicity of many doctors and pharmacists, had gotten so wealthy that they were able to buy themselves out of trouble by paying fines. Very few of the manufacturers faced any serious penalties, or at least any penalties severe enough to put them out of business.

Intervention: uses and effects of Oxycontin

Oxycodone, the active ingredient in Oxycontin, is classified as a prescription opioid analgesic and it is used to treat pain. It is described as having a high potential for abuse. This is due to the euphoria experienced by early users. When snorted or injected the effects are faster and more potent than when taken in pill form, and this form of abuse has become widespread. While it is effective in treating pain, one of its properties is that it affects brain chemistry in a powerful way. Oxycodone use has been found to be associated with kidney and liver failure, as well as a reduction in the brain's ability to adapt to new input, which may account for the shift from controlled to compulsive use.³ This property - reducing the brain's ability to adapt to new input makes the drug much more likely to be abused. This is the basis of many of the lawsuits that Purdue Pharma and other manufacturers have faced and are facing. They have been accused of understating the addictive quality of the drug despite evidence that they knew of its addictive properties. The numbers bear this out. In a study of the treatment of patients using opioids compared with people who were treated without opioids, there seemed to be a small increase in the number of people who were successfully treated with opioids. Estimates of continuing established therapy without opioids, in which 448 per 1000 people were treated. With opioid therapy, 560 per 1000 people treated. This shows a slight but significant increase in the number of people who

were treated successfully for pain with opioids.¹ That is, opioids are effective, but the question of whether they are effective enough given their terrible rate of addiction and overdose remains open.

Though this is not the usual way of dealing with the intervention aspect of a drug and its effects, it may be useful to consider at this point that intervention should be treated as a more comprehensive rubric than it has been to date. That is, intervention should imply an examination of the entire chain of production and distribution, including prescriptions. If there were some penalties for doctors for over-prescribing these drugs, it may be possible to attack the most immediate source of the problem, which is bureaucratic. Pharmacists can point to the prescriptions as being the enabling agent in their own participation in the chain of distribution. If there were fewer prescriptions, there would, at a minimum, be fewer overdoses. But since there are no real penalties at any point in the chain, intervention becomes a last resort rather than a tool that can be used to identify and treat the problem. In this case the bureaucratic/political problem is clearly the source of the addictions and overdoses that have been going in West Virginia. Without administrative or political tools with which to deal with it, the entire problem becomes an exercise in catch-up, or chasing the problem without really being able to provide a solution.

Comparison Group

Other states have opioid problems similar to West Virginia's, but for comparison it is useful to measure West Virginia's rate with the rates of the states which have not had epidemics. Two states with smaller populations are the ones reporting the lowest opioid-related deaths, Nebraska and Montana. The rates in those states declined in the past two years, as opposed to West Virginia's rates, which went up 23% from 2016-17. More significantly, and strangely, are the next two lowest-reporting states. They are California and Texas, the two most populous states, according to the official US census. They each reported rates of 4.9 deaths per 100,000 people. West Virginia's rate is 43.4 deaths per 100,000 people.^{2a} This seems counter-intuitive, yet it is true.

The implications of this are very powerful. How is it that West Virginia, with a much smaller population, has such a greater rate of overdoses and deaths? To find the answer it may be necessary to go beyond the normal range of scientific investigations. There is something going on here that belies a scientific explanation. Are people in West Virginia in more pain than in other states? If so, what is the source of the pain that seems to have engulfed the state? Are there activities going on in West Virginia that are somehow more physically taxing than they are in other states? There appear to be none, leading to the conclusion that West Virginia's problem of lax regulation and poor oversight must be the source of the problem. That would imply that another form of intervention than scientific/medical is needed.

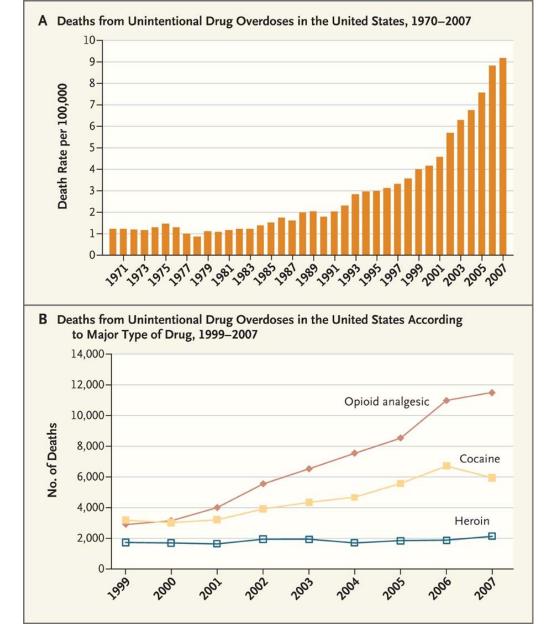
Outcome

The outcome of the opioid epidemic is tragic. Led by Oxycontin the United States has, in the last twenty years since the drug was introduced, fallen into a massive opioid epidemic. It has been estimated that the cost to the economy is over \$500 billion, and that is just in the next two years.¹² The deaths from this epidemic now total over 48,000 per year in the whole country. In West Virginia this amounts to nearly 1000 deaths a year from opioids alone, with the principal delivery vehicle being Oxycontin. Opioids, overall, were involved in over 42,000 deaths in 2016, five times higher than in 1999.¹³ This is an enormous increase over time. In West Virginia alone the number of deaths from May 2016 to May 2017 increased by more than 25%. ¹³ The problem was terrible, but it has recently gotten much worse in West Virginia. The small fines paid by the drug manufacturers have so far been a very insufficient amount of money considering how much it will cost to clean up the disaster that has been caused. That is why many municipalities and states are now joining together in a concerted legal effort to hold many of these manufacturers accountable, including Purdue Pharma. But if the past is any indication it does not seem that this will stop the flow of oxycodone and other opioids in the United States. Time

The timelines referred to here demonstrate that this is not an organic problem. The numbers continue to skyrocket. Since 2000 the rate of drug overdose deaths has increased by more than 100%.¹⁰ The spike and steady growth of the number of opioid-related deaths are related not to any existing environmental issues, or the presence of a new source of pain in the form of a biological issue, nor any possible relationship between some new industrial process and the workers who are apparently affected by them. Instead this problem has shown itself to be driven entirely by a marketing strategy for a class of drugs developed after years of research and development by at least one major pharmaceutical manufacturer. The adroit manipulation of the system of checks and balances, testing and research, and most significantly of the political system by the Sackler family would point to a shrewd group of people maximizing their profits in time-honored capitalist tradition. The unfortunate side-effect of this successful marketing campaign, from the point of view of the public relations of the company, is that their product kills people. Much energy and money has been spent by the Sackler family (and other manufacturers) to avoid any responsibility for this, which in the face of the overwhelming scientific evidence can only be seen as a cynical attempt to maintain their market share at the expense of thousands of deaths and millions of cases of addiction. Again, this is not a casual charge. The numbers as long ago as 2007 demonstrated a steep rise in deaths, each one of which represents many more people addicted.

That means that it has been well-known to the authorities for years that the current system of Risk Evaluation and Mitigation Strategy (REMS) could not keep up with the problem. This escalation is correlated with the 10-fold increase in the medical use of opioids since 1990. This has been led by the aggressive marketing of OxyContin, which was approved in 1995, and clinicians were encouraged to become more proactive in the treatment of chronic pain.¹¹ The blandness of the language used here shows that efforts to identify and treat the actual issue are far behind where they need to be to actually grapple with this public health crisis.

This problem has been brewing for many years, and it has its own political protection now. The issue is not likely to go away soon, since the pharmaceutical manufacturers have little incentive to cut off their own profit stream. That means that until there is concerted political. action taken, in the form of a much more rigorous oversight of the distribution of these very dangerous drugs nationwide, there will continue to be mounting numbers of deaths from opioid-related prescription drugs



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Source: National Vital Statistics System, Centers for Disease Control and Prevention.

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