The FDA Caused the Opioid Epidemic by Banning Pp

Dr. Warren Albrecht

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Mark Thornton, of the Mises Institute, points to the Iron Law of Prohibition as a contributor to the opioid problem. Any prohibition will cause a switch from lower potency of drugs to higher potency. Examples are states with cannabis legalization who have fewer overdoses. But what if a good, middle of the road potent drug was removed from the options leaving the only low strength and high strength medication? When the FDA removed Propoxyphene (Pp), most commonly known as Darvon or Darvocet from, the market, they caused the opioid epidemic in 2010. A snowball effect began.

FDA's error

The New York Times reported in 2010 about the FDA decision to remove Pp from the market. The FDA initially describes Pp as a mild to moderate pain reliever, which they approved in 1957. The concerns for Pp were the possibility of poor effects on pain control, as well as new findings of potential heart complications. Per the FDA,

Because the elderly and patients with renal insufficiency have a reduction in the clearance of propoxyphene and its cardioactive metabolite, norpropoxyphene, through the kidneys, these populations can be especially susceptible to proarrhythmic effects of the drug.

At the time, 10 million Americans used Pp. Britain placed a ban on Pp in 2005 and the European Union in 2009, absent of the cardiac concerns. Eventually, the FDA voted to remove the medication from the market after 50 years by a slim 14-12 vote.

Consumer Reports in 2010 reported

The FDA noted that propoxyphene had been associated with more than 2,100 reports of serious problems—including suicide, overdose, cardiac arrest, and death—since it was first launched in 1957.

Consumer Reports then went on to recommend codeine, morphine, and oxycodone: today's stronger category of pain medications and drugs of the current epidemic.

FDA chose opinion over science

In 2006, the far left consumer group Public Citizen (PC), petitioned the FDA to begin a phased removal of the drug propoxyphene. Ralph Nader co-founded Public Citizen. In the petition, PC referenced an article in the Journal of American Medical Association (JAMA) critically reviewing Pp. PC also referenced testimony from the Testimony before the Select Committee on Small Business, U.S. Senate, discussing Competitive Problems in the Drug Industry in 1979.

From the testimony, I found and reviewed both the article and quotes within the petition. These look at the concerns and benefits of Pp. One physician points to a concern about the drug's involvement in a high number of deaths. However, PC leaves out that the physician recorded over 3/4 of the deaths as suicides. Also, the JAMA article looks at cancer pain, which is usually severe. Many articles refer to Pp as a mild to moderate pain medication.

The Reality of Propoxyphene

I prescribed this medication routinely for post-operative care during my residency and my first years of surgical practice. I wrote hundreds of prescriptions. Anecdotally, I never had any patient die of unusual sudden cardiac death. I rarely saw the need to use more powerful pain medication like hydrocodone or oxycodone. But today, these are the go-to post-operative medications.

I performed a Medical Literature search from 1960 to present-day looking for articles reviewing Propoxyphene. From the 1970s through 2010, journal articles, medical examiner and coroner reviews for causes of deaths, and comparisons to Tramadol and Methadone were reviewed. In comparison to all the issues of currently used opioid medications, there is no reason for the FDA to remove Pp from the market. The FDA removed this medication under the misguided belief that there were better and stronger medications.

Specific efficacy studies comparing modern opioids to Pp would not be done since Pp is 50 years old. The cost alone makes that unfeasible. Ely Lilly, the original patent owner, ceased marketing the generic form in 2010. The number of prescriptions, as well as its years of presence in the market, show that a great number of physicians and patients see this as a worthwhile drug.

Public Citizen Activision, not Science

It is important to note that Oxycodone was not marketed to the public in 1979 when the Public Citizen evidence against Pp was published. PC does not understand, nor do they care about, treating different types of pain. Also, PC did not care about how losing a low cost mild to moderate generic analgesic that was on the market for decades with no obvious evidence of acute sudden death would result in changing abuse and market forces. 50 years of Pp's presence on the market does not correspond with acute sudden death. PC's claim that any increase in drug use is multifactorial in society and cannot be stopped by banning one drug simply makes no sense.

Another aspect missed by both PC and the FDA is that since 1957 many "opioid" deaths were recorded as accidents, supposedly illustrating an epidemic. However, no attorney decided to sue any pharmaceutical company. That would be a rainmaker lawsuit waiting to happen.

Regulation-by-Litigation

As the Wall Street Journal reported in 2018, President Trump entered the opioid debate by asking Attorney General Jeff Sessions to consider the possibility of bringing a lawsuit against the Drug Companies which make the pain killers in question.

The National Review compares this attempt by Trump to the big tobacco lawsuits of the 1990s. Unfortunately, no good will come of this.

The New York Times documents the paucity of dollars used from those tobacco settlements to reduce any tobacco use. The usual case of government waste and monetary abuse are evident in the results from these settlements.

The FDA is to assist congress with relevant data to be able to regulate any medicines. However, I point to the fact that the FDA is guilty of poor data interpretation and therefore, is guilty of poor decision making.

"More Restriction, More Deaths"

Cato research supports the theory of "more restriction, more deaths". In a comprehensive review of the literature looking for the causes and asking appropriate questions, the authors took on 3 basic claims.

One, the fact that long-term use of opioids causes addiction, or an epidemic needing intervention from the FDA, is not substantiated in the literature. Two, the claim long-term use or addiction causes more overdoses does not stand. Three, looking at the statistics documented, the literature may not be accurate.

FDA as Cause. Cato Agrees?

In the Cato article, many deaths are multifactorial. Also, it is important to note that many cases have multiple drugs involved. However, if opioids are detected, then "opioid overdose" is listed as a cause of death. In the article, both the CDC and the DEA acknowledge the fact that that the of the mixing of illicit drugs makes classifying the exact cause of death difficult. Therefore, overdose statistics may overstate the prescription opioid as an etiology for death, which leads to the FDA's misconception of an epidemic.

A statistic that is left out of Public Citizen's propaganda, but is reviewed by Cato, is the nonmedical use of pain relievers. Specifically at the time in 2010 when Pp was removed from the market. In all age groups, nonmedical use of pain relievers was already stable to decreasing, even with the increase in prescriptions. Therefore, the increased number of opioid prescriptions did not influence addiction or deaths. Finally, we see the concern about the number of prescriptions compared to an increased number of opioid deaths, constituting an epidemic, is not supported and documented in an article graph.

Drug Marketing and Writing Prescriptions are not the cause

Unfortunately, in his article Mark Thornton also points to causes that include marketing by the pharmaceutical companies. Though there have been fines, this is a false reason. Heritage Foundationalso fell for this into this trap. Also, the Brookings Institute wrote about much of the trouble using any data including marketing or prescriptions to confront the opioid issue.

In an article reprinted at American Enterprise Institute, Sally Satel M.D., an addiction Psychiatrist, wrote with her co-author, that limiting pain prescriptions are harming patients.

The number of opioid prescriptions written by health care providers has fallen since 2011, and the number of high dose prescriptions… fell 41.4 percent from 2010 to 2015.

In a second article, Satel deconstructs the anti-prescription narrative in Politico, reprinted for the AEI,

The latest numbers from the Centers for Disease Control and Prevention show fatalities spiraling up to about 42,000 in 2016, almost double the casualties in 2010 and more than five times the 1999 figures.

This supports the interpretation that as the Pp was removed from the market, then the opioid epidemic developed and now continue to worsen.

However, in another Mises article Mark Thorton may be on to something. The cronyism between large companies and the federal government may have been related to Pp prohibition.

Essentially, the pharmaceutical companies bribe medical researchers, doctors, and health bureaucrats to recommend to authorities such as the FDA to promote the use of drugs such as Oxycontin and Vicodin, instead of less powerful and less addictive alternatives that were used in the past.

FDA uses Fake Data

The World Health Organization documents that from 1999 to 2015, 183,000 people died from overdoses related to prescriptions of opioid medications. Oddly, only uses one year of prescriptions, 2012. In this year, 250 million were written, which the WHO states are too many. But this works out to 0.07% deaths per prescription written only using one year of prescriptions written. That is 1/700 percent risk of death. This percentage drops significantly if the total number of prescriptions written for the years 1999-2015 is used.

The Public Citizen (PC) petition to the FDA used a 2,110 accidental death rate from the years 1981 to 1999, 18 years. That is 0.000092 percent death per prescription written using only 2004 as PC documented in the petition.

After the FDA decision in 2010, Dr. Sidney M. Wolfe, Director of Public Citizen, thereby called for a Congressional inquiry because of the slow progress of the FDA on the Pp "opioid epidemic" matter.

"I would have praised them if they had done this six years ago," Dr. Wolfe said, "but it's hard to praise them when there have been 120 million more prescriptions filled since 2005 and conservatively 1,000 to 2,000 more deaths. It's inexcusable."

That is 16 deaths per one million prescriptions. None of these were documented sudden cardiac or specific medication complications. Abuse and suicide would remove the majority of these numbers.

Results of the FDA Today

In the United States during 2017, deaths included 14,495 from oxycodone and hydrocodone type medications, 28,466 from fentanyl and tramadol type medications, 3,194 from Methadone and 15,482 from heroin. This dwarfs any concern raised for Pp. However, the FDA is not raising any concerns over these types of opioids. In comparison, 2017 records that there were more than 40,000 deaths related to motor vehicle accidents.

The World Has an Opioid Problem

The people of the world have always found means of euphoria through many types of drugs. For the 50 years, Propoxyphene was on the market until the time of its unfortunate prohibition, legal and illegal means of obtaining some sort of euphoria continued. If Pp was still on the market, you would see a split in the numbers of opioid prescriptions with Pp being a common, short term pain medication for procedures with oxycontin or hydrocodone for stronger needs.

The so-called opioid problem is a multifactorial drug abuse problem in which the war on drugs has failed, government entities such as the FDA escalated, and current regulation is a political band-aid. Bring back Propoxyphene. Let us truly discuss drug addiction as a humanitarian issue, not a political one.

In 2013, Public Citizen called for more restrictions to pain medications. This time hydrocodone because of the large number of prescriptions written.