Opioid Policy Solutions: Administrative Law, Legislation, and Constitutional Reform

Trevin Stevens
Opioid Policy Solutions: Administrative Law, Legislation, and Constitutional Reform

By
Trevin Stevens

Honors Thesis

Submitted to:

Jepson School of Leadership Studies
University of Richmond
Richmond, VA

May 3, 2024

Advisor: Dr. Jessica Flanigan
# Table of Contents

Opioid Policy Solutions: Administrative Law, Legislation, and Constitutional Reform  1  
Preface  3  
Introduction  4  
**Brief 1: Pharmaceutical Marketing and Constitutional Reforms**  8  
Introduction  8  
Background on Direct to Consumer Drug Marketing  9  
Background on Physician Prescribing Practices  17  
Previous Rulings on Commercial Speech in Healthcare  23  
Regulation of Tobacco Marketing  28  
FDA/DOJ Authority  29  
Suggestions for DTC Marketing Restrictions  32  
Suggestions for Physicians  34  
**Brief 2: Analysis of Administrative Law regarding Labeling**  37  
Introduction  37  
Background on Labeling  41  
Suggestions on Labeling  53  
Limitations  57  
Conclusion  59  
**Brief 3: Proposing State and Federal Policy Reforms for Drug Diversion and Misuse**  61  
Introduction  61  
Background Information  62  
Notable Research by Public Health Officials  73  
Case Study: Drug Diversion and Misuse with OxyContin  76  
Drug Diversion Policies by State  80  
  Doctor Shopping Laws  82  
  Prescription Drug Physical Examination Requirements  83  
  Regulation of Pain Management Clinics  83  
Suggestions  84  
Challenges  87  
Conclusion  88
When coming up with my honors thesis topic, I knew I wanted to write about the pharmaceutical industry and the failures of leadership involved. Initially, I thought I was going to write about Martin Shkreli who has been in the headlines quite a bit, including for his ban from the pharmaceutical industry. But after watching Painkiller, a documentary about the birth of the opioid epidemic, I knew this was what I wanted to write about. The documentary goes into grave detail, allowing for a look into the individual lives that were forever changed by OxyContin. It also sheds light on the influence of pharmaceutical companies on healthcare policies, including marketing and drug diversion. Some criticize the documentary for being too critical of the industry, but it paints a pretty detailed picture of what was going on at the peak of OxyContin.¹ The documentary made me very angry, and after doing more research, I found that the failures that cost people their lives were not just the fault of pharmaceutical companies but a failure of the government as well.

The opioid epidemic resulted in an extreme amount of overdose deaths and devastating effects of addiction. One of these victims was Bryan Nelson, who died from an overdose at age 20 after being prescribed OxyContin to treat pain caused by a car accident. Kara Trainor’s son was born addicted to OxyContin, and she is in recovery. Brian Bishop died at age 45 after being prescribed OxyContin after a construction accident. Tiarra Renee Brown-Lewis died at age 28 after being prescribed for her pain as a result of sickle cell disease. Paige Mazurek was prescribed OxyContin for a root canal, but this started the chain of addiction, which led to her untimely death at 22.² There are thousands of stories just like these, stories that family members live on to tell in courtrooms as the Sacklers face civil liability. All the money in the world is not going to bring their family members back.

---
I believe untimely death should be a major policy priority for utilitarian reasons. Death creates a loss of your ability to experience pleasure and happiness. It also limits the ability of the individual to contribute to society through relationships and work, creating an economic void. Lastly, these overdose deaths are highly traumatic for family members. Family members often find their loved ones in this state, which creates psychological harm that they have to live with for the rest of their lives. Many of these individuals have spoken about this emotional experience in the court proceedings against the Sacklers. For all of these utilitarian arguments against death, it follows, in my opinion, that paternalism is necessary to prevent people from ending up in this state. The goal is to increase happiness and healthy living by any means necessary. We should restrict people from engaging in actions that are inherently harmful to them. As I will discuss, individuals do not have all of the required information to make informed decisions. Therefore, it is okay for the government to take a stand in the name of well-being. Long-termism is essential, and the healthcare system should preserve this by following the Hippocratic oath.

Introduction

The opioid epidemic became a problem because of overprescribing, misleading marketing, and a lack of regulation on the part of the government. The public felt the pressures of addiction through economic and social costs on communities. The healthcare system was strained, crime rates were driven up, and families were broken by job loss and death. My goal with this project is not to solve the problem of OxyContin and the opioid epidemic but rather to learn from it to make sure something like this does not happen again. There is an ability to prevent an OxyContin 2.0, and that stems from significant policy reform. The goal of this policy analysis is to suggest paternalistic policies that are politically feasible. This is not meant to be an ideological policy proposal. Neither Democrats nor Republicans are paternalistic and there are flaws in both perspectives that can be reconciled in this policy plan. Republicans are too concerned about free speech to allow for proper regulation of the industry. Democrats
are too libertarian on drug use and give too much power to the people. In Oregon, decriminalizing drugs resulted in a tripling of opioid deaths between 2019 and 2022, with many deaths being attributed to fentanyl usage. This uptick in deaths has caused the state government to recriminalize possession of small amounts of heroin and fentanyl.\(^3\) Neither side is paternalistic, and neither side uses a utilitarian lens to craft policy. Public officials should be paternalistic to ensure that the public good is protected. The medical system is rooted in the Hippocratic oath, preventing people from being exposed to harm. Having paternalistic healthcare policies regarding pharmaceutical practices is a step toward avoiding harm. Many of the policies I lay out make decisions for patients, but this is a necessary tradeoff to creating a utilitarian society where people are protected from harm.

Having proper solutions will limit the economic and social burden on the healthcare system and allow for resources to go to where there is need. Just 18% of Americans have a positive perception of the pharmaceutical industry, a record-low.\(^4\) The pharmaceutical industry is the only industry to have a lower popularity than that of the federal government. Good policy can start to bring back trust in the industry. Good policy would solve the ethical failures of the system that allowed for OxyContin to get out of hand. First, policies should address the aggressive marketing tactics that companies use with both patients and physicians. Physicians saw their integrity compromised by the motivation of profits. Purdue should never have been able to target vulnerable populations with their marketing tactics, which they did intentionally. Purdue did little to address potential risks of OxyContin until it was circulating through communities. Purdue was eventually held responsible both criminally and civilly but this did not bring back the people that had died of an overdose. The biggest ethical failure was the negative consequences on communities. The issues with OxyContin contributed to widespread addiction, overdose deaths, and social upheaval, underscoring the profound ethical failures of Purdue Pharma and other parties involved.

---


Deeper analysis shows pharmaceutical companies are not the only ones to blame. Pharmaceutical labels are far too complex for the patient to feel like they are giving informed consent. Patients should be empowered and they are not being empowered with information that is not accessible to them. There are legitimate concerns about drug diversion and misuse. Physicians let so much OxyContin into the market that some patients sold and misused. No one is completely innocent in this situation which is why the policy should be multifaceted. Autonomy in the healthcare industry is extremely important and the system should be patient first. At the same time, an unregulated system puts too much faith in those who are not experts in the field of medicine. Good policy will be paternalistic but it will not go so far that it is politically unacceptable under the legal context of the First Amendment. It is important to have tradeoffs between paternalism and autonomy. Patients should be empowered in terms of obtaining more knowledge about medication but this information should be truthful. Ultimately, public officials should be working to maximize the good of society and this can entail making decisions for people to protect them from potential harms from pharmaceutical companies who may not be acting in their best interest. The ethical failures of the opioid crisis cannot retroactively be solved but it is extremely important to prevent this from repeating itself in the future.

In these three subsequent theses, I address three different areas of pharmaceutical regulation that are currently not paternalistic enough which is creating an environment that is not utilitarian, resulting in death and destruction. First, I address pharmaceutical marketing, both to patients and to physicians. I write this as an amicus brief, addressing potential jurors who may rule on a commercial speech dispute between the federal government and a pharmaceutical company. I refer primarily to court rulings on commercial speech to make the argument that paternalistic policy can work to prevent these anti-utilitarian harms while still abiding by the Constitution. Next, I address pharmaceutical labeling policy which is far too complex for the average person to understand. I consider medical journals and social science literature to analyze existing federal policy and the ways that it is falling short. The federal government can do more to regulate pharmaceutical labeling in a way that looks out for
people and shields them from complex medical information that they are unable to understand. I also lay out information about Purdue Pharma and their labeling process to show that the current policies are leading to societal harms, being death and economic burden. Within this brief, I suggest policies that are not subjected to electoral oversight and rather than be laid down by the executive branch of the federal government. Lastly, I analyze drug diversion and drug misuse policies. My goal with this policy brief is to persuade lawmakers to adopt more paternalistic policies to once again protect this public good. People should not be free to use drugs as they see fit, the government should do more to maximize overall well-being. With this brief, I include a lot of news articles detailing the metaphorical and tangible costs of our society being overrun by addiction and overdose. My goal is to create legally feasible policy reforms that protect the American public from the societal destruction of well-being that results from a drug crisis. These policies weigh concerns of constitutional viability while doing what government and the healthcare are supposed to do, serve the interests of the public.
Brief 1: Pharmaceutical Marketing and Constitutional Reforms

Introduction

In January 2022, 26 individuals impacted by the opioid epidemic, coming from 19 states, were invited to attend the virtual bankruptcy hearing for the Sackler Family, the owners of Purdue Pharma. The Sacklers had to watch as family members spoke on behalf of their lost loved ones, calling the Sacklers murderers, drug dealers, and abusers. People going through addiction recovery lost their marriages, houses, jobs, and even their lives. The victims range from Marines to doctors to firefighters, people from every socioeconomic class and race. More than 140,000 people have filed legal claims against Purdue but they have not gotten as much public attention as the aggregated lawsuits filed by cities, counties, tribes and states. These lawsuits held the Sacklers civilly liable for Purdue’s deceptive practices that they used to obtain $10 billion in profits for OxyContin alone. The way they marketed OxyContin was extremely creative, for example, hiring young women to seduce doctors, but this also started the trickle down effect that eventually resulted in the deaths of hundreds of thousands of Americans.

My goal with this brief is to analyze current marketing policies both in the way that pharmaceutical companies market to consumers as well as how they market to physicians and propose policies that maximize well-being by limiting overdose-related psychological and economic harms. A lot of the information laid out analyzes legal cases as well as law review articles because constitutionality is a major barrier to regulation of

---

commercial speech. There is a tension in values here between paternalism and autonomy. However, there is a way to bridge the gap to create informed consent. Paternalism is important for the healthcare industry, there is no way for patients to fully have a say in what is going on because that would eliminate the role of the healthcare professionals. However, patients should be receiving truthful information that is made for them as a target audience. There is plenty of information that only needs to be given to physicians but the current system of marketing to consumers is overly positive and does not give patients a proper insight into risk. This deception runs counter to a utilitarian society because hiding the truth limits social cohesion and may lead people to act in ways that hinder their well-being because they are not properly informed. The policies laid forth are guided by evidence from studies by healthcare professionals that express concerns in the current system and the way it does not look out for the average person. Paternalistic marketing policies are the way to maximize utilitarianism.

**Background on Direct to Consumer Drug Marketing**

In this section, I will lay out evidence from healthcare professionals that considers utilitarian concerns and examines the practices that are in place. In this section, I will show how current policies on DTC are not paternalistic enough and allow for too much unfiltered commercial speech from pharmaceutical companies to the government. Later, I will argue for reforms to create a more paternalistic system that preserves the utilitarian considerations of protecting consumers from information that may harm them.

There are two countries in the world that allow pharmaceutical companies to directly market to consumers: The United States and New Zealand. The argument for this practice is that it allows consumers to have a more equal relationship with physicians because they are educated on potential treatment options. For example, Pat

---

Kelly argues that DTC’s benefits outweigh its imperfections because it empowers patients to take a greater role in their healthcare, persuades hard to reach patients, and improves compliance with treatment regimens. Proponents of DTC, such as Eugene Volokh, see information in pharmaceutical advertisements as truthful speech that advocates lawful conduct. However, in the United States, DTC has created the potential for misinformation to be spread, underemphasized treatment risks, and promoted drugs over healthy living. For example, certain drugs that are advertised on television are being used for weight loss rather than for their original intention, which has caused a shortage in the market.

In my opinion, the FDA oversight system is not doing enough to prevent incorrect claims from slipping through the cracks. Public health experts Natasha Parekh and William H. Shrank argue protocols “are not prescriptive enough in terms of the extent and format by which quantitative benefits and risks should be present.” Parekh and Shrank believe that it is not surprising that quantitative information is lacking because this information is not explicitly required. Additionally, FDA enforcement of rules for DTC advertising has been weakened by increased bureaucratic procedures. A study by Klara et al. shows that 26% of advertisements provided quantitative information for efficacy and benefit, 0% provided quantitative information on risks, and 13% promoted off-label use of medications (which is banned by the FDA). The lack of required quantitative evidence opens the door for pharmaceutical

companies to promote their products in deceptive ways. Major pharmaceutical companies have launched multi-million dollar marketing campaigns and have used all sorts of mass media promotion. A majority of marketing will be targeted towards doctors but millions of dollars are spent each year to market to consumers as well.  

From 1997 to 2016, medical marketing expanded substantially, and spending increased from $17.7 to $29.9 billion, with direct-to-consumer advertising for prescription drugs and health services accounting for the most rapid growth, and pharmaceutical marketing to health professionals accounting for most promotional spending. More money being spent on marketing has driven up drug costs and caused less attention to be directed towards future creations. In 2013, Johnson and Johnson spent $17.5 billion on marketing but just $8.2 billion on R&D.  

There are instances where pharmaceutical companies make false claims about benefits and risks of their products based on manipulated data. The government has come down on these companies for violating the False Claims Act. For example, Pfizer was fined $2.3 billion for false promotion of several drugs. Deception as a marketing practice is seen as wrong under the False Claims Act but the FDA only handles these issues after drugs circulate through the market. Patients can sway their physicians to prescribe a particular medication when requested. There are studies to back this claim up. One study found that 77% of patient medication requests were honored but 49% of the fulfilled requests were deemed to be inappropriate. If the patient has received incorrect information from an advertisement, they may have leverage to go to another doctor that will comply and prescribe a drug that they do not need or that puts them at risk.

Pharmaceutical companies were always able to market directly to consumers and they certainly did so. However, the structure changed in 1997 when the FDA undid regulations that required advertisements to include the entire brief prescribing information. With this change, pharmaceutical companies only had to mention the main side-effects and give a website, phone number, or other mechanism to get more information.\(^\text{20}\) This loosening of regulations generated an immediate response: In the four-year period from 1996 to 2000 promotional spending on direct to consumer advertising within the United States tripled (from $791 million dollars to $2.5 billion dollars).\(^\text{21}\) While there is evidence that direct-to-consumer advertising may improve health outcomes\(^\text{22}\), it increases taxpayer, insurance, and individual costs.\(^\text{23}\) The heavy costs of DTCA for pharmaceutical companies contribute to higher drug prices and are a hurdle for market entry of new competition. Increased demand for medication drives up the price as pharmaceutical companies have oversight on pricing. Revenue from DTCA creates a conflict of interest for media companies, because such advertising can undermine the media’s freedom to report critically on the drug industry.\(^\text{24}\)

Pharmaceutical companies have capitalized on looser policies that grant these companies freedoms. In 1997, when the FDA instituted their new policy, their justification was that advertisements could now be more open about what products treat and create more consumer awareness. But at the same time, pharmaceutical companies were given more power and could use this to “promote new, expensive products that might not work as well as older, less profitable drugs.”\(^\text{25}\) This focus on

---


marketing to consumers distracts from the focus on research and development of new medications.

Maguire (1999) suggests that American physicians are being asked to ‘rubber stamp’ self-diagnoses and self-prescriptions by patients. If the doctors do not give the patients what they want, they will lose their business. If one doctor didn’t honor a request, then patients could just go to different doctors to get what they wanted. With so much market pressure from patients, doctors care about keeping their business and will honor their patients’ requests. This is a process known as doctor shopping, defined as seeing multiple treatment providers, either during a single illness episode or to procure prescription medications illicitly. According to the available literature, prevalence rates of doctor shopping vary widely, from 6.3 to 56 percent. Physician attitude was determined to be one of many factors that motivated doctor shopping.

If they don’t want to go to doctors or their doctors will not give them what they desire, consumers are able to purchase all kinds of prescription drugs online often without need for a prior prescription. These drugs come from other countries in many cases. A lot of times, the first exposure consumers have to the medication is through online advertisements or television commercials. In my opinion, they should be learning about treatments from doctors who are the ones tasked with determining what is wrong with someone and coming up with a remedy to make the person feel better. The risk with information coming unfiltered to consumers is rooted in potential false claims. A study found that the FDA filed violation notices in one in four products that were supported by direct to consumer advertising. In many cases, companies overstated the effectiveness of the drug or minimized its risks. The notices oftentimes come after the damage has already been done.

---

Social media is another way that pharmaceutical companies can market to consumers. Some companies that have used social media advertisements have not been providing proper links to information regarding risk which has been subjected to FDA scrutiny. For example, third-party Tiktok advertisements for Ozempic ignored discussion of side effects or downplayed the issues they were causing. Social media messages can also get twisted by third parties in a way that deviates from the intended messaging of the manufacturer. Similar problems to the issues raised when it comes to television advertising exist and are even exacerbated by the lack of regulation of social media. Misleading advertising leads to unrealistic expectations of the product. Patients may abuse the medication if they are not receiving their preferred outcome.

Advertisements often do the bare minimum to educate consumers about risks of taking a particular medication and focus mostly on benefits. If you fall into a particular category of people that cannot take a certain medication, you may not properly get this information from a commercial. This is because advertisements have become more positive over time. The portrayal of endurance increasing as a result of medication use (eg, showing a character being able to go to work, participate in family activities, etc) nearly doubled in the 2016 sample (23.5%) compared with the 2004 sample, indicating a further broadening of claims that the medications can help with patient’s daily tasks and responsibilities. This has directly been correlated with a decrease in the percentage of ads conveying information such as risk factors. The FDA has been caught up in bureaucratic red tape so misleading advertising has remained on air. In recent years, there has been a reduced number of warnings issued after the Department of Health and Human Services started to require “all regulatory warnings to be reviewed by the Office

---

of Chief Counsel." This has caused some regulatory warnings to be sent long after advertising campaigns have already ended.

Lying about risks is clearly a major issue, the clearest example of this was the case with OxyContin. The marketing of OxyContin by Purdue Pharma followed the same general pattern of problematic marketing to consumers. Purdue Pharma displayed pain-related information to consumers through websites, and it also sponsored painfullyobvious.com, which discusses the dangers of abusing prescription drugs. But while Purdue was trying to limit the abuse of prescription drugs, they were also lying about how addictive OxyContin had the potential to be. Purdue kept citing the common claim of Porter and Jick that the risk of addiction was less than one percent. In brochures and videotapes to patients and its “Partners Against Pain” Website, Purdue claimed that the risk of addiction from OxyContin was extremely small. They knew this was a lie, Purdue knew in the first year of OxyContin’s introduction to the market, that there was “significant” abuse of the product.

Through their marketing to consumers, Purdue played a major role in shifting the narrative around pain. Pain was no longer seen as something to ignore or to try to get through. Patients were encouraged to go see physicians to get their pain treated and physicians were encouraged to treat pain as a vital sign. The way that Purdue went about doing this was misleading. Patients were told that OxyContin would be effective in treating long term pain with minimal risk. Treating pain is extremely important but there has to be a way to ensure that people claiming pain is a way to have access to unnecessary treatments.


There is a legal concern regarding regulation of commercial speech because of America’s strong free speech tradition rooted in the First Amendment. As commercial speech, pharmaceutical marketing is protected under the First Amendment. At the same time, there is also an important government interest to protect the public from misinformation. Regulations may aim to ensure that marketing materials are accurate, balanced, and not deceptive. I will discuss court rulings on off-label marketing for example which has been extremely controversial in the present day. In my opinion, false claims regulations and fraud standards are in place to attempt to mitigate this problem but they are inadequate as they are loosely enforced and contain major loopholes. Seana Shiffrin raises a really logical argument arguing that commercial speech should be treated differently from other types of speech under the First Amendment. She sees commercial speech as really focusing on promotions of goods and services which require less protection than types of speech that are important for a democratic society. Shiffrin proposes a standard that evaluates commercial speech based on its potential to harm consumers or manipulate them through deception. She believes that commercial speech should be regulated to protect the public from misleading or harmful advertisements.

According to Constitutional Scholar David Vladeck, the First Amendment restricts the government from interfering with truthful and non misleading communications between companies and consumers. According to Vladeck, courts generally affirm the government’s role in ensuring that drugs are sold only for their intended uses, and support the use of off-label manufacturer communications as evidence of the manufacturer’s intent to sell for uses FDA has not evaluated. Vladeck explains how the FTC plays a role in the process, they are able to sue a company after the fact for deceptive advertising. If the FTC is able to sue after the fact, they should be involved in the approval process for marketing. When the FDA and FTC seek financial compensation for damages, they are trying to punish something that has already gone wrong, in this case a violation of federal law. However, if they really want to solve the

problem, they should prevent it from becoming a problem. Courts have upheld the agencies’ ability to enforce that substantiation requirement, despite the speech implications, when companies are making unsubstantiated claims.

Background on Physician Prescribing Practices

In this section, I will detail pharmaceutical marketing policies in the way that pharmaceutical companies interact with physicians. I will argue that lack of paternalistic policies has created too much of an emphasis on profits, conflicts of interest, and a lack of transparency. A more paternalistic approach would emphasize patient well-being and informed decision-making. Under the current system, there is a subversion of patient welfare because patients may be prescribed medications that are well branded but unnecessary. If pharmaceutical practices lack transparency, patients are unable to give proper informed consent which is an important aspect of utilitarianism.

The relationship between large pharmaceutical companies and physicians is too closely linked. In theory, “pharmaceutical marketing is the most organized and comprehensive information system for updating physicians about the availability, safety, efficacy, hazards, and techniques of using medicines.” The majority of Big Pharma’s marketing budget is directed at physicians and those with prescribing power. Doctors should not be fully admonished from blame but in my opinion, they are the middlemen in this system. In 2002, the Canadian Medical Association Journal estimated $19 billion is spent by Big Pharma annually in promoting drugs to doctors in the United States alone. Promotion of prescriptions to doctors can take up a third of annual budgets for pharmaceutical companies. Expenditure per physician can total over $8,000. This can take the form of advertising, gift giving, and support for medically

---

related activities such as travel to meetings and conferences. So much money is spent on marketing to doctors because they are gatekeepers to the success of individual brands.

If a physician consistently prescribes another drug over the company’s drug, this can destroy a brand. Doctors talk to each other about treatments and make recommendations so their decisions go a long way. Pharmaceutical companies even use medical journals to advertise their products and doctors are sent these journals for free. There is even found to be deception in these medical journals. A 1992 study by Wilkes et al. found that reviewers would not have recommended publication of 28% of the advertisements and would have required major revisions in a third. This is because independent reviewers disagreed with claims raised and saw information about efficacy “was not balanced with side effects and contraindications.” Some medical journals have stricter standards about reporting potential conflicts of interests but this does not apply to all journals. The structure of benefits has become so mainstream that it has caused marketing scholars like Joan Buckley to ask, “how did we reach a point where so many doctors won’t attend an educational meeting unless it’s accompanied by free food and a bag of ‘goodies’?” This constitutes a clear conflict of interest, which is defined as a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest.”

Doctors have sometimes been required to be open about their potential conflicts of interest. Multiple public reporting programs list payments and other gifts that doctors have received from drug and medical device companies. But this does not necessarily solve the problem of the conflict of interests, it just makes the system slightly more transparent.

Pharmaceutical companies sometimes will provide inaccurate information to deceive doctors into prescribing medications that are harmful to patients. A systematic review by Wazana combining 29 empirical studies shows that due to the conflicts of interest, doctors are unable to “identify accurate claims about medications” and “rapid adoption and prescription of new drugs” which translates to “nonrational prescribing behaviors, increased prescribing rates, and prescribing of fewer generics and more expensive new medications at no demonstrated interest.”48

Small benefits can influence prescription patterns and the effects become stronger as more benefits are provided. The system is currently self-regulating, with very few external barriers to marketing. Sunshine laws are a newer phenomenon but this just means pharmaceutical companies must report what they do for doctors, it does not do a whole lot to stop it from happening. In the current system, the marketing teams of pharmaceutical companies are the ones that are tasked with updating physicians “about the availability, safety, efficacy, hazards, and techniques of using medicines.”49 But profits are so important to big pharmaceutical companies that this often gets ignored.

Loose marketing regulations to doctors allowed Purdue Pharma to aggressively market OxyContin to physicians and played a big part in this opioid epidemic. After OxyContin was approved, Purdue Pharma formed arguably the most aggressive pharmaceutical marketing campaign of all time. Purdue Pharma would hire sales representatives to manipulate doctors into prescribing more pills. From 1996 to 2001, Purdue conducted more than 40 national pain-management and speaker-training conferences at resorts in Florida, Arizona, and California. At this same time, Purdue “paid more than 5000 physicians, pharmacists, and nurses” to attend speaker training conferences and pain education programs.50

Purdue deceived doctors with false claims about the chances of addiction to get them to prescribe Oxycontin. “Employing aggressive sales tactics and exploiting data on physician prescribing patterns, Purdue targeted the marketing of OxyContin to leading

opioid prescribers, normalized its use as a treatment for noncancer pain, and downplayed its potential for addiction.\textsuperscript{51} Physicians were also told that because this drug had an extended release formula, that this would limit the ability for addiction. So doctors were easily convinced that they were only helping their patients with debilitating pain rather than setting them up to get addicted and become increasingly dependent on opioids.

Physicians are not formally trained to identify drug-seeking behaviors and therefore if a patient said they were in pain, they were inclined to prescribe a remedy.\textsuperscript{52} So based on the misguided claim that less than 1% of patients get addicted, doctors were more likely to prescribe OxyContin. In turn, doctors were also compensated and provided with benefits based on how much they prescribed. It practically translates to doctors being paid double to provide this harmful prescription to uneducated patients. The marketing scheme used by Purdue was a clear example of quid pro quo. By 2003, nearly half of all OxyContin prescriptions were done by primary care physicians.\textsuperscript{53} The FDA later found that many physicians were not properly trained in pain management, which is why they were simply prescribing Oxy if a patient was in pain. As a result, sales of OxyContin ballooned from $48 million in 1996 to almost $1.1 billion in 2000.\textsuperscript{54} In 2001, Purdue spent $200 million in an array of approaches to market OxyContin.\textsuperscript{55} They knew their marketing strategy was a large success as they saw this with their large profits.


Another flaw in the system that feeds into this is that private pharmaceutical companies should not have access to records of individual doctors and how many pills they are each prescribing. According to primary care physician Art Van Zee, these profiles can show a drug company the highest and lowest prescribers of particular drugs in a single zip code, county, state, or the entire country.\textsuperscript{56} We have strict medical privacy rights for patient-doctor relations and this should be no different. It opens the door for these doctors to become easily manipulated with more pressure and benefits on the table. Doctors were catching on that the more drugs they prescribed, the more they would receive benefits from Purdue.

So there were some pill mill doctors like David Procter who only cared about maximizing the amount of pills he prescribed. Procter saw as many as 80 patients a day while charging $80-$120 to write prescriptions for narcotics.\textsuperscript{57} In a trial of one of his associates, he admitted to running a prescription-for-cash operation. Patients were also going doctor shopping, which meant patients were going to different doctors to obtain prescriptions for the drug. It is bizarre to me that we have a system where a pharmaceutical sales representative can see week-to-week prescription changes, breakdown by diagnosis and specialty of doctor, and compare the data elsewhere to create the most effective sales strategy. That only prioritizes the big pharma companies over the patients and sets them up to bribe doctors. The AMA supports this and enables the system of surveillance, which needs to change.

**Sunshine Laws**

In this section, I will detail sunshine laws, which are a step towards paternalistic policy that accounts for utilitarian concerns. Sunshine laws shield patients from having to make an informed decision without disclosure of their doctor’s financial relationships. In my opinion, it is important that when patients make a decision they


have all of the information. While some may argue that sunshine laws presume that doctors are biased, this is not the intention, the intention is to allow patients to make the best decisions for their livelihoods to prevent potential individual and societal harms.

As part of the Affordable Care Act, Congress passed the Physicians Payments Sunshine Act to increase transparency and mitigate potential conflicts of interest. This requires medical product manufacturers to disclose to the Centers for Medicare and Medicaid Services any payments or transfers of value made to physicians or teaching hospitals. This data is published annually in a public database. Before the data is released to the public, both parties can review the data and suggest corrections. A 2009 survey found that nearly 84 percent of physicians had financial interaction with manufacturers of drugs, devices, biologicals, and medical supplies, the majority coming from meals provided in the workplace. This number was down from five years earlier and represents the idea that there is increased scrutiny of potential conflicts of interest that can impact physician decision making which may encourage inappropriate prescribing. The Sunshine Act has a detailed reporting process that ensures healthcare providers are reporting general payments (from gifts to trips), ownership or investment interests (including stocks), and research payments. The maximum penalty for not reporting is $1 million. The bill also allows states to create additional reporting requirements.

The Physicians Payment Sunshine Act is certainly a move in the right direction. The provision of gifts and direct payments by pharmaceutical companies dropped from 84% in 2009 to 72% in 2017. However, there are still gaps in the system. Educational materials that were oriented to patients were a large part of the OxyContin marketing pitch by Purdue Pharma. The distribution of these materials to doctors is still exempt from being reported in the public database. In addition, the public database is not going to be easily accessible to most of the population, nor is it something well-known to the

public. Once I was able to get on the website, it was easily navigable but the problem is getting started. Additional problems include inaccurate data and misleading presentation of data. In this process, the responsibility lies on the pharmaceutical group, not the physician. As profit driven companies, there is always potential to distort existing data. This may also lead to public skepticism of legitimate physician collaboration and transactions. The avenue in the Physicians Payments Sunshine Act for states to add additional requirements has allowed California to up the ante. Since January 2023, California physicians and surgeons are required to provide patients at their initial office visit with a written or electronic notice of the Open Payments database.61 They are also required to post in every location that they practice, an Open Payments database notice that includes the link to the database. Effective January 1st, 2023, physician and surgeon practice websites must post the Open Payments database notice as well. These are important steps to increase accessibility to this information to the average consumer. Nationally, the database and sunshine law is a great start but there is certainly room for improvement. It is also promising how sunshine laws have not been struck down by the Supreme Court as a violation of the 1st Amendment. To propose future reforms, I think it is important to first look at how the Supreme Court has handled regulation of commercial speech in the past.

**Previous Rulings on Commercial Speech in Healthcare**

As this is written as an amicus brief, it is important to engage with the legal precedent and law review articles. With the suggested regulations of commercial speech, it is important that the policy laid out is not just the best policy but a policy that is legally viable and would hold up in court. I will discuss cases where the government has acted in paternalistic ways to protect the best interests of the public. This is exactly

---

what I desire to do with this amicus brief, show there is a legitimate public interest for the government to act in a way that limits the ability for members of the public to do individual or societal harm.

In the next section, I will discuss the ways that the government should regulate pharmaceutical marketing and labeling. I anticipate the main objections to these changes will be rooted in the idea of the First Amendment right to free speech which is applicable to commercial speech as well. With that in mind, I will provide some background information in how the Supreme Court has intervened in the healthcare sector in the past.

The First Amendment states “Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances.” The concern with regulating pharmaceutical companies and their marketing tactics is this brings about a potential violation of commercial speech and this first amendment.

The Supreme Court has made it clear that there are limits on individual and commercial freedom of speech. Previous courts have also established important tests that are applied to future cases in free speech disputes. One of these important tests emerges from the United States v O’Brien (1978) case. In this case, David O’Brien had burned his draft card at a Boston courthouse to express his opposition to war. He was convicted of a federal crime that made destruction or mutilation of draft cards a crime. In a 7-1 decision, the Justices determined that the government had an important interest to ensure an effective draft system but the act of burning a draft card did not show a substantial speech interest. The intermediate scrutiny test was used in other cases with the standard being alleged government interest justifying the scope of the restriction on expressive conduct. Warren’s O’Brien test states that the law in question must 1) be within the Constitutional power of the government to enact and 2) further an important

or substantial government interest. That interest must be unrelated to the suppression of speech (or "content neutral", as phrased in later cases).  

The Supreme Court’s stance on free speech truly does vary from Court to Court. In the case of *Central Hudson Gas & Electric Corporation v. Public Service Commission of New York* (1980), the decision was completely different from that of the O’Brien case. In this case, The Public Service Commission of New York (PSC), in the interest of conserving energy, enacted a regulation that prohibited electric utilities from promoting electricity use. The regulation drew a line between promotional advertising and informational advertising, which was allowed. Central Hudson Gas and Electric Corporation challenged the regulation on free speech grounds. In an 8-1 decision, this Court decided that New York’s ban violated the right to commercial speech.  

The Court acknowledged that the PSC had an interest but that the regulation was too restrictive in scope. The Central Hudson test was established in this case. For a regulation to not constitute a violation of free speech, 1) the government must have a substantial interest, 2) the regulation must directly and materially advance the government’s substantial interest, and 3) the regulation must be narrowly tailored. This test has been criticized by Justices Thomas and Scalia for its confusing and “contradictory” premises.

In the past, the Supreme Court has been very hesitant to allow limitations of free speech for businesses in the medical sector. Those that object to my arguments may point to *Sorrell v IMS Health*, Inc. In 2007, Vermont passed a law banning the sale, transmission or use of prescriber-identifiable data for marketing or promoting a prescription drug without the consent of the prescriber. The law also prohibited the sale, license or exchange for value of PI data for marketing or promoting a prescription drug. Three pharmaceutical companies challenged the law in court as a violation of their speech rights. In a 6-3 majority, the Supreme Court upheld a decision made by the Second Circuit Court of Appeals which held that the law did in fact violate the First

---

Amendment as it restricted the speech of data miners without a legitimate state interest.\textsuperscript{67} The majority in this case believed that it met the standard of heightened judicial scrutiny meaning that the onus is on the government to show the need for the law limiting the first amendment.

Justices Breyer, Kagan, and Ginsburg dissented in this case arguing that the First Amendment does not require courts to apply a special 'heightened' standard of review when reviewing such an effort.\textsuperscript{68} I agree with the minority in this case and I do not think that banning companies from seeing this specific data violates free speech rights. But even if the Supreme Court backed up this precedent, there are other cases decided that make my solutions plausible.

In \textit{Zauderer v Office of Disciplinary Counsel of Supreme Court of Ohio}, the Supreme Court decided that a State may require advertisers to include factual disclosures without violating the First Amendment rights of the advertiser as long as the disclosure is in the State's interest in preventing deception of consumers.\textsuperscript{69} This set the precedent that commercial speech has weaker First Amendment protection than noncommercial speech. This also set something called the Zauderer standard to determine if state laws were constitutional.\textsuperscript{70} I would argue that due to the fact that 645,000 people have died from opioid overdose between 1999 and 2021, many of them because of OxyContin, the government should be able to regulate the deceptive tactics used by OxyContin in the way they marketed to doctors and patients.\textsuperscript{71}

In 2018, the United States Court of Appeals for the Second Circuit vacated the criminal conviction of a pharmaceutical sales representative who was found guilty of conspiracy to introduce a misbranded drug, under the Food, Drug & Cosmetic Act (FDCA), because he spoke about off-label uses of a particular drug. In the case of \textit{United

States v Caronia, the court held “that the government cannot prosecute pharmaceutical manufacturers and their representatives under the FDCA for speech promoting the lawful, off-label use of an FDA-approved drug.” A lot of the rationale for the Court of Appeals decision was rooted in the Sorrell decision. While technically the court’s ruling only applies to states located in the 2nd Circuit, the opinion has provided fuel to many companies who are currently in various stages of investigations or negotiations with the federal government regarding alleged off-label promotion.

There are countless examples of the FDA filing civil suits against companies, such as Pfizer, GlaxoSmithKline, and Abbott Laboratories, for illegally marketing medications and manipulating medical studies. These companies were rightfully held responsible. However, these fraud protocols fail to do anything for patients who are already suffering and may have faced catastrophic consequences as a result of being misled. Maybe the family of the patient sees a little bit of the $2.3 billion that Pfizer had to pay in 2009 but this does not bring their loved one back. If First Amendment rights are not infringed when action is taken on the back end, First Amendment rights will not be infringed if more action is taken on the front end to prevent this type of deceptive marketing before it begins. As Matthew Griffin rightfully points out in his analysis of Direct-to-Consumer advertising, “certain limited types of prohibitions, so long as they do in fact serve a substantial governmental interest and are properly tailored, have been upheld as commercial speech restrictions under intermediate scrutiny.” More regulation would directly advance interest in safeguarding public health, advance interest in reducing healthcare costs, and be no more burdensome than necessary to protect the public.

---

Regulation of Tobacco Marketing

In this section, I discuss the government approach to tobacco marketing regulation, which follows a similar pathway than that of my proposals for pharmaceutical marketing regulation. The government decided to act in a paternalistic way for utilitarian reasons. Regulation of tobacco marketing aims to reduce the individual harm caused by tobacco use, such as the high rates of morbidity and mortality associated with smoking-related diseases like cancer, heart disease, and respiratory illnesses. This is why commercials for tobacco are no longer on television. In addition, the government acknowledged the economic burden of tobacco consumption on society. Tobacco use is correlated with higher healthcare costs and environmental pollution. The government is involved in prioritizing informed choice for people to use or not to use tobacco products by giving people all of the truthful information, which is what the government should be doing in the case of pharmaceutical regulation.

When it comes to marketing, the First Amendment is not absolute. A clear example of this was the regulation of marketing of tobacco products, which was banned in 1971. The FDA has cracked down on companies who have tried to evade the laws in place banning tobacco marketing on television and radio. In 1995, the Department of Justice reached a settlement with Philip Morris to remove tobacco advertisements from the line of sight of television cameras in sports stadiums.74 Restrictions on commercial speech in the context of tobacco have passed the Central Hudson Test. Under this free speech test, government restrictions on commercial speech (where the speech is not about illegal conduct and is not misleading) are constitutional where: (1) the asserted government interest for the regulation is “substantial;” (2) the regulation “directly advances the government interest,” and (3) the regulation is “not more extensive than is necessary to serve that interest.”75 The Supreme Court held, in Lorillard Tobacco Co. v. Reilly, that restrictions of self-service displays met the intermediate scrutiny requirement because they were tailored to serve a substantial government interest that

was unrelated to regulating expression (preventing access to tobacco products by minors), still allowed retailers to convey product information, and permitted consumer inspection of the products prior to purchase.\(^7^6\)

If similar regulations were challenged under free speech grounds, it is possible that the outcome would be the same. The government must establish a compelling state interest but there clearly is one, protecting the lives of the American people. If pharmaceutical companies are able to keep dominating the marketing sphere by investing millions of dollars to maximize profits, things are never going to improve. Doctors will continue to enjoy kickbacks, while patients suffer.

**FDA/DOJ Authority**

To propose politically viable policies, there must be discussion of what authority the federal government agencies have in the matter. In this section, I will discuss the congressional legislation that has granted the FDA and DOJ jurisdictional authority over pharmaceutical marketing. This section will show that these proposed solutions are possible and are not ad hoc but rather guided by existing paternalistic authorities that strive to protect the public good.

There is a lack of public knowledge about what power that the FDA has over these pharmaceutical companies. The Federal Food, Drug, and Cosmetic Act of 1938 was passed in response to a toxic elixir that was legally marketed which killed over 100 people. This elixir was stopped in its tracks rather quickly by the FDA who discovered that this drug contained diethylene glycol, which is deadly.\(^7^7\) Far more lives could have been lost had the government not been reactive. So it is interesting how the FDA took so long to step in after thousands of lives were lost as a result of OxyContin addiction and eventual overdose.

\(^{7^6}\) Lorillard Tobacco Co. v. Reilly, 533 U.S. 525 (2001)

Another law, the Kefauver-Harris Amendments of 1962, was passed which were inspired by the thalidomide tragedy in Europe (and the FDA’s vigilance that prevented the drug’s marketing in the United States), strengthened the rules for drug safety and required manufacturers to prove their drugs’ effectiveness. This was a large shift in FDA authority. The FDA is responsible for evaluating and approving new drugs before they can be marketed and sold in the US. As was the case with Curtis Wright, those tasked with reviewing applications rarely did their due diligence and took the word of the company about potential negative consequences at face value. In 2015, the FDA was approving around 96% of drug applications. Some argue that a lot of things are getting rejected by the FDA. This seems to be misguided as many drugs that fail are pulled before this FDA process. But what is true is that it takes 46 months for the FDA to withdraw a failed drug with accelerated approval. It is also true that 65% of drugs approved by the FDA in 2022 were approved based on a single study. Some drugs were approved based on failed tests or minimal data. This also creates a revolving door effect because these FDA reviewers end up going to work in the private sector.

The FDA also oversees regulatory compliance while the drug is on the market. These regulations improve the Current Good Manufacturing Practice standards as marketing regulations. The FDA still does inspections and makes sure policies related to manufacturing, marketing, and labeling are being followed. Companies are required by law to report any adverse events. This allows the FDA to change the labeling or even remove a drug from the market. The FDA also does have power over advertising and promotion. Ideally, they are supposed to make sure that information being provided to

---

82 “6 Drugs Approved Despite Failed Trials or Minimal Data,” BioSpace, n.d., https://www.biospace.com/article/6-drugs-approved-despite-failed-trials-or-minimal-data-.
doctors and patients is truthful. So clearly the authority is there, now the FDA needs to use their authority. Their powers are being expended by Congress. As recently as February, laws have been passed to allow the FDA to hold companies accountable for not doing proper research.

The DOJ, working with the FDA, also has authorities over pharmaceutical companies. The DOJ can ensure that antitrust laws are being properly enforced. This is helpful for patients as pharmaceutical companies have been known to jack up prices when they have a monopoly on a medication, which occurs quite often. For example, Martin Shkreli’s Turing Pharmaceuticals acquired a monopoly over Daraprim and raised the price from $13.50 to $750 overnight. The FTC and the DOJ stepped in to file a lawsuit to break up the monopoly over Daraprim.

The DOJ also enforces the False Claims Act, preventing pharmaceutical companies from submitting false claims to government healthcare programs, such as Medicare and Medicaid. Purdue promoted its opioid drugs to health care providers it knew were prescribing opioids for uses “that were unsafe, ineffective, and medically unnecessary, and that often led to abuse and diversion.” The big part of this is the kickbacks that Purdue enjoyed and shared with doctors. Purdue received revenue from claims submitted to Medicare and Medicaid for misuse of OxyContin which they then funneled back into aggressive marketing to doctors.

The DOJ should be enforcing the Anti-Kickback statute, which prohibits offering money (in this case to doctors) in exchange for referrals or to generate the purchase of goods or services reimbursed by federal healthcare programs (in this case OxyContin). The DOJ has fined pharmaceutical companies for violations of this as recently as November 2023. However, it took far too long for the government to punish Purdue for what they were doing. The only reason this all came to light is because of the amount of

---

devastation the opioid epidemic created. However, Purdue was taking advantage of the lack of action on the part of the government. The company was trying to maximize their profits so they were content with all of the negative consequences of what was ongoing in regards to OxyContin. The DOJ also needs to step in sooner to prevent drug diversion. The DOJ can take action to prevent deceptive marketing strategies as well. The tools are there for the FDA and the DOJ in terms of authority, they just need to use them.

**Suggestions for DTC Marketing Restrictions**

In this section, I will provide some of the paternalistic policy solutions to handle the societal harms of an under regulated DTC marketing system. While these solutions may employ some burdens on pharmaceutical companies, they are extremely important to protect the livelihoods of Americans. These practices will protect vulnerable populations, prevent misinformation and deception, promote rational choice, and minimize harm. The biggest goal of the government is to protect public safety and these policies will ensure there is protection of the public from societal harms.

The problem starts and finishes at the FDA, they created the problem by expanding the freedoms that pharmaceutical companies have when it comes to direct-to-consumer advertising and now they need to fix it. The way that pharmaceutical companies are able to deceive patients is anti-utilitarian in every possible way. There is no ethical reason why marketing to consumers should be allowed in a way that undercuts potential risks and overstates potential benefits. The FDA needs to have more regulatory oversight and any sort of advertising standards should be examined on a regular basis. The FDA should have to individually approve any advertising and marketing materials that are distributed to consumers. The US should reform their system to be more consistent with the rest of the world. The European Union only allows marketing for over the counter drugs. It makes sense because doctors are not a barrier to receiving this form of medication. For prescription medications, the government should modify the system so doctors can interact with the pharmaceutical industry without having patient pressure impacting prescription patterns. The
government needs to pass policies that limit the ability for pharma companies to interact with individual consumers. Whether this involves setting a maximum financial limit, doing away with any sort of promotion of prescription medication to consumers, or requiring all marketing materials to be approved, something has to give.

Some may object to these regulations as running counter to the First Amendment in terms of regulating commercial speech. I anticipate that the pushback would be rooted in the idea that the constitutions in these other countries vary from the US Constitution when it comes to free speech. But letting things run rampant has created the problem that we find ourselves in. Pharmaceutical companies are allowed to perpetuate false claims about risk and hide them within the fine print. Patients who have been spoon fed these false claims about benefits and minimal risks of addiction should not be in a position where they can bully doctors into prescribing these potentially harmful medications. Patients can receive more accurate information from their doctors, who will be in contact with these pharmaceutical companies. Concerns of the First Amendment may be rooted in how the Supreme Court and lower courts have handled commercial disputes in the past. Precedent is important for future rulings on regulation of commercial speech.

However, the Supreme Court has overturned their rulings in the past when there is a state interest to protect public health. In 1905, the Supreme Court, in *Lochner v New York*, struck down the New York Bakeshop Act, which forbade bakers to work more than 60 hours a week or 10 hours a day.\(^\text{86}\) The Court held that the New York law failed the rational basis test for determining whether government action is constitutional. However, the Court struck down this decision in *West Coast Hotel Company v Parrish* (1936).\(^\text{87}\) The Court ruled in favor of a minimum wage law for women, allowing the state to intervene to restrict individual freedom of contract. Their goal was to remedy a public harm, the exploitation of women for their labor. A similar trend can take place here with commercial speech for pharmaceutical companies, the Supreme Court has to be able to draw the line in the name of public health.

\(^\text{86}\) *Lochner v. New York*, 198 U.S. 45 (1905)  
\(^\text{87}\) *West Coast Hotel Co. v. Parrish*, 300 U.S. 379 (1937)
Those concerned about free speech should look to the Zauderer decision where the Supreme Court decided that advertisers may be required to include factual disclosures without violating the First Amendment rights of the advertiser as long as the disclosure is in the State's interest in preventing deception of consumers. This case shows that commercial speech is not absolute. Having proper regulations will be beneficial to producers and consumers because it promotes the truth and ensures that doctors can properly treat patients in a way that is consistent with the hippocratic oath. The hippocratic oath is the code of conduct for the healthcare profession and there are many regulations in place to uphold this hippocratic oath, this would just be another example of this. As Shiffrin argues, commercial speech is not absolute and should be limited more than non-commercial speech. In her opinion, commercial speech is about transactions rather than anything that is going to impact our democracy. Other legal scholars such as Ed Baker and Eugene Volokh argue that commercial speech should not receive the same protections as non-commercial speech. Even Volokh, who has the most favorable opinion of commercial speech, acknowledges the government has a legitimate interest in regulating false, misleading, or deceptive commercial speech to protect consumers and maintain fair market practices. According to Baker, the core purpose of the First Amendment is to protect individual autonomy and self-expression, especially in political contexts, rather than commercial transactions.  

**Suggestions for Physicians**

In this section, I will provide some of the solutions to handle the societal harms of an under regulated marketing system to physicians. While these solutions may employ some burdens on pharmaceutical companies and on medical professionals, they are extremely important to protect the livelihoods of Americans. These practices will strengthen the ethical framework laid down by professional organizations through protecting against conflict of interests, promoting decision making based on scientific evidence rather than marketing, and in turn create more patient trust. The biggest goal

---

of the government is to protect public safety and these policies will ensure there is protection of the public from societal harms which will maximize public health outcomes.

There are many policies that the government could pass to create greater enforcement on the part of the FDA. Sunshine laws are a step in the right direction but this does not do nearly enough. All this does is make information about potential conflicts of interests more public. It fails to actually solve the problem though and to get rid of potential conflicts of interest. And without more transparent resources, patients are not going to take the time to see how much their physician is mingling with the pharmaceutical industry and reaping the benefits of certain prescriptions. The government should ban the exchange system where doctors reap the benefits of prescribing more with paid vacations, paid dinners, and other rewards. There needs to be a concrete system which benefits patients over profits. Pharmaceutical companies should not be rewarding doctors for how many pills they prescribe. There should be a relationship with physicians to ensure there is proper postmarket surveillance but this should not amount to quid pro quo, which is the case right now. Expensive gifts should be banned or severely limited to a certain dollar amount, just as we do with campaign finance on an individual level. There should also be a limit on the amount a company can spend on marketing prescriptions. As Purdue made more money off OxyContin, they doubled down and continued to funnel resources for sales representatives to market towards doctors. Self-regulation does not go far enough and there needs to be strict codes of conduct. There also needs to be stricter penalties for companies that violate the marketing regulations put forth. A big part of the issue is the lack of an enforcement mechanism. Fines are not going to fix the problem because the fines are pocket change to a multi-billion dollar corporation. Criminal sanctions need to be in place for pharmaceutical executives and representatives. Doctors like David Proctor faced multi-decade sentences, big pharma companies should face the same treatment.

There will be similar arguments that this is over-regulating of commercial speech, as the Courts found in the 1980s in the *Central Hudson Gas v. Public Service*
One may argue that sunshine laws do enough to have a more transparent system. Legal scholar Mark A. Rodwin, for example, believes conflict of interest statutes should be conserved because expansion would complicate the interpretation of what would be considered a conflict of interest. However, we need to have a healthcare system that prioritizes people over profits. It is one thing to allow the markets to take place and it is another to let millions of people die because doctors are tricked into prescribing medications that cause patients to become addicted. These restrictions still will allow for all players to make profits but also make sure that physicians are abiding by the hippocratic oath. One may say that this reduces competition but it also creates more competition because the marketing budget is a barrier to entry. So although there are some objections, none of them show that these solutions should not be put in place. Legal scholars Frieder Keller, Krzysztof Marczewski and Draško Pavlovic argue that more transparency and independent ethical oversight will empower patients to have a better judgment of their doctors and create better outcomes. The definition of conflict of interest can be something that is clear cut rather than something confusing. As Keller, Marczewski, and Pavlovic argue, physicians must have an intrinsic interest that patients and colleagues trust what he or she is saying and doing. If they know they are under some scrutiny, their behavior will likely change.

**Brief 2: Analysis of Administrative Law regarding Labeling**

**Introduction**

The Federal Drug Administration requires pharmaceutical labels on all retail items containing any kind of drugs, including both prescription and OTC (over-the-counter) drugs. For example, hand sanitizer, sunscreen, rubbing alcohol, and toothpaste all require pharmaceutical labeling. For the sake of this white paper, I will only be focusing on labeling of prescription drugs, which are the most extensive, rather than all labels. Assuming patients read them, prescription labeling is crucial for patients because it helps them avoid serious reactions or medication errors. Having doctors take the time to go through protocols is important as well, labeling should be a review of the information that the patients have already been exposed to.

With these goals in mind, the FDA is constantly modifying guidelines to ensure that labeling is more concise and accessible to patients. FDA regulations require all medications labels to include Name of Product, Table of Drug Facts, Active Ingredients, Proper Use and Purpose, Warnings, Directions, Allergic Reactions/Harmful Side Effects, and Inactive Ingredients. But the door still remains open for things to go wrong. Medication error is defined as a missed dose, wrong dosage forms, wrong time interval, wrong route, etc. These errors are a big deal in ensuring better patient care. Over 50% of medication use errors in terms of dosing, intervals, route of administration, etc, are associated with poor prescription drug labeling. The most common errors are a result of name confusion or the inability to read/understand prescription labels.

---


Patients who have low health literacy or receive multiple prescriptions are at highest risk for medication error. The FDA gets their statutory authority from the Federal Food, Drug, and Cosmetic Act of 1938. Under the FDCA, the FDA has the power to regulate the labeling of drugs, including prescription and over-the-counter (OTC) drugs.

The FDA enforces labeling standards through a combination of premarket approval and postmarket surveillance. For new prescription drugs, the FDA conducts a review of labeling ensuring, in theory, that the label is clear, accurate, and not misleading. Postmarket surveillance is where a lot of the FDA work takes place. The FDA monitors the safety of drugs through reporting of adverse reactions and requires modification of labels to include new warning information when necessary. The FDA may periodically review drug labeling based on new data or other sources of information. The FDA also conducts audits of manufacturing facilities to ensure compliance with standards. If the FDA identifies violations, such as misleading or inaccurate labeling, it can issue warning letters to the manufacturers, giving them an opportunity to correct the violations. Future actions such as drug recalls may be taken if the manufacturers choose to not abide by the warning.

Labeling standards allow for FDA oversight and scrutiny of the process throughout. However, these regulations are not absolute. A large debate related to prescription usage is off-label use. In the case of United States v Caronia, the United States Court of Appeals for the Second Circuit held “that the government cannot prosecute pharmaceutical manufacturers and their representatives under the FDCA for speech promoting the lawful, off-label use of an FDA-approved drug.” This limits the

---

98 “Postmarketing Surveillance Programs,” FDA, April 1, 2020, https://www.fda.gov/drugs/surveillance/postmarketing-surveillance-programs.
power of the government to take legal action against pharmaceutical manufacturers. Although this case deals with off-label marketing, it is still an important decision as it relates to regulation of commercial speech. Some other court cases have applied a looser standard to commercial speech, arguing protections for commercial speech should be held to a lower standard than that of individual speech. An example of a case like this would be Zauderer v Office of Disciplinary Counsel of the Supreme Court of Ohio. In this case, the Supreme Court decided that a State may require advertisers to include factual disclosures without violating the First Amendment rights of the advertiser as long as the disclosure is in the State's interest in preventing deception of consumers.100

Research has shown that medication errors would be reduced if patient-centered labeling were implemented with standardization of labeling text, scheduling, indication, language, typography, and other display standards.101 But in its current form, the FDA’s labeling requirements are meant to be physician centered rather than patient centered. Labels that are being distributed to patients are just like long contracts or terms and conditions that patients are quickly told to sign off on rather than going through the important details. This is not helpful for patients to be receiving terminology that they have no idea how to understand unless they are willing to ask their doctor. Even if they were to ask their doctor, doctors may take this as questioning their expertise and not properly answer the patient’s question in layman terms.

People are starting to pick up on the problems of the current system in place. The US Pharmacopeia, a more than 200-year old nonprofit organization focused on “building trust in the supply of safe, quality medicines” has made recommendations such as “patient-centered prescription labels, simplifying language, using explicit text, including the reason for prescription, improved readability, labeling in a patient’s preferred language, supplemental information, and standardized patient directions.”102 Others have stressed the importance of physicians and pharmacists collaborating to ensure patients are using medications safely. Studies have shown that a significant

---

number of households in the United States fail to comply with proper medication storage guidelines, thereby increasing the risk of compromising the sterility and stability of the drugs.

There are so many opportunities to improve things in the realm of labeling which will also bridge the gap between physicians and patients in terms of medical care. Black box warnings are not the most effective way for patients to understand what they are putting into their body and the potential risks with this. This is exactly like checking the box agreeing to the terms and conditions of something, without actually reading it. Doctors must be able to brief patients on what they are putting into their bodies, including discussion of potential benefits and risks. There are many people out there that are skeptical of the medical industry, if doctors broke down their barrier in the way they spoke to patients, this would go a long way to fix the problem. In addition, labels that are read by patients when they open a box to take their medication, should be made for patients.

Paternalism already manifests itself in certain drug labeling protocols in existence today. Labels are paternalistic because it summarizes all of the information regarding potential risks and side effects for a patient to make a decision on a medication. Additionally dosage and consumption instructions are another way that the healthcare system is paternalistic. These existing practices aim to balance patient autonomy with protecting consumers from harm. My goal is to expand upon these practices to empower patients to make the best decisions for themselves and their well-being with the most amount of information available. In order to craft labeling policy that is both politically viable and also impactful, it is important to analyze the existing policies in place and the ways that they fall short. A lot of information in this brief comes from FDA guidelines that are currently on their website. I also appeal to social science literature to show how the current system does not equal informed consent because it functions like terms and conditions. Lastly, I cite studies from public health officials who have discussed labeling shortcomings in depth. With this information, I have proposed solutions that allow for prioritization of well-being. Informed consent should be the goal but in order to achieve utilitarian ends,
paternalism has to be a part of the system. In a well-regulated system, labeling requirements support individual autonomy while also promoting consumer welfare and safety.

**Background on Labeling**

Prescription drug labeling is a flawed part of our current pharmaceutical system. Labels are often several thousand words long and filled with medical terms that the average person cannot properly comprehend. People may ignore or even misinterpret what a warning label is saying. This can be detrimental to patient well-being because patients may misuse medication which increases the risk of individual harm and contributes to the loss of societal well-being. In this section, I will talk about how current labels set patients up for an increased likelihood of misuse.

In 2006, the FDA rolled out a new rule for how to present information on a prescription label. Prior to 2006, important information could have been left out or not been easily accessible even by a physician. This new rule ensures there is a table of contents as well as information about how long the drug has been on the market. A label is now divided into highlights of prescribing information, contents of the full prescribing information (FPI), and the FPI. The highlights section is a half-page summary of the information that health care practitioners most commonly refer to and view as most important. These changes made it easier for health care professionals to easily find, read, and convey information important for the safe and effective use of prescription drugs. However, there is still progress to be made in terms of the labels that are being given to consumers. A comparative study of the US, Canada, and UK on labeling by Dr. Alshammari et al found that the amount of words on a label from the US average a total 10,704 words, while the UK labels average a total of 5,637 words. This

---

is being impacted by the laws in place that are not conducive to patient consumption. In addition, US labels have the lowest proportion of total safety information. As the authors of this study remark, “A larger volume of information might have poor readability and can lead to adverse reactions from the drugs.”

Sample Drug Label on Medication Bottle

Black box warnings exist as a description of serious adverse reactions, limitations in use imposed by them, and steps that should be taken if they occur. The black box warning is ordinarily based on clinical data. The FDA informs pharmaceutical companies when a black box warning is required. Black box warnings are often sorted into specific categories such as warnings for high-risk patients, information on dosing or drug interactions, and warnings about the need for special training. Some drugs obtain a black box warning after being brought to market because of a new reaction to

---


the drug. Researchers estimate the probability of a new black box warning for a drug or the drug being pulled from the market is about 20%. Drug labeling is found to have a mean informativeness score of 35%, which is extremely low.\(^\text{108}\) Laws in place about labeling specify that labels should be “informative, accurate, and neither promotional in tone nor false or misleading, and should be based on data derived from human experience whenever possible.”\(^\text{109}\) Labeling regulations are well thought out with clear stipulations of how categories should be sorted. For example, there is an entire section of labeling dedicated to situations in which the drug should not be used because the risk of use clearly outweighs any possible benefit. Even after initial market approval, the FDA (in theory) continues to monitor drug safety through “postmarketing surveillance.” Researchers found that during the 33-year period from 1969 to 2002, about 2.3 million case reports of adverse events for the cumulative number of approximately 6000 marketed drugs were entered into the AERS database.\(^\text{110}\)

One of the issues with labeling are the lengthy warning labels that are included when you pick up a prescription. According to a study by Panagiotou et al, black box warnings are the strongest medication-related safety warnings in a drug’s labeling information.\(^\text{111}\) But some of these black box warnings are either too long, too complex, or are not present. Some drugs are able to be brought to market without clear black box warnings. They may be flagged or pulled later but for some this is too late. In addition, the study found that some black box warnings are different even among the same class of drug. The study found 25 black box warnings across the 176 drugs they examined with 15 differences among the same class of drug.\(^\text{112}\)

---


This is really impactful because black box warnings may influence if and how a drug is prescribed, particularly when alternatives without these warnings exist. Black box warnings can decrease sales because of transparency of risk. An example of this was that drug use dropped more than 50% after the black box warning for increased mortality in dementia-affected elderly was released. There are tradeoffs as profits will drop but patient well-being will improve. It is important for these companies to be honest about potential risks and companies. In a system where ethics and morality are so important, honesty and transparency must be at the forefront of pharmaceutical labeling. If patients cannot understand the complex terminology on the boxes and bottles of their medication, then they are more likely to make mistakes such as missing a dose, using the wrong time interval, or improperly mixing medications meant to only be taken separately. Evidence shows that there is a correlation between an individual’s health literacy level and accidental drug misuse. This brings about a socioeconomic disparity which shows a clear ethical dilemma. A study showed that patients at an urban primary care clinic who underwent structured interviews to address their understanding of specific one-step warnings (ie, take with food) and multi-step warnings (ie, avoid prolonged exposure to sunlight while taking this medication), largely struggled with retention of information. The majority of the study population had low or marginal health literacy, defined as reading at an 8th grade level or lower. Patients with low literacy were significantly less likely to correctly interpret warning labels, and multi-step instructions were misinterpreted by the majority of respondents across all literacy levels. Some may argue that doctors are already taking steps to inform patients of proper usage techniques as well as potential side effects. Some doctors may be more thorough than others, while others may do the bare minimum to ensure their patients are educated when given a prescription medication. However, this does not

---


change the fact that labels still need to be streamlined and made more accessible to the average person.

Throughout the rest of the paper, I will discuss social science literature regarding informed consent in general society. I will examine Margaret Jane Radin’s argument about how boilerplate impacts all parts of modern life and inhibits our ability to understand potential harms in a given circumstance. After discussing the existing social science literature, I will examine the shortcomings of our current labeling system through an examination of OxyContin labeling. Then, I will offer my arguments for reform including potential laws and regulations that should be put into practice. I will acknowledge and discuss potential limitations and barriers to the implementation of these regulations. Finally, I will conclude with discussions of long-term implications of labeling laws as boilerplates became even more common.

Social Science Literature

In order to make an argument of why labeling policy should change, I equate the current process to terms and conditions. Both labeling and terms and conditions involve disclosing information to consumers. They both have the end goal of ensuring informed decision making. Ultimately, the end goal of both pharmaceutical labeling and terms and conditions is to limit harms and manage potential risks to consumers.

A lot of large scale social science research regarding informed consent is applicable to pharmaceutical labeling. Similar to the reading of terms and conditions, no one is taking the time to read thousands of words written in complex medical jargon. Margaret Radin expresses concern with blanket consent to boilerplate, fine print provisions like terms and conditions. 116 Very few people take the time to read this and may agree to things that limit their privacy, for example. Nili Steinfeld finds that privacy policies are quickly ignored only even if they are “required” to read before signing. Even in the sphere of mental health related care, consent is muddied waters. 117 Jitka et al.’s

study also is quite important because it shows how literacy can impact ability to give consent. As Dr. Philip Saylor shows, length plays a big role in accessibility and readability as well. Saylor says, “Our patients absolutely want information, but they just do not want it in our current quantity or format.”

In “Boilerplate, the Fine Print, Vanishing Rights, and the Rule of Law,” Margaret Radin examines arguments for boilerplate provisions, fine-print terms and conditions that we become subject to when we click, “I agree”. Proponents of boilerplate provisions argue that consumers freely consent to them. But as Radin properly notes, we really do not freely consent because we are not properly informed on what we are agreeing to. She characterizes boilerplates as an “involuntary agreement.” She argues that boilerplate contracts often create imbalances in bargaining power, drafted by the stronger side to oppress the weaker consumer. Radin also argues that boilerplate, as a mass-market system of contracts, leads to democratic degradation by undermining the rights of the consumer. She argues this muddies the waters between private and public actions. Radin makes the argument that people that blindly agree to terms and conditions are showing sheer ignorance, which does not equal consent. Radin even examines whether boilerplate clauses should be legally enforceable. She argues that the state should intervene when individuals are unable to protect themselves. Radin goes on to offer possibilities for new methods of boilerplate evaluation and control, suggesting that tort law rather than contract law provides a preferable analysis for some boilerplate schemes. A boilerplate clause is standard protocol for a contract that outlines certain conditions that parties must comply with. It is commonly referred to as the “fine print” that people often gloss over.

Researcher Nili Steinfeld examined how users read privacy policies online and how the privacy policy is displayed (optional or required to read before signing). Privacy policies are the common method for online providers to regulate their interactions with users, giving users the power to allow or deny companies from using personal data.¹¹⁹

These policies are often ignored because they are easy to skip over. Steinfeld uses eye tracking technology to determine how these policies are being read. Steinfeld sees a gap between evidence showing users’ desires to be informed of the use of their personal data and their own statements about not reading privacy policies. Steinfeld hypothesizes this is possibly due to complexity of reading policies. He also suggests the possibility that users who are asked to agree to a privacy policy as a default will be more receptive to reading terms and conditions than those who have the choice of clicking to find terms and conditions. The average policy length is 2,400 words so people generally do not go out of their way to find this information if it is not put directly in front of them.

Steinfeld found his hypothesis to be true, only 20.3% of his non-default group clicked to read the policy, while when it was the default, there was evidence showing those in the group did spend some time reading it carefully over.\(^\text{120}\)

Another article by Powell et al. found that people seeking mental health services online often face complex privacy policies which can compromise consent for people with mental health problems. The improvements in technology have yielded positive outcomes, allowing for mental health related care 24 hours a day, 7 days a week. But it is important to note that cutting corners can sometimes yield adverse outcomes. Agreeing to privacy policy is a prerequisite for using most apps. But this is as easy as scrolling down without reading the information and then hitting “I agree”. Even if you do take the time to read the terms and conditions, they are often “littered with legal jargon that can affect accessibility.”\(^\text{121}\) Powell et al did a study examining accessibility of app privacy policies including rewording complex language. They found most app privacy policies were too long and complicated to obtain proper informed consent. The researchers examined reading level and determined that the mean reading level was 13.1, while the FDA recommends an 8. The authors in the reading note that about 15% of people in the

---


\(^{121}\) Adam C Powell, Preeti Singh, and John Torous, “The Complexity of Mental Health App Privacy Policies: A Potential Barrier to Privacy,” JMIR mHealth and uHealth 6, no. 7 (July 30, 2018): e158, https://doi.org/10.2196/mhealth.9871.
United Kingdom have literacy rates at or below those expected of an 11-year old.\textsuperscript{122} Similar trends exist in the United States as well. Consent is undermined if people are not properly informed of what they are signing up for. You have to meet people where they are and that includes the way information is portrayed to them. Nearly all privacy policies in their current form are not accessible to the general public. As the public becomes more aware of how their data is being used, one of two things is going to happen: 1) people are going to be apprehensive about using any of these apps or 2) the company is going to have to present privacy policies in a simpler, more transparent format.

As Dr. Philip Saylor notes, clinicians are well aware how the current informed consent process fails patients in many facets but especially when it comes to clinical trials. He begins his article by discussing one of his patients that was suffering from metastatic bladder cancer. He decided that he wanted to participate in a clinical trial and wanted to get started as soon as possible. But for the study, there were 45 pages of prescreening and main protocol consent documents that he was required to review.\textsuperscript{123} Remarkably, the doctor went through the policy line-by-line, which does not happen all the time especially in the healthcare industry. But both parties agreed that 45 pages was far too much to go through. Saylor compares the informed consent documents for clinical research to that of terms and conditions. He believes that if patients were given the option to “scroll to the bottom” that they would.\textsuperscript{124} After all, when you go to the doctor’s office, do you look through all of the information or do you just sign on the dotted line where the receptionist tells you to? Saylor sees a tension between providing patients with helpful and pertinent information and providing legal coverage for the sponsor in the form of a paper trail. Saylor again emphasizes that length is something that is largely ignored despite being an important part of accessibility. Because of overwhelming lengths and complex terminology, Saylor says his patients often ask if

\textsuperscript{122} Adam C Powell, Preeti Singh, and John Torous, “The Complexity of Mental Health App Privacy Policies: A Potential Barrier to Privacy,” J\(\text{MIR} \) m\text{Health and uHealth} 6, no. 7 (July 30, 2018): e158, https://doi.org/10.2196/mhealth.9871.


they can just sign the document and move on. Saylor goes on to propose limiting consent documents to just a few pages, going over risks and logistics.

The reason that I present this information about the issues with terms and conditions is because there is a clear connection that can be drawn between privacy policies and the labeling/black box warnings for prescription medications. The same problems exist: there are too many words and the language used is too complex. Informed consent in the healthcare industry is taking a back seat. As some patients are disinterested in trying to learn more about their treatments and just willing to sign off as soon as possible, others are increasingly skeptical of the system as a whole. But when patients are being prescribed medication or considering treatment options, doctors should meet patients where they are and take the time to discuss the potential risks and benefits in simple, understandable terms. Your relationship with your doctor is vital for your well-being. Your doctor should be able to explain to you what medication they are prescribing, how it will help, how you should take it, and what could possibly go wrong in lay terms so you can feel confident in what is going on.

Case Study

To inform good policy reforms, I examined the case study of OxyContin and how vague labeling policies led to anti-utilitarian outcomes. Evidence has shown that the opioid crisis was caused in part due to “inadequate oversight by the Food and Drug Administration.”¹²⁵ But the policies in terms of approving and labeling have yet to change in a substantial way. When pressed by government officials on their inaction, the FDA has become defensive and shifted blame. According to the Food, Drug, and Cosmetic Act, drug makers are prohibited from promoting off-label uses without premarket review by the FDA.¹²⁶ But they did not follow their own policy when it came to the rollout of OxyContin by Purdue. If they had done so on the front end, the label would have specified more narrow conditions in which the benefits outweighed the

risks such as relief from severe pain from a life-limiting illness rather than labeling for common conditions. They could have caught their mistake in 2002 which would have limited the extent to which oxycodone prescriptions ran ragged. In 2002, the FDA convened an advisory committee meeting of 10 outside experts to examine if the broad indication on opioid labels should be narrowed to prohibit marketing for common chronic pain conditions. Eight of these experts had financial ties to pharmaceutical companies, including Purdue, and advised the FDA against narrowing the indication.\textsuperscript{127}

The way Purdue labeled the black box for OxyContin for example deceived those that were prescribed OxyContin. Purdue downplayed the potential risks including the risks of overdose and addiction. Purdue did not properly draw attention to the presence and importance of the black box warning in its promotional materials, patient education materials, or discussions with healthcare providers. They also again were allowed to perpetuate the claim that addiction happened in less than one percent of cases which was simply incorrect and not guided by any empirical evidence.\textsuperscript{128} This claim was put into lay man’s terms so the patients could see this and be at ease when they took OxyContin. The social science literature from the last section applies here in the sense that the pharmaceutical companies strategically put what would help them fulfill their narrative. When they originally brought the drug to market, the original label stated “iatrogenic addiction was ‘very rare’ if opioids were legitimately used in the management of pain.”\textsuperscript{129} Because of lack of proper warning about addiction and overdose, people saw their body was no longer phased by their normal prescription amount. Because they wanted to treat their moderate to severe pain, some individuals took higher doses of OxyContin to achieve a stronger or more immediate effect. Many people that took OxyContin for the first time had no idea how dependent they would become. As their immune system got used to their normal dosage, they decided to take more.


As the FDA began to see increased reports of abuse, diversion, and even death, they worked with Purdue Pharma to change OxyContin labeling in the form of strengthening the warning and precautions sections. It was not until 2001 that the FDA required a black box warning for OxyContin to try to ensure that it was only being used to treat moderate to severe pain. The label was “intended to change prescription practices and ‘increase physician focus on the potential for abuse, misuse, and diversion.”\textsuperscript{130} The new label deleted the statement associating extended release of oxycodone with a lower risk of abuse. These were steps in the right direction but the new labels were still too complex and too long for the average patient to digest. This was once again another instance of boilerplate style text in action. The average person simply cannot understand all of this medical terminology on the label. In addition, the damage of addiction had already largely been done.

Even after the label changed, rates of overdose and addiction did not. In April of 2010, a reformulated version of OxyContin entered the market and the original form was taken off the shelves by Purdue Pharma.\textsuperscript{131} The new formula is abuse deterrent. The new tablet is harder to crush, break, or dissolve and contains a hydrogel that cannot be easily injected.\textsuperscript{132} Oral abuse is still feasible but cutting away outlets for misuse is a major step in the right direction. Opioid abuse rates, including prescription opioids, are unfortunately consistently rising even today. Labeling clearly matters, Purdue Pharma was peddling false claims at the beginning and then trying to cover this up with medical jargon when the FDA noticed a problem. Labels need to be transparent and they need to be understandable to the patients who are taking them. This is a matter of life or death.

Of course, these people deserve some responsibility for their actions but Purdue is misguided to point the finger at these people completely when they were told the risk of addiction was extremely low. All of the actors have blood on their hands, there are


ethical failures all around. The FDA should be held responsible for not even following their own labeling policies and protocols. Purdue should never have been allowed to market their medication and create a misleading label that opened OxyContin to be used and abused by patients with common conditions that brought about pain. Physicians should have been more cognizant of signs of misuse. Patients should have only taken the medication as prescribed and as listed on the label. But all in all, the existing policies in place fail to go far enough to ensure that prescription labels are properly oriented in a way that is helpful for those that will be consuming them. Dr. Andrew Kolodny summed this up perfectly, “The label should reinforce, rather than contradict, guidance from the CDC, the Department of Veterans Affairs, the Agency for Healthcare Research and Quality, and other public health agencies that are calling for more cautious prescribing.”

The FDA approval process applied to this case clearly failed to protect the people from false claims made on black box warnings and labels. The consequence from this is that patients (and physicians) were misled by Purdue Pharma with false claims about the risk of addiction and misuse. This could have been avoided if the FDA had more individualized approval of materials going on labels. Rather than taking Purdue at its word, the FDA officials who approved Purdue’s original label should have pushed for more scientific evidence rooted in studies rather than rooted misleading data. The policy does not even have to be that different, the FDA just has to properly enforce the policies that are in place. A study has found that the Food and Drug Administration’s expedited development and review pathways have higher rates of safety related label changes after approval compared with drugs approved through standard non-expedited pathways. The FDA needs to make approval more difficult in order to prevent an increase in problems on the back end.

Suggestions on Labeling

The policy proposals below are all backed by studies from healthcare professionals who see gaps in the current labeling policy. All of these policies will increase overall well-being by preserving patient safety through prevention of medication misuse and abuse. This benefits the system because it also leads to increased consumer trust and confidence.

Modifications

- Black box warning uniformity- 750 words at 5th grade reading level for every drug with risks, potential complications, and information about proper use
- Step-by-step instructions on proper medication usage, using illustrations when necessary
- Doctors discussing medications with patients before prescribing, giving an opportunity for patients to ask questions
- More information on how medication impacts daily activities
- Multilingual labeling, labels in the spoken language of the patient
- More transparency about instances of severe reactions to medication
- More patient education materials in doctor’s offices and hospitals
- FDA case-by-case approval of labels including scrutinizing of claims not backed up by studies
- Accessible feedback mechanism for patients to critique existing labels

Black box warnings must be organized in a way that gets the most pertinent information out there first, and does so in a way that those who are not highly educated understand. The National Adult Literacy Survey reported that about 25% of the adult population in the United States could not read and understand labels, which are above 5th grade level. In August 2010, FDA published a guidance document regarding label readability which contains “Nonbinding Suggestions” admits that the standard practice to present the medical information is 4th to 5th grade level. It recommends that attempts should be made to present the information on nonprescription labels at
4th-5th grade level, and no higher than 8th grade level.135 If other aspects of medication information are presented in 4th to 5th grade level, there should be uniformity with this as well. In addition, there needs to be step-by-step directions for proper usage. A big part of the problem is also accidental drug misuse. If there were diagrams, patients could follow these instructions to take their medication properly. As stated above, not all patients have an upper level reading capability so pictures are a way that everyone can understand what the instructions are.

Doctors should be discussing medications with patients before prescribing and giving the opportunity for patients to ask questions. In theory, this is a practice that is supposed to be ongoing as doctors are supposed to discuss the purpose of the medication, the proper dosage and administration, potential side-effects, and the duration of the treatment. However, evidence from a study shows that although the purpose of a medication was explained in 87% of cases, adverse effects and duration of medication were only discussed in 34% of the time.136 Similarly, there needs to be more information on how medication impacts daily activities such as driving. People need to really understand the dangers of not following medicinal labeling.

Multilingual labeling needs to be implemented because many people taking medications do not speak English as a first language and therefore they are even less likely to read labels. According to a major pharmaceutical translation agency, multilingual labeling is crucial to bridge the gap for vulnerable populations. They argue, “Language should never be a barrier to accessing essential healthcare services, including medication information. By offering labels in multiple languages, pharmaceutical companies can promote inclusivity and ensure that all patients, regardless of linguistic background, have equal access to vital medical information.”137

Labels also need to be accurate so if the pharmaceutical company makes a claim not backed up by studies, the FDA needs to strike it down. Rather than adopting a more

---

thorough process, the FDA has expedited review for 35% of new drugs between 1997 and 2016. As these drugs were more likely to have safety related changes, this shows the process needs to be more thorough. 138 If something goes wrong with a medication, patients should know about this. Feedback mechanisms are in place for consumers to report a problem to the FDA. There is a form on the FDA website whether consumers can report everything from a bad side effect, an instance of incorrect product use, a problem with the quality of a product, or when there was a problem switching from one product maker to another. 139 This feedback should be expanded to doctor’s offices rather than only being accessible online where some people are unable to navigate technology. 140

There are several reforms to resolve the issues of labeling. Black box warnings must be more uniform and more concise. For example, opioid agonists like Vicodin have no black box warning but some others in the same drug class do. 141 There is no reason why there should be drugs of the same class with such varying black box warnings or even drugs where there is no black box warning at all. The system lacks efficiency and conciseness. When people get their medication, their goal is to take it and feel better. They are not going to read a lengthy script about all of the potential risks of taking their medication.

The current black box warning system is like telling people to read the terms and conditions. As Dr. Philip Saylor noted, patients often will brush aside and hurry through a 45 page consent document for a treatment. That does not equal informed consent. 142 A more concise version that outlines known risks and concrete logistics will be much more accessible to the average reader. The same holds true for prescription labeling. The major scrutiny of a drug should start with the approval process, perhaps if there are

10,000 words to be said about a particular drug, that drug should not be circulating through the market. The FDA must follow their own policies and regulations. The broad label for OxyContin that allowed the drug to be prescribed for any and all instances of pain was a lapse in judgment on the part of the FDA. It is their job and responsibility to keep pharmaceutical companies in check, and unfortunately the record has shown that they have done a lousy job of this. Warnings on the sides of prescription bottles should be limited to 750 words, only portraying how to take the medication, the frequency the medication is meant to be consumed, and the major risks/side effects that are most likely to occur. Less significant information could be covered by the doctor and/or pharmacist. The font also must be enlarged to account for the average person. If we focused on the most pertinent information, this would limit rates of accidental drug misuse such as missing a dose or taking medication too frequently.

Doctors should be the primary source to walk patients through risks and procedural techniques for taking medication, not a label that people are bound to ignore. People are more likely to remember a concise explanation from a doctor about potential risks than a printed piece of paper with a small font of all the potential problems that could occur. The paper can be thrown in the trash but when your doctor is writing you a script, you cannot fully ignore what they are telling you. If doctors took the time to tell patients about the real risks of medication, especially if people try to misuse and abuse it, this will gain more headway with patients. It is not going to scare people away from ever taking medication because people generally speaking trust their doctors and know they are prescribing pills for the person’s benefit.

The solution is two fold, labels themselves need to be reformed but the behind the scenes action also needs to be reformed. There are laws in place for doctors to go over prescriptions with their patients before prescribing. However, not all doctors are doing their best to follow these policies. There is the possibility that medical licensing needs to be reformed as well to ensure doctors are doing what they are required to do by law. In addition, liability should potentially come into play for doctors rather than only holding pharmaceutical officials liable.
Someone may raise the concern about COVID vaccines and how many people were closed off to this despite doctors recommending vaccines to their patients. A study from Silver et al. found that mistrust in the medical profession, one’s doctor and national experts contributes to vaccine hesitancy. Medications are responding to a problem where vaccines are a preemptive measure. Most people are not general vaccine skeptics but they were skeptics of the FDA approving something that was not fully researched. There just needs to be more oversight in what these companies put on warning labels. Just as was the case with marketing to doctors and patients, Purdue and other companies are able to dictate what is on these labels with minimum scrutiny or even oversight from the FDA. This needs to change. Again, the government needs to be more involved in the system and pharmaceutical companies will be forced to fall in line. The opioid crisis was a failure of the government which shows that if the government did their part properly, a lot of the early dominoes that led to opioid overdose and addiction. When lives are at stake, the government needs to protect the people.

Limitations

An objection to these reforms is that changing the black box methodology will scrutinize the system and disincentive pharmaceutical innovation. Delong notes “Medications with boxed warnings associated with them may have adverse financial consequences as these warnings can affect the marketability of the drug and generate negative news reports.” This is misguided, changing the system will only make things safer and ensure products are safe before they are brought to the market. Having a more transparent but concise black box system is actually going to allow pharmaceutical companies to spend less time on designing labels and more time on making sure their product is safe. It also prioritizes honesty about risks of addiction and overdose rather

than deception. Another normative objection is that the people are the problem for ignoring warnings and putting themselves in these positions of dependence on this drug. Purdue Pharma made this point in their Congressional subpoena appearances and throughout the opioid epidemic.\textsuperscript{145} Richard Sackler wrote in an email, “Abusers aren't victims; they are the victimizers.”\textsuperscript{146} This is disrespectful to the everyday Americans that became dependent on OxyContin because of genuine pain that they faced. They were told by their doctors and by Purdue through marketing materials and even on these black boxes that the risk of addiction was less than one percent.

Another concern is that negative messaging will deter patients from properly taking prescriptions that may help them. Studies have found patients' adherence to medication procedures is associated with stronger perceptions of necessity of treatment.\textsuperscript{147} This honest messaging is not meant to be negative but it is to be honest. Of course there is risk in everything in the medical field, but just as doctors educate patients on risks before they consent to surgery, doctors should properly educate patients on potential risks before they take medication. Informed consent is a pillar of the healthcare industry, patients need to know what they are consenting to before they take medication or receive a treatment.

Relatedly, people in favor of the status quo will say more scrutinizing of the black box warning system will impact prescription practices of doctors. This seems like faulty logic because doctors take a hippocratic oath to do what is best for their patients. If they see a medication where the benefits to the individual outweigh the potential harms, they are not going to be deterred from prescribing this medication. Again, this is the case with surgery and other procedures as well.


\textsuperscript{147}https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3846635/
Conclusion

Drug labeling is a very important part of the pharmaceutical system. A lot of the information in its current form exists in databases made for physicians to understand what prescriptions are going to help treat what conditions. For example, when you go onto the FDA website to examine resources for human prescription drugs, you are given four core databases: DailyMed (NIH’s labeling tool), Drugs@FDA, FDALabel, and Medication Guides. All of the resources on the FDA website are clearly designed for healthcare providers. Under a heading titled “Who is the audience for this webpage?”, the answer says “industry staff who develop patient labeling for prescription drugs.” The British government, on the other hand, acknowledges that patients do not always understand warning labels and this should be taken into account with new labeling practices. The FDA site provides templates of what information should be included in a medication guide such as most important information, what is the drug, who should not take it, how it should be taken, how it should be stored, and what are the active and inactive ingredients. A lot of this information is important but it could be condensed. Before your doctor prescribes a drug, they should know whether you fall into a category that should not be taking it. There are many ways to streamline the labels to 750 words and doing so will allow patients to be able to read and understand how to take and store their medication. Proper storage is vitally important because drugs that are not stored properly will likely be contaminated or lose their full positive effect.

Organizations that exist to advocate on behalf of patients are making it known that current labels are not patient-focused with far too complex language, legal terminology, and too many words in general. It will take a village to fix the problems with labeling alone but it certainly is possible. Language must be simplified, in the patient’s preferred language, and translated into lay terms in order to be fully accessible to the clientele that are consuming these drugs. Radin’s boilerplate argument is applicable to this system as well. The rights of the people to give informed consent, not blind consent, are being limited by the existence of complex terms and conditions.

and/or privacy policies that may or may not require the consumer to read them before they can click or sign “I agree”. Oftentimes, people blindly sign, not knowing what they are agreeing to, and this can, in extreme cases, come back to bite them in the end. Changes will be hard to attain on a macro level but in terms of pharmaceutical labeling, there are clear tangible changes that can be made. As the US Pharmacopeia recommended, we can institute “patient-centered prescription labels, simplifying language, using explicit text, including the reason for prescription, improved readability, labeling in a patient’s preferred language, supplemental information, and standardized patient directions.”149 Doctors should do more to bridge the gap with their patients. Your relationship with your doctor is one of the most important relationships that you will have in your life. Your doctor should be able to explain to you what medication they are prescribing, how it will help, how you should take it, and what could possibly go wrong in lay terms so you can feel confident in what is going on, rather than not having a clue.

These recommended policies are rooted in utilitarianism and protecting patients from societal harms related to drug diversion and misuse. Some may argue that there is a tension between labeling that supports informed consent and paternalism but I see the two as both combining to serve utilitarianism. By shielding the public from information that is not important or relevant to the patient, the government is promoting true informed consent to allow patients to make the best decisions for them which will also benefit societal public health.

Brief 3: Proposing State and Federal Policy Reforms for Drug Diversion and Misuse

Introduction

The goal of this brief is to propose policies that limit drug diversion and drug misuse. Paternalistic policies are a necessity to ensure people are protected from harm. An unregulated system like that of Oregon has led to a tripling of opioid deaths of just three years. Because this causes societal costs like emotional loss and economic burden to the healthcare system, policies must be in place to limit the possibility for patients to harm themselves. Improper drug use does not just harm the patient firsthand but may impose psychological damage on a family member who finds the user in this state or may impact innocent bystanders if someone uses medication improperly and carries out a daily routine such as driving. Ultimately, the preservation of social order should be the main priority of the government to maximize utilitarianism. This system may be inconvenient for law abiding citizens but it ensures protection of society as a whole which should be the most important priority of the government. This policy brief is intended for lawmakers which is why there are a lot of news articles detailing real events of drug diversion and drug misuse. This information shows that policies are not doing enough to limit the problem and much more needs to be done.

In this brief, I will discuss some background information defining what drug diversion and drug misuse entail. I will also explain how opioids impact the body and the way that people can easily become reliant on them to function. I will also discuss overdose in the context of the opioid epidemic. I will analyze opioid overdose levels by state including providing some analysis of socioeconomic factors that make people more likely to misuse prescription medication. I will look at scientific studies outlining
addiction within vulnerable populations such as teenagers. I also have a case study of OxyContin where I will discuss what went wrong in terms of drug diversion (pill mill doctors, pharmacies not following protocols, patients selling drugs in black market) and misuse (overconsumption, injection, and inhalation). Then, I will discuss state level policies that help mitigate problems as a result of drug diversion and drug misuse.

My solutions:

- Stricter prescription drug time and dosage limits
- Physical examination requirements to receive medication
- Laws against doctor shopping including the institution of a national prescription tracking database
- Identification requirements to pick up medications
- Closing of pain management clinics.

**Background Information**

This section details how drug diversion and drug misuse eventually lead to overdose. The underregulated system is harming individuals on a systemic level. There are of course first-order health risks involved with drug misuse such as inability to carry out daily functions and even death. These risks increase suffering which is bad for a utilitarian society. There are also social and economic costs involved such as the cost of law enforcement intervention or the cost of people being on disability benefits. Drug misuse can lead to other crimes which limits social cohesion. All of this undermines the goal of public health which is to not do harm.

Prescription opioids are used to treat acute and chronic pain. Opioids work with receptors in the brain to produce a variety of effects including pain relief. They activate an area of nerve cells in the brain and body called opioid receptors that block pain signals between the brain and the body.¹⁵⁰ Opioids create a sense of euphoric high for some people.¹⁵¹ Not everyone experiences this euphoria but for those that do, it can

create a feeling that the person taking it wants to feel all the time. This is one of the risks of opioid use, addiction. A person that uses opioids over time can develop tolerance or physical dependence to the opioid. They may act in erratic ways when they do not have the drug that they feel they need to function. This is something called opioid use disorder which brings about the risk of overdose and death. As a person’s body becomes more accustomed to the dose of opioid, this may convince the person that they need more to achieve the same euphoric, pain-free state. This brings about the risk of overdose as a result of drug diversion or drug misuse.

Drug diversion is the process of obtaining prescription medications illegally. Prescription drugs are prescribed to the patient and this person has to pick their medication up at the pharmacy or receive their prescription in the mail. But sometimes people will sell their medication to other people to make a profit or trade drugs for other drugs. During the opioid epidemic, older people were the most likely to sell pills to make a profit. Some sell their pills due to a financial crisis or to make ends meet. Others are victims of drug dealers, who target them for their prescriptions. And in some cases, caregivers and family members are stealing and selling their medications for profit or to feed their own addictions.\textsuperscript{152} The most common types of drug diversion are selling prescription drugs, doctor shopping, illegal Internet pharmacies, and drug theft.\textsuperscript{153} A common example of drug diversion for college students is a student selling the adderall that they are prescribed for their ADHD. Healthcare providers have been held liable for stealing medication including opioids for their own use. This puts patients at risk because it may cause them to receive care from an impaired healthcare provider, be denied pain medication, or even become infected because of tampering with medication. Pharmacists are also capable of drug diversion as has been the case with oxycodone. For example, in 2011, a CVS in Sanford, Florida ordered enough painkillers to supply a population that was eight times the size of Sanford.\textsuperscript{154}

\textsuperscript{154} Tom Schoenberg, “Cardinal Health Blocked From Shipping Painkiller in Florida,” \textit{Bloomberg.Com}, February 29, 2012,
Health care fraud is unfortunately not uncommon and directly related to drug diversion. Fraudulent activity within pharmacy benefits can take many forms, including patients acquiring prescriptions under false pretenses, providers writing illegitimate prescriptions and pharmacies processing phantom claims. Doctors may file false claims in order to profit off of patients or give them medications that they do not actually need. Pharmacy fraud primarily occurs when Medicare is billed for a medication that was not received or a beneficiary is intentionally given a different prescription drug than was prescribed. This practice is rooted in deception from doctors or patients directly.

Drug misuse is a catch-all term for not taking a prescription medication as intended. This can describe when prescription medication is used for its stimulant properties to create mood alteration or intoxication rather than treating a legitimate medical condition. This may come about through mixing the drug with other substances such as alcohol. This can also involve not taking the medication as prescribed, for example injecting or snorting a medication meant for oral consumption. It can also involve taking more of a drug than prescribed or taking it more frequently than prescribed. With some medications such as opioids, tolerance and dependence is built up in such a way that stopping or reducing use can create withdrawal symptoms.

The headlines about drug overdose are never ending and they only seem to be getting worse. Headlines like “Overdose deaths continue to rise in the US, reaching another record level, provisional data shows”, “A Silent Epidemic: 22 Teens Died Each Week From Overdoses in the United States”, and “Treatment for teens is inaccessible, costly as U.S. opioid deaths rise” are just a few examples of how drug diversion and drug

---

misuse are costing Americans their lives.\textsuperscript{157 158 159} As the headlines show, adults are not the only ones that are paying the ultimate price, children are as well. One article states how prescriptions of buprenorphine are declining but overdose deaths among those aged 10-19 have more than doubled.\textsuperscript{160} This is not a state specific issue either, nationwide the effects of opioid misuse and diversion are being felt.

Opioids are often one of the most commonly diverted drugs, which often leads to overdose. Since 2016, the vast majority of deaths are the result of synthetic opioids with the primary culprit being fentanyl. But it is worth noting that dependence on prescription opioids has been the factor in tens of thousands of deaths as well. Even if it was not the direct drug that led to the overdose, dependence on prescription opioids can cause individuals to become dependent on opioids and look for easy access to opioids that may be laced with fentanyl. Between 2010 and 2021, the number of national overdose deaths involving any opioid grew from 21,089 to 80,411.\textsuperscript{161} This trend has been completely linear since 1999. In terms of isolating prescription opioid deaths, the number of deaths has ebbed and flowed over the years. In 2021, 16,706 died from a prescription opioid overdose.

Drug diversion and drug misuse play a major role in overdose. Allowing medication to get into the hands that they were not intended for decreases the likelihood that the person will be properly educated on the potential risks of consuming that medication and the proper procedures necessary to take the medication in question. If a doctor prescribes you a drug, there is a reason why they feel as if that is

necessary for you to take. If you allow this drug to get into the hands of someone else, not only are you losing medication that you need but that other person is also being put at risk. When someone obtains a drug illegally, this is often driven by desire to feel something like a euphoric high or a sense of dissociation. This is where drug misuse comes into play. Take OxyContin for example, an extended-release opioid that if taken orally will provide relief for a length of 12 hours. But if you were to mix this drug with water and inject it intravenously, the formula will not enter your body as intended and cause your body to be overwhelmed by the opiate entering your bloodstream.

Prescription instructions may vary across different patients because of characteristics such as weight or age. Especially with opioids but even with other medications, drugs should only be taken by those they are intended for. Even if you are taking a drug meant for you, you should only take it as prescribed. Even if you take more of the medication than prescribed to you or take it more often than instructed, this can cause you to overdose. Similarly, if you miss a dose, this may cause your body to experience withdrawal or be negatively affected. Drug misuse does not always have dire consequences but it certainly can.

**Overview of Opioid Overdose Rates by State**

<table>
<thead>
<tr>
<th>Location</th>
<th>Opioid Overdose Age-Adjusted Death Rate (per 100K Population)</th>
</tr>
</thead>
<tbody>
<tr>
<td>United States</td>
<td>24.7</td>
</tr>
<tr>
<td>Alabama</td>
<td>21.2</td>
</tr>
<tr>
<td>Alaska</td>
<td>27.6</td>
</tr>
<tr>
<td>Arizona</td>
<td>28.8</td>
</tr>
<tr>
<td>Arkansas</td>
<td>13.7</td>
</tr>
<tr>
<td>California</td>
<td>17.8</td>
</tr>
<tr>
<td>Colorado</td>
<td>21.7</td>
</tr>
<tr>
<td>Connecticut</td>
<td>38.3</td>
</tr>
<tr>
<td>Delaware</td>
<td>48.1</td>
</tr>
<tr>
<td>District of Columbia</td>
<td>48.9</td>
</tr>
<tr>
<td>Florida</td>
<td>28.9</td>
</tr>
<tr>
<td>Georgia</td>
<td>17.1</td>
</tr>
<tr>
<td>State</td>
<td>Value</td>
</tr>
<tr>
<td>--------------</td>
<td>-------</td>
</tr>
<tr>
<td>Hawaii</td>
<td>6.1</td>
</tr>
<tr>
<td>Idaho</td>
<td>12.8</td>
</tr>
<tr>
<td>Illinois</td>
<td>23.7</td>
</tr>
<tr>
<td>Indiana</td>
<td>34.2</td>
</tr>
<tr>
<td>Iowa</td>
<td>8.6</td>
</tr>
<tr>
<td>Kansas</td>
<td>15.7</td>
</tr>
<tr>
<td>Kentucky</td>
<td>44.8</td>
</tr>
<tr>
<td>Louisiana</td>
<td>30.5</td>
</tr>
<tr>
<td>Maine</td>
<td>42.4</td>
</tr>
<tr>
<td>Maryland</td>
<td>38.5</td>
</tr>
<tr>
<td>Massachusetts</td>
<td>32.5</td>
</tr>
<tr>
<td>Michigan</td>
<td>26</td>
</tr>
<tr>
<td>Minnesota</td>
<td>17.9</td>
</tr>
<tr>
<td>Mississippi</td>
<td>20.3</td>
</tr>
<tr>
<td>Missouri</td>
<td>27.1</td>
</tr>
<tr>
<td>Montana</td>
<td>11.1</td>
</tr>
<tr>
<td>Nebraska</td>
<td>6</td>
</tr>
<tr>
<td>Nevada</td>
<td>18.9</td>
</tr>
<tr>
<td>New Hampshire</td>
<td>28.4</td>
</tr>
<tr>
<td>New Jersey</td>
<td>28.6</td>
</tr>
<tr>
<td>New Mexico</td>
<td>37.2</td>
</tr>
<tr>
<td>New York</td>
<td>24.5</td>
</tr>
<tr>
<td>North Carolina</td>
<td>33.3</td>
</tr>
<tr>
<td>North Dakota</td>
<td>10.2</td>
</tr>
<tr>
<td>Ohio</td>
<td>40.1</td>
</tr>
<tr>
<td>Oklahoma</td>
<td>12.1</td>
</tr>
<tr>
<td>Oregon</td>
<td>18.1</td>
</tr>
<tr>
<td>Pennsylvania</td>
<td>32.8</td>
</tr>
<tr>
<td>Rhode Island</td>
<td>35.9</td>
</tr>
<tr>
<td>South Carolina</td>
<td>35</td>
</tr>
<tr>
<td>South Dakota</td>
<td>5.7</td>
</tr>
<tr>
<td>Tennessee</td>
<td>45.5</td>
</tr>
<tr>
<td>Texas</td>
<td>9.4</td>
</tr>
<tr>
<td>Utah</td>
<td>14.1</td>
</tr>
<tr>
<td>Vermont</td>
<td>37.4</td>
</tr>
<tr>
<td>State</td>
<td>Rate</td>
</tr>
<tr>
<td>--------------</td>
<td>------</td>
</tr>
<tr>
<td>Virginia</td>
<td>26</td>
</tr>
<tr>
<td>Washington</td>
<td>20.5</td>
</tr>
<tr>
<td>West Virginia</td>
<td>77.2</td>
</tr>
<tr>
<td>Wisconsin</td>
<td>25.9</td>
</tr>
<tr>
<td>Wyoming</td>
<td>12.4</td>
</tr>
</tbody>
</table>

Knowing which areas have the greatest need is helpful in crafting policy that properly addresses the problem. The policies should be most parental where there is the biggest gap in social cohesion and biggest amount of societal harm caused by drug diversion and drug misuse. Age-adjusted death rates apply the age-specific death rate to the 2000 U.S. standard population age distribution. This accountables for premature deaths as a result of opioid overdose with account for life expectancy. This chart regarding opioid overdose death rates by state from the CDC in 2021 brings about some troubling takeaways.\(^{162}\) It is important to note that this includes all opioid overdose deaths including synthetic opioids like fentanyl. According to the CDC, prescription opioids were involved in nearly 21% of all opioid overdose deaths in 2021.

Rates of opioid devastation do vary depending on what part of the country people are in, combined with varying aspects to strong healthcare. The national death rate is 24.7, but the most remarkable number is the West Virginia rate which is 77.2. Of the 1,501 overdose fatalities in West Virginia in 2021, 83% involved opioids.\(^{163}\) The problem has gotten so dire for the small state that the federal government awarded $33 million to the state’s Department of Human Resources, Bureau for Behavioral Health.\(^{164}\) Tennessee is another state that has had a staggering rate of overdose. They have expanded naloxone training and passed Good Samaritan laws to protect those who attempt to provide lifesaving care.\(^{165}\) Out of the 2,463 overdose deaths in Louisiana in 2021, 54% of

---

\(^{162}\) “Opioid Overdose Death Rates and All Drug Overdose Death Rates per 100,000 Population (Age-Adjusted),” KFF, https://www.kff.org/other/state-indicator/opioid-overdose-death-rates/.


\(^{165}\) “Naloxone Training Information,” Tennessee Department of Mental Health & Substance Abuse Services, n.d.,
them involved opioids. The state responded by creating the Louisiana Opioid Surveillance Program to improve data collection to determine what areas of the state have an increased need. It is clear that states are trying to cut away at the alarming rates of opioid overdose. It is important to understand the problem to create a solution.

Of course, investigative reporters like Eric Eyre have written books like Death in Mud Lick about how the opioid epidemic perhaps made its strongest impact in coal country, hitting blue collar workers the hardest. This book by Eric Eyre is about the town of Kermit, West Virginia. Despite a population of 382 people, a single pharmacy distributed 12 million opioid pills. This represents another clear example of drug diversion. This caused thousands of citizens of Appalachia to become dependent on prescription opioids. So this explains the phenomena going on in West Virginia to an extent. But the fact that the death rate is nearly an entire 50 per 100,000 higher is extremely troubling and this will not be solved overnight. The opioid crisis is quite costly, costing the US at least $596 billion annually. In areas such as West Virginia, the burden on the economy is quite significant.

It is clear that this is not a regional problem either despite what some rhetoric may say. States like Delaware and Ohio also have high rates of opioid overdose. Ohio was another area hit especially hard by the OxyContin crisis in particular. The first pill mill doctor was David Proctor out of Portsmouth, Ohio. He is now known as “The Godfather of Pill Mills.”

Noting the troubling numbers in certain states, for context, I also examined how the rates vary from 2020-2021. Nationally, the age-adjusted death rate went from 21.4 to 24.7. It was also the case that in every state aside from Maryland, New Jersey, Ohio (which stayed the same), and South Dakota, the overdose rate increased. Some states experienced a minimal increase but states like Louisiana and Alaska saw increases by nearly double digits. Perhaps, this has to do with COVID-19 causing a general uptick in


167 https://www.nber.org/system/files/working_papers/w29983/w29983.pdf
mental health crises and suicides, but regardless alarmingly high numbers are only getting higher.

The Mortality Disparities in American Community Study discovered important takeaways from how factors such as race, gender, disability status, education, and socioeconomic status impact opioid overdose rates. In general, opioid overdose was an overrepresented cause of death among people ages 10 to 59. Compared to Hispanics, Whites and American Indians had an elevated risk. Risk was higher among those who are disabled, men, unemployed, widowed, and noncitizens. Those with high school degrees were at significantly higher risk than those who graduate degrees. People who rented had higher risk than those who owned homes. Rural residents were at slightly higher risk. People without health insurance and those who were incarcerated were also at higher risk of dying of an opioid overdose. Those living in households at least five-times above the poverty line were less likely to die than those in poverty. As we generally see with the data, people in South Atlantic and Mountain states saw the highest risk compared to the West North Central states. It is clear that indicators of lower socioeconomic status were associated with opioid fatality.

Even though prescription opioid overdoses are only the cause of one out of five opioid-related overdoses, this is still thousands of people dying from something that is highly preventable. Addiction and dependence on prescription opioids is a slippery slope to drug misuse and diversion, as well as a potential factor in future synthetic opioid overdose. This chart from the CDC shows how opioid overdose deaths have increased over the last 20+ years. This has occurred in three stages. The first was prescription opioid overdose deaths started in the late 1990s, associated with the FDA approval of OxyContin. The second stage was a rise in heroin consumption. More recently, there has been an uptick in synthetic opioid overdose, largely caused by fentanyl. Fentanyl can be made cheaply in large supply but is extremely lethal even in small doses. Between 2020 and 2021, synthetic opioid-involved death rates increased

---


more than 22%. At the same time, prescription opioid-involved death rates remained constant.

There is quite a bit of social science research that puts some of this information in perspective. Many studies focus on spillover effects of opioid policies into other aspects of society such as crime. A study of opioid scheduling finds that tightening prescribing restrictions on one opioid leads to decreases in its use, but also causes some increases in prescriptions of close competitors, leading to no statistically detectable short-run reduction in total opioid prescriptions. This shows that changes have to be made on a macro level rather than just for prescription.171 Another study found that an increase in opioid supply drives up substance abuse treatment and overdose deaths. The study states that “evidence suggests that increased opioid supply is associated with economically-important levels of diversion for nonmedical purposes.”172 One study finds that prescription drug monitoring programs are associated with a reduction in crime. This shows that monitoring programs are an effective “social policy tool to mitigate

---


some of the negative consequences of opioid misuse.” In the case study, I will discuss OxyContin in more detail but a study found a spillover effect relating abuse-deterrent OxyContin to lower levels of intimate partner violence.  

**Synthetic Opioids**

Discussion of synthetic opioids is important to get the full picture of the opioid epidemic. As the chart above shows, prescription opioid abuse was only the start of the opioid epidemic. Prescription opioid misuse has the potential to create a gateway that ends in eventual fentanyl use. Synthetic fentanyl use is far more dangerous than that of a prescription opioid because the formula is not approved by the FDA and is extremely lethal. Synthetic opioids currently impose the greatest societal harm.

Fentanyl can be prescribed pharmaceutically to treat severe pain but oftentimes this is localized to treat pain from late stage cancer. Fentanyl is 50 to 100 times more potent than morphine. Oftentimes, prescription fentanyl is taken in the form of transdermal patches or lozenges. There is potential for diversion and misuse of fentanyl. However, most of the carnage related to fentanyl comes from illegally made fentanyl that may be sourced from other countries. It is sold in illegal markets and often combined with heroin and cocaine to amplify the euphoria that the person feels. Nearly 71,000 drug overdoses in 2021 involved synthetic opioids. There are analogs of fentanyl such as carfentanil that are 10,000 times more potent than morphine. Another main concern of fentanyl is how easy it is to contaminate other illegal drugs. This can lead to an increase in overdose deaths among people who may or may not be aware that their drugs include this deadly additive, and among people who have not used opioids before, and thus are at greater risk for overdose. Oftentimes, people who died from an overdose tested positive for fentanyl also tested positive for cocaine, meth, or heroin.

The first wave began with the prescription opioid overdose rise associated with the rolling out of OxyContin. The second and third waves represented a growth from

---


the original problem, addiction to prescription opioids as a result of diversion and misuse. To learn from this in the future, the trends need to be cut off at Phase 1 before they grow out of control into something far more dire. Phase 2 and 3 represent patients taking illegal substances in order to feel the euphoria they had originally felt with prescription opioids. So if we can limit the drug diversion by cracking down on pill mills and pharmaceutical malpractices, this will also limit drug misuse. It will also limit the dependence on heroin and synthetic opioids such as fentanyl.

### Notable Research by Public Health Officials

When determining how to proceed in terms of modifying policy, it is important to factor in what the experts are saying about diversion and misuse. I will examine a study focusing on some of the specifics of diversion and misuse such as potential motivations, geographic differences, and effects on children. All of these individual characteristics are important to consider when making more utilitarian policy that protects public health interests.

A study by Dr. Noelle Spencer et al. found that the risk of contracting substance use disorder is highest for those who initially took opioids during their early teen years. They examined the contexts in which people first misuse opioids and the motivations for future misuse. This study was conducted by interviewing 26 individuals in Allegheny County, Pennsylvania that have a history of opioid misuse. Some of the participants disclosed that they lived in an environment that normalized and even accepted opioid misuse. The participants have the similar experience of first using opioids to treat physical pain. They also recognized and sought out the psychological benefits from opioids. A lot of the participants shared a similar conception that opioids were a requirement to feel “normal”. These people that now suffer from opioid misuse had originally had good intentions for using opioids. The authors describe lessons that can be learned to end this trend of opioid misuse. Opioid use should be hyper-analyzed

---


and education should be oriented. If the signs show that risk of substance use disorder is highest for those in their young teens, doctors should be extremely careful when deciding to prescribe opioids to these individuals and look to alternatives when possible.

Dr. Shannon Monnat and Dr. Khary Rigg found that people from rural areas have the highest odds of prescription opioid misuse. They examined differences in prescription opioid misuse among children in rural, small urban, and large urban areas of the United States. This article is slightly dated, examining national data from 2011 and 2012. Among children, 6.8% of rural, 6.0% of small urban, and 5.3% of large urban engaged in past-year prescription opioid misuse. The authors found that rural adolescents have 35% higher odds of prescription opioid misuse and small urban adolescents have 21% greater odds of prescription opioid misuse compared to large urban populations. Criminal activity, lower perceived substance use risk, and greater use of emergency medical treatment partially contribute to higher odds among rural adolescents, but they are also partially buffered by less peer substance use, less illicit drug access, and stronger religious beliefs. With this information in mind, the authors recommend how individual, social, and community factors play into such an extreme disparity. For rural areas especially, the authors recommend early education about addiction, use of family drug courts to link criminal offenders to treatment, and access to nonemergency medical resources as ways to reduce rural adolescent opioid misuse rates. The federal government should be investing in more education initiatives to educate vulnerable members of the population such as children and the incarcerated.

Dr. Melissa Schaefer and Dr. Joseph Perz found that drug diversion is best prevented by healthcare facilities having strong narcotics security measures. They

---

examined how drug diversion by healthcare personnel led to multiple outbreaks of infections between 2000 and 2013. The authors discuss six outbreaks in hospitals as a result of nurses and technicians tampering with injectable controlled substances. Two of these were as a result of tampering with opioid via patient-controlled analgesia pumps. This resulted in bacteremia being transmitted to more than 30 patients. The remaining four outbreaks involved tampering with syringes or vials containing fentanyl, which resulted in transmission of Hepatitis C. These outbreaks left nearly 30,000 patients potentially exposed to bloodborne pathogens. Although healthcare professionals are expected to be the ones vetting patients for potential misuse and diversion, they are also given access to things that the rest of society are not. They do have the ability to take advantage of their circumstances and even get away with it if it weren’t for these infection outbreaks. Without showing mistrust of healthcare personnel, we need to enhance security for injectable controlled substances. Perhaps, two people should be present at all times when retrieving injectable controlled substances. This is standard practice for other aspects of healthcare such as surgery.

Dr. Lisa Merlo et al. found that expansion of drug diversion protocols is vitally important to safeguard pharmacies and the patients they service. They examine instances of prescription drug diversion by substance-impaired pharmacists. The authors organized anonymous guided group discussions with 32 pharmacists who were being monitored due to substance-related impairment. Participants documented six methods of drug diversion by pharmacists: 1) taking expired drugs that can no longer be sold by the pharmacy and are awaiting disposal; 2) assuming responsibility for managing the pharmacy inventory and/or changing inventory records to prevent detection of missing drugs; (3) forging prescriptions for themselves, family members, friends, or customers in order to gain access to the drugs; (4) using “sleight of hand” techniques to acquire drugs while filling prescriptions or shelving products; (5) blatantly stealing drugs from the pharmacy, even in front of coworkers or video cameras, and (6)

collecting patients’ unused medications and keeping them.\textsuperscript{182} Participants have noticed weaknesses in current protocols such as forged medications never being discovered. Pharmacists should have to pass a specific test related to diversion in order to get their license.

A lot of information about drug diversion on the part of pharmacies emerged from the national headlines surrounding two CVS pharmacies in Sanford, Florida. In 2011, the DEA was called into investigate two pharmacies in Sanford for allegations of excess OxyCodone. In 2011, the average pharmacy in the US ordered around 69,000 oxycodone pills while these two pharmacies ordered 3 million oxycontin pills despite being 5 miles apart from each other.\textsuperscript{183} The DEA discovered evidence that drugs were being diverted to those without legitimate prescriptions and that CVS was aware or at least should have been aware that this was ongoing. As a result of this, CVS Health paid a $22 million fine for their role in violating the Controlled Substance Act. The DEA also opted to take away DEA licenses at both of these stores. This caused more attention to be drawn to pharmacy practices to limit instances of pill mills. Pill mills were actually created with opioids in mind and became much more widespread as a result of OxyContin. This only perpetuated the problem of opioid misuse and diversion. The government needs to increase surveillance of pharmacies including conducting regular, unannounced audits.

Case Study: Drug Diversion and Misuse with OxyContin

Once again, to create better policy for the future, there must be an understanding of where previous policy has gone wrong. This is why analysis of a case study is pivotal


to finding key takeaways of where more paternalism would have generated more utilitarian outcomes such as less prescription addiction and less diversion.

As the literature shows, drug diversion is often perpetuated by healthcare professionals and pharmacists. Vulnerable people often may exploit the system for monetary profits or be put in situations where misuse and addiction become not only possible but likely. The case of OxyContin is a clear instance of where drug diversion and drug misuse became common practice and got out of hand. Part of this had to do with patients being led down the wrong path with false claims about the risk of addiction.

After OxyContin became a very trendy drug that was being prescribed in high doses, drug diversion and misuse really took off. In terms of misuse, people were crushing OxyContin pills and snorting them to create an immediate effect. Other people crushed OxyContin pills in water and injected the solution.184 Some people were no longer feeling any benefits of their dose as prescribed so they consumed OxyContin in larger doses or took the drug more often. In terms of diversion, doctors were reaping the benefits of a system where they received more benefits from Purdue Pharma if they prescribed more OxyContin pills. The pharmaceutical company had access to individual physician prescription data records and aggressively tailored marketing to those who were not prescribing.185 With this pay for play system, pill mills became common practice. The situation with the CVS pharmacies in Sanford are just one of the many examples of diversion of OxyContin. It was not just doctors and pharmacists that were not acting ethically. Patients were dying to get their hands on more OxyContin, either to sell it or to consume for the feeling it gave rather than treatment of pain. As people became dependent on OxyContin to get through the day, they became more likely to misuse. Some people had reasonable beginnings of taking the medication as prescribed

---


but this quickly created a slippery slope. Patients also turned to crime, mostly break-ins, to have something to offer in exchange for OxyContin.\textsuperscript{186}

Research shows that there are a number of factors that contributed to the problem of OxyContin abuse. The most important factor was the ability of users to manipulate the drug and therefore receive the full dose of oxycodone that was intended to be given over a length of time in the extended release formula. There is evidence showing that Purdue Pharma actually knew that this would be the case even when the drug was up for review with the FDA.\textsuperscript{187} Tests conducted by Purdue themselves showed that rushing a capsule of OxyContin would allow a would-be recreational user to immediately receive up to 68\% of the oxycodone contained in a capsule of OxyContin.\textsuperscript{188} Only in 2010, when the opioid epidemic was well under way, did Purdue re-release an abuse-resistant formula for OxyContin. Pharmaceutical advertising and promotion was also a large part of the problem, patients had their testimonials manipulated by Purdue for promotional purposes. In 2001 alone, Purdue Pharma spent \$200 million on advertising and promotion for OxyContin. In addition to advertisements in medical journals, the company conducted more than 40 national pain-management and speaker-training conferences.\textsuperscript{189}

In the book Dreamland, author Sam Quinones discusses how in Portsmouth, Ohio, Walmart served as the hub for rural junkies who needed to “get well”.\textsuperscript{190} What this meant is people would shoplift merchandise from Walmart, often hundreds of dollars worth, just so they could sell these off in exchange for OxyContin. Someone directly connected to the town described that people would sometimes spend a half hour in Walmart and only acquire enough for a single pill or two. People would modify their

\begin{itemize}
  \item \textsuperscript{190} Sam Quinones, \textit{Dreamland: The True Tale of America’s Opiate Epidemic} (Bloomsbury Press, 2015).
\end{itemize}
prices of what they would ask for in exchange for OxyContin based on how desperate the addict was. No one would stop the shoplifting because employees were either too fed up about their low wages or also strung out. These people went all out to get away with the shoplifting, wearing baggy clothing and stuffing items in jackets or emptying boxes and filling them with other products. People would even steal goods and then “return” them in exchange for a gift card.

There are statistical findings that show that exposure to initial OxyContin marketing increased rates of fatal synthetic opioid–related overdose. OxyContin’s controlled-release formulation, which made the drug beneficial for the relief of pain over an extended period of time, enabled the drug to contain more of the active ingredient oxycodone than other, non-controlled-release oxycodone-containing drugs. This made it more attractive for misuse and abuse. The FDA failed to realize it could be dissolved in water and injected, which would undercut the controlled extended release characteristics. Doctors were not properly vetting patients who often showed signs of abuse, they were just prescribing more pills to the patients to meet their demands.

Demand for OxyContin led to increased diversion. Doctors often were nervous that they would lose their patients if they did not meet their needs. They would file insurance claims for unnecessary prescriptions so patients would be satisfied. Other doctors like Larry Proctor just wanted to make as much money as possible. Pill mill doctors were known to only accept cash as payment and prescribe any drugs that patients wanted for real or fake conditions. A doctor remarked that he knew of a physician in his area that would meet patients in a local coffee shop to exchange prescriptions for cash. There is evidence showing that some doctors sold millions of opioid pills and even engaged with street drug dealers to increase their patient base. People would find doctors that were seen as prescription friendly, they would claim pain, and they would get their hands on the medication. Then, they may travel to

---

another doctor and claim the same thing. Individuals would go to multiple doctors to try and stock up on OxyContin that they would abuse themselves or deal to others.

By the peak of the epidemic, most people were using OxyContin for non-medical purposes and obtaining OxyContin illegally. Obtaining the drug illegally made people susceptible to receiving counterfeit or laced medication. People were also combining Oxy with other drugs in a very risky way. The worst part of all is that the system was so overwhelmed that there were no proper mechanisms to combat the alarming rates of addiction and overdose. It also took awhile for red flags to start appearing. As previously mentioned, these red flags included increased crime rates and instances of intimate partner violence. The economy also took a hit as hundreds of millions of dollars went towards dealing with the skyrocketing rate of addiction and overdose.

**Drug Diversion Policies by State**

Currently laws do vary by state in terms of specific ways to mitigate aspects of drug diversion and eventual misuse. As states have most of the jurisdiction, it is important to focus on the policies that are working at the state level and should therefore be applied in the areas where there is the most need. Under the current governance system, the states have most of the jurisdiction to regulate and enforce prescription drugs practices to the states. State laws are often used to prevent various injuries, with demonstrated benefits, yet little information exists about the effectiveness of state statutes or regulations designed to prevent prescription drug abuse and diversion. I will examine how states vary in terms of laws related to: 1) prescription drug time and dosage limits, 2) physical examination requirements, 3) doctor shopping laws, 4) state prescription drug identification requirements, and 5) pain management clinics.

**Prescription Drug Time and Dosage Limits**

Many states have responded to the prescription drug overdose epidemic by enacting laws that set time or dosage limits on prescriptions of controlled substances. Forty-seven states and the District of Columbia have laws that set time or dosage limits for controlled substances. However, the specifics of these policies do vary from state to state. Five states have laws setting time limits for all controlled substances. Florida, for
example, limits supplies of prescription drugs to thirty-four days or a standard supply of treatment. Twenty-three states and DC have laws setting time limits for specific schedules of prescription drugs. In Missouri, Schedule II drugs are limited to a 30-day supply while Schedule III, IV, and V are limited to a 90-day supply. California law says a care provider may dispense “directly to an ultimate user a controlled substance classified in Schedule II in an amount not to exceed a [seventy-two]-hour supply for the patient in accordance with directions for use given by the dispensing practitioner only where the patient is not expected to require any additional amount of the controlled substance beyond the [seventy two] hours.”

Several states have day or hour limits for oral prescriptions. Some states also have time limits when there are multiple prescriptions involved. Thirty-six states and the District of Columbia provide day or hour supply limits for members of certain benefit plans such as Medicaid or Medicare programs. Some states have day or hour limits for prescription drugs dispensed in the context of an emergency. Others set time limits for prescription drug refills. Some states limit dosage amounts of prescription drugs.

Identification Requirements

Twenty-five states have laws mandating or allowing pharmacists to request identification before dispensing prescription drugs. All but one of these states has at least one law mandating that the pharmacist request identification generally or under specific circumstances before dispensing prescriptions. The mandatory identification laws may specify the circumstances under which identification is required or the drugs to which the requirements apply, the type of identification required, or whether the pharmacist must record the identifying information. Delaware is the only state that requires mandatory identification specifically from the intended receiver in all circumstances rather than just for a specific scheduling of drugs. Some laws are rather open-ended stating that pharmacists are required to obtain identification if they are unsure about the identity of the person picking up the medication. States with identification laws vary in the extent to which they specify what form of identification is

---

required. A few require only a photograph for example. In my personal experience in Tennessee, I could pick up my dad’s prescriptions as long as I provided my ID and gave his address and birthday.

**Doctor Shopping Laws**

Doctor shopping is defined as a patient obtaining controlled substances from multiple healthcare practitioners without the prescriber’s knowledge of the other prescriptions. All fifty states and DC have a general fraud law that is applicable to doctor shopping. Twenty states have also adopted stand alone doctor shopping laws. These specific laws prohibit a patient from withholding information from the practitioner the patient is seeing about prescriptions they have received from other healthcare providers. “States with general doctor shopping laws prohibit patients from obtaining drugs by any or all of the following means: fraud, deceit, misrepresentation, subterfuge, or concealment of material fact.”\(^{195}\) The states that have specific laws prohibiting doctor shopping generally specify a timeframe for which information should be disclosed from such as thirty days. Other states such as Connecticut require disclosure of controlled substances or prescriptions being taken at the same time as the new treatment. Nearly half of all states have laws specifying that information shared between doctors and patients about a patient’s intent to commit fraud is not privileged communication that is protected by doctor-patient confidentiality. Public health officials such as Jeffrey Singer may object, arguing that these laws impact a patient’s individual right to privacy.\(^{196}\) He believes that patient confidentiality is both a legal obligation and an ethical requirement. He finds these laws to be counterproductive and harmful to patients. I will push back by arguing that fraud is a crime and if a patient says they are going to commit a crime, the doctor should get involved to protect the patient.


Prescription Drug Physical Examination Requirements

Forty-one states and the District of Columbia have one or more laws that require a prescriber or dispenser to ensure that prescriptions for medications are based on an examination of the patient. Some states have laws that only impact physicians, requiring them to see a patient as part of prescribing requirements. Others also mention how pharmacists are prohibited from dispensing certain drugs if there is doubt that the drugs were prescribed following a physical exam. Some of these descriptions are rather arbitrary stating that an examination or evaluation must be deemed “appropriate” or “sufficient”. Thirty-six states and DC require physical examinations for all drugs, while others vary by scheduling. Florida is an anomaly and requires physical examination laws for prescribing and dispensing of all drugs including pain management drugs. Many states have responded to the rise in telehealth electronic questionnaires by prohibiting this mechanism from being the sole factor in a physician prescribing a drug.

Regulation of Pain Management Clinics

There are laws on the books in a few states targeting pain management clinics that are often associated with the practices of pill mills. As of 2012, only eight states addressed these pain management clinics that are noted hubs of drug diversion and fraudulent practices. States use language that describes pain management activity as either the primary practice component of such facilities, the provision of pain treatment to a “majority” (or more than 50 percent) of facility patients, or both in order to qualify as pain management clinics. All eight states require pain management clinics to register with the state or obtain a license or certificate with the state. In some states, inspections of pain management clinics are mandated at regular intervals to determine compliance with license/administrative regulations. Laws also often dictate specific requirements for ownership and operation of pain management clinics. All eight states

have some form of provision prohibiting non-law-abiding or restricted licensees from becoming owners or employees of pain management clinics.

**Suggestions**

*Need for a National Benchmark*

The issue of opioid diversion and misuse is much more complicated than what crowds the headlines. There is no way to fully eradicate this epidemic but there are policies that could and should be set as a national benchmark. In our government system of dual federalism, it is important to account for state sovereignty. The problems in West Virginia are more severe than that of Texas for example. So the protocols in West Virginia should be tailored towards the problems that exist in West Virginia. But there should be a national minimum benchmark and then states should be able to add on the policies that they deem necessary. The federal government should put forth recommendations for state governments to pass. These recommendations are listed below and sorted into multiple categories.

*Identification Requirements*

In terms of identification requirements, so much of the responsibility is on the pharmacist. Of course, these people are well-trained in their field and for the most part, judgment is sound. However, this creates an arbitrary standard where some states require identification, some states allow the request to happen at the discretion of the pharmacist, while other states do not have any laws on the books related to discretionary or mandatory identification. The policy should be uniform and any form of identification should be required in addition to verifying date of birth and address. If there is a wide list of usable identifications, this will not be discriminatory. You need identification to open a bank account, to apply for unemployment, to get on an airplane, and to rent a hotel room. You should be required to show identification to obtain a prescription medication that requires a doctor to prescribe it in the first place.

*Doctor Shopping Laws*

Perhaps, the most head scratching policy failure around drug diversion is the lack of nationwide laws against doctor shopping. Laws existing on the books to limit
fraud are too watered down and lack proper enforcement mechanisms. Even specific laws lack any sort of channel to determine whether or not a patient is withholding information from a healthcare professional about their current prescriptions. Without violating HIPPA and doctor patient confidentiality, there is a way to establish a federal database to ensure doctors are not double prescribing patients with a particular description. New York has already instituted a system just like this through the Internet System for Tracking Over-Prescribing Act. Starting in August 2013, doctors became required by law to consult the database before writing any prescriptions for a Schedule II, III, and IV controlled substance.\textsuperscript{199} Less than a year after this was instituted, doctor shopping dropped by 75%.\textsuperscript{200} Instituting mechanisms like this database are especially helpful for opioid abuse. Opioids are the most commonly acquired drug which may lead to short supply if doctor shopping is so mainstream. Doctor shoppers often see 10 doctors a year, receiving upwards of 32 prescriptions, and paying in cash whenever possible.\textsuperscript{201} This was one of the biggest factors in the amplification of the oxycontin epidemic. Having a centralized database of prescriptions will allow the federal government to be more involved in surveillance and to be able to detect any irregularities. There is a direct relationship between pill mills and doctor shopping and if one is undercut, they are both bound to fail.

_Criminal Liability and Pain Management Clinics_

Public officials should also enforce criminal sanctions against physicians who contribute to diversion and misuse. Pill mills still exist, even today. Just in November 2023, a physician was sentenced to seven years in prison for prescribing combinations of controlled substances in exchange for cash. In just over a year, the “pain management clinic” made about $1.2 million in cash off these transactions.\textsuperscript{202} Punishing the


individuals responsible is important but it does not fix the problem on a macro sale. There are laws that could prevent this from being such a present issue. In 2011, Florida passed a law that banned pain management clinics from dispensing drugs. Due to these new regulations, the number of pain payment clinics in Florida declined over the next three years. These laws are a good start but there should be some limits of how physicians advertise to patients in terms of controlled substances. A lot of patients that do not know any better are enticed by misleading advertisements from physicians. There are clear signs of pill mills such as a large volume of patients, patients traveling across state lines, patients carpooling, and clinics running on a cash only basis. These signs should be recognized and reported. Having a nationwide database tracking prescriptions by location and even at the individual patient level will allow the federal government to be more involved in surveillance and to be able to detect any irregularities.

*Physical Examinations*

With COVID and general technological advancements, telehealth is constantly on the rise. This is really convenient for certain follow up appointments or just general consulting with a physician. That being said, in-person physical examinations should be a requirement to receive an initial prescription. Currently, nine states do not have this policy in place in an explicit law. This should be nationwide protocol. Unfortunately, not all patients can be completely trusted to be transparent and honest with their doctor about their conditions. As was the case with OxyContin, people would often feign pain for prescriptions and this becomes even easier with reliance on online communication. Some laws are still quite vague and only require an “appropriate” or “adequate” examination. This puts a lot of the onus on the doctor to ensure that they are doing their due diligence. The law should specify what an “appropriate” examination consists of or at least provide a set of questions to screen the patient, vetting the person to ensure they are not likely to divert and misuse medication.

---

Challenges

Mitigating the problem of drug diversion and misuse will require five major reforms because there are many different policy gaps that contribute to the problem. A study conducted in Ohio and Tennessee has already shown that pill mill laws alone did not impact prescription overdose rates. But if you take pill mill laws and combine that with laws surrounding doctor shopping, physical examination requirements, maximum length of prescription, and identification requirements, opportunities for drug diversion and misuse become severely inhibited. A lot of these policies already have been tested in states and even have proven results. The most effective policies should be applied in states where drug diversion and misuse rates are the highest.

The primary barriers to the implementation are concerns about privacy and free speech. In terms of the pharmaceutical industry, pharmaceutical companies strive to maximize profits. Anything that undercuts this will be seen as a threat so they will likely push back against laws that prevent pain management clinics from prescribing medication. They also would likely object to extreme regulation of doctor shopping and the institution of a federal database. These laws might have a bit harder of a time getting through Congress. Concerns about privacy and HIPAA are extremely important when implementing policy. It is important to note that in certain circumstances, clinical information sharing without patient authorization is permitted under HIPAA. Perhaps some of my suggested policy changes such as regulating how doctors advertise may be violations of the First Amendment but it seems reasonable to me that there is a compelling state interest to ensure physicians are abiding by ethical codes that are not going to bring people into the cycle of risky behavior and addiction.

Public officials may raise concerns about over incarceration with increased liability and stricter policies. However, patients will feel less of the blame for the failures of the system and so this will limit the incarceration of patients while increasing potential liability for physicians and pharmaceutical officials. Another concern is the cost of enforcement. However, the public health costs of diversion and misuse are extremely high already. Enforcing these policies may increase costs but it will also save lives and protect the average patient which is worth the cost. The answer
to an out-of-hand problem is to regulate the problem, not decriminalize hard drugs like Oregon has done.

**Conclusion**

Drug diversion and drug misuse are prevalent problems in society that undercut the utilitarian goals of protecting the public good. Controlled substances get in the wrong hands only to be sold in under the table markets or crushed and snorted by someone dealing with addiction. In conditions of desperation and poverty, people will sell their medications to make a profit or pay cash for controlled substances that they do not need. This is not a generational problem, it affects younger and older people alike. No one, not doctors, patients, or pharmacists, is fully innocent or fully responsible for the problem. Doctors need to ensure they are abiding by their ethical code and acting in the best interests of their patients rather than trying to maximize their profits. Patients need to be transparent with their physicians about their active prescriptions rather than trying to defraud the healthcare system by stocking up on prescriptions. Pharmacists need to be empowered to properly screen patients rather than having to be judges of moral character and suspect behavior. Dosages should be limited to a shortened period of time, doctor shopping should be tracked through state databases, pill mills should be supervised closely and be prohibited from prohibiting medication unless the state approves this, performing physical examinations should be required, and verifying identification when picking up a prescription should be mainstream. Without all of these policies coming together, the system will stay the same and the issues plaguing our country will only continue to do so. These policies will not harm everyday people that do what they are supposed to in the current system, it will only serve to ensure more people are falling into the category of ethical behavior which will in turn limit drug diversion and drug misuse. The reputation of pharmaceutical marketing in America has never been lower. Only 18% of Americans have a positive view of pharma, while a record 60% view the industry negatively. Now more than ever, the government
should pass paternalistic policies to reform the industry to act to prevent a repeat of the opioid epidemic and to protect the people from harm.\textsuperscript{204}

\section*{Conclusion}

The current pharmaceutical system is extremely unpopular among the general American public, with only 18\% of Americans having a favorable opinion of the pharmaceutical sector.\textsuperscript{205} However, as the opinion of the industry continues to go down, the amount of revenue brought in for pharmaceutical companies continues to go up.\textsuperscript{206} The influence of the industry is not going away. So to protect the public good, the government needs to properly regulate the industry. Lack of proper regulation and too much reliance on unprompted utilitarian behavior played a major role in the growth of the opioid epidemic. The government was too trusting of the pharmaceutical companies, too trusting of the physicians, and too trusting of the patients.

Pharmaceutical marketing and labeling policies were doing little to protect the people from harm and largely speaking led to deception. Deceptive practices cost people their livelihoods and even in many cases their lives. This played a part in the widespread drug diversion and drug misuse throughout the opioid epidemic. Unfortunately, there is no way to undo the damage that has already been done. However, there is a way to learn from the future.

My goal with this project was to propose practical policies that were consistent with the constitution and served to prevent another public health crisis like that of the

\begin{footnotesize}
\begin{itemize}
\end{itemize}
\end{footnotesize}
opiod epidemic. I laid out an amicus brief addressing both direct to consumer marketing and marketing to physicians where I discussed how regulation of commercial speech could hold up in the courts. Then, I wrote a white paper brief where I discussed existing federal policy on labeling at the FDA and DOJ level. I analyzed where there were policy gaps and proposed solutions to bridge the gap between informed consent and paternalism. Lastly, I wrote a policy brief intended for lawmakers where I discuss policies addressing drug diversion and drug misuse. A lot of policies are too laissez-faire which has created the problems that exist in the system. As shown in Oregon, too much freedom for individuals has translated to an increase in drug-related deaths.

My proposed reforms are driven by paternalism and utilitarianism. Paternalism gets a negative reputation but it can actually be a super positive force to protect the public good. Paternalistic drug policy protects vulnerable populations that are more likely to be taken advantage of. It also prevents harmful behaviors which are likely to impose negative consequences on society. Paternalism is good on a macro level because it prioritizes health and safety. These policies proposed may be seen as burdensome to some but they are important steps to ensure a safe society. Informed decision making is ultimately at the root of these policies. It may seem as if there is tension between paternalism and consent but these two goals can exist cohesively. Paternalism allows people to make decisions that are going to be to their benefit long-term. Paternalism is also important to correct the market failures of the opioid epidemic, which benefits society as a whole. All of this leads to social cohesion and limiting societal costs. Society should abide by a utilitarian ethical code. This is the best way to promote well-being of individuals and society as a whole by limiting suffering. The opioid epidemic brought about so much preventable suffering and by learning from these policy failures, we can move forward to prevent a repetition of this tragic public health crisis.