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Solving the Opioid Epidemic in Ohio

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SOLVING THE OPIOID EPIDEMIC IN OHIO

LACY LEDUC, CLEVELAND MARSHALL COLLEGE OF LAW, J.D. 2019

I.	INTRODUCTION.....	111
II.	BACKGROUND	114
	A. <i>What Are Opioids?</i>	115
	1. Why Are They Harmful?	116
	2. What Is Heroin, and Where Does it Come From?	116
	3. Why This Issue is Important to the Government	118
	4. The Role Of The Food And Drug Administration	119
	B. <i>What Role Are Drug Pharmaceutical Companies Playing?</i>	120
	1. Drug Representatives Provide Information to the Medical Community	122
	C. <i>The Learned Intermediary Doctrine</i>	124
III.	ANALYSIS.....	127
	A. <i>The Solution: An Exception to the Learned Intermediary Doctrine</i>	128
	B. <i>The United States Supreme Court has the Authority to Make this Exception</i>	130
	C. <i>The Role of the FDA</i>	130
	D. <i>The Ohio Supreme Court has the Authority to Make this Exception</i>	131
	1. Repealing The Learned Intermediary Doctrine.....	132
	2. Punishment this Late would be Ineffective	132
IV.	CONCLUSION	133

I. INTRODUCTION

“Providers wrote nearly a quarter of a billion opioid prescriptions in 2013; enough for every American to have their own bottle of pills.”¹ This high number of pills per American has started a tidal wave of problems that is sweeping across America. However, it is the drug manufacturers that are responsible for these growing problems. The opioid epidemic that is striking the nation is drawing serious attention and raising questions about what to do to solve it. While it is a nationwide problem, it has also hugely affected Ohio. These drugs are no longer those that can be associated with the common image of a ‘drug addict;’ they are being found far more frequently in high schools, affluent neighborhoods, and families of all races, cultures, religions and income statuses alike.² The key to stopping this problem lies within the prescription drug community. Prescription drug manufacturers have a major influence on the number of pills being prescribed by doctors. In 2016, 631 million opioid pills, such as OxyContin, Percocet, Vicodin, Lortab, and Percodan were given out, and this number showed a 20.4% decrease since 2012.³

These national problems target families and people all over the country, including Daniel,⁴ who went to high school in a small affluent town right outside Cleveland, Ohio. He was in high school the first time he began using pain pills. What started out as pain medication after an injury, quickly led Daniel to take illegal means to obtain more pain medication. Unbeknownst to his family and friends, this is how Daniel’s problem began. He went off to college after graduating high school, and that is when it became very apparent to his family he was having problems. After plummeting grades and learning he had sold nearly everything he owned, his parents had no choice but to bring him home. It was not until Daniel got home that his family was really able to understand the severity of this problem. Not only was he selling his own belongings

¹ IMS Health, National Prescription Audit (NPATM). Cited in internal document: Preliminary Update on Opioid

Pain Reliever (OPR) Prescription Rates Nationally and by State: 2010-2013.

² David Armstrong, *52 weeks, 52 faces*, STAT (Dec. 20, 2016), <https://www.statnews.com/feature/opioid-epidemic/obituaries/>; see also Vince Grzegorek, *Another Brutally Honest Obituary From a Family Who Lost a Loved one to a Heroin Overdose*, SCENE & HEARD (May 5, 2017), <https://www.clevescene.com/scene-and-heard/archives/2017/05/05/another-brutally-honest-obituary-from-a-family-who-lost-a-loved-one-to-a-heroin-overdose>; see also Dan Horn and Terry DeMio, *Seven Days of Heroin; This is what an Epidemic Looks Like*, CINCINNATI.COM (Sept. 10, 2017), <https://www.cincinnati.com/pages/interactives/seven-days-of-heroin-epidemic-cincinnati/>; see also Jen Steer, *Local man Shares Emotional Account of Daughter’s Heroin Overdose*, FOX 8 NEWS (Dec. 27, 2017), <http://fox8.com/2017/12/27/local-man-shares-emotional-account-of-daughters-heroin-overdose/>.

³ OHIO AUTOMATED RX REPORTING SYSTEM ANNUAL REPORT (2016).

⁴ Busch Funeral Home, *Obituary for Daniel Wolanski*, (April 20, 2015), <http://buschfuneral.tributes.com/obituary/show/Daniel-Joesph-Wolanski-102411062> (daniel was a high school kid, growing up in an affluent neighborhood, right outside of Cleveland, went to a nationally ranked high school, and would go on to attend a well-known College, University of Cincinnati. This story is significant, important and relevant to this topic because it shows that this epidemic is harming and reaching further than just our visualizations of “drug addicts” or people who are using drugs, but reaching into high schools, middle schools, colleges, and tearing apart families).

for pills, but he was stealing from his family and selling whatever he could get his hands on from the ones he loved just to get his next round of pills.⁵ With the help of his family, Daniel agreed to go to a rehabilitation facility and get the help he so desperately needed.

After completing his program, he stayed clean for a period of time, but eventually fell right back into his old habits, except this time, it became deadlier because the pills were no longer affordable. Daniel turned to heroin, a much cheaper and stronger option, and it was not until his first overdose that his family realized the true battle he had ahead of him. Daniel was denied rehabilitation treatment the next time around because health insurance refused to pay and the cost was far more than the family could afford out of pocket.⁶

Unfortunately for Daniel, this was happening at a time when heroin was being mixed and cut with a new drug called fentanyl, a much stronger drug than heroin and usually kept quiet when it is mixed in with heroin. Shortly thereafter, when Daniel was only 24 years old, he was found dead in his apartment, and it was determined that this occurred from an accidental overdose of heroin. This is unfortunately the tragic yet common ending we are seeing in today's society. What started out as prescription pills for an injury, eventually lead to the untimely death because of addiction.

The opioid epidemic that Ohio is faced with today is taking the lives of people across all age ranges.⁷ Between 2014 and 2015, Ohio had the greatest number of opioid related deaths in the nation – with 1 in every 14 deaths from opioids in the United States occurring in the state.⁸ With these alarming numbers, states like Ohio, that are

⁵ NATIONAL INSTITUTE ON DRUG ABUSE, *Principles of Drug Abuse Treatment for Criminal Justice Populations – A research-based guide*, (“Individuals who use illicit drugs are more likely to commit crimes, and it is common for many offenses to be committed by individuals who had used drugs or alcohol prior to committing the crime, or who were using at the time of the offense”), <https://www.drugabuse.gov/publications/principles-drug-abuse-treatment-criminal-justice-populations/introduction>.

⁶ AMERICAN ADDICTION CENTERS, *Heroin Addiction and Treatment*, (rehabilitation from heroin addiction uses medical detox, however, most heroin users want to be free of drugs upon arrival and tend to rush the process, causing a relapse, or they will complete the medically assisted detox, but have no way of dealing with the addiction once they leave treatment, and then end up relapsing again), <https://americanaddictioncenters.org/heroin-treatment/#The%20Best%20Way%20to%20Treat%20Heroin%20Addiction> (last updated Sept. 4, 2018).

⁷ Elizabeth Llorente, *Opioid Addiction Crisis spurs brutal Candor in Obituaries*, FOX NEWS (May 14, 2017), (a 23-year-old man from Staten Island, New York dies from an overdose), <http://www.foxnews.com/health/2017/05/14/opioid-addiction-crisis-spurs-brutal-candor-in-obituaries.html>; *see also* Shelly Bradbury, PITTSBURGH POST-GAZETTE (May 4, 2017) (an 11 year-old girl dies from a heroin overdose), <http://www.post-gazette.com/news/overdosed/2017/05/04/11-year-old-girl-overdoses-heroin-Beechview-Pittsburgh-Narcan/stories/201705040162>; *see also* Pat Grossmith, *Heroin Overdoses take Their toll in NH's Largest City*, UNION LEADER NEW HAMPSHIRE (Sept. 23, 2015), (the oldest fatality due to a heroin overdose was a 51-year-old man), http://www.unionleader.com/Heroin_overdoses_take_their_toll_in_NHs_largest_city_ (all of these examples show the significance of this epidemic. It is not only affecting those we consider “drug addicts,” but it is ravaging through the young and the old alike, all across the country).

⁸ THE HENRY J. KAISER FAMILY FOUNDATION OVERDOSE DEATHS, (2014-2015); *see also*

being hit hardest with this problem, are looking for the best solutions to decrease these numbers. Ohio can be found at the top of that list, among other states, aggressively looking for ways to combat this terrible but growing problem.

On May 31, 2017, Ohio Attorney General Mike DeWine decided to take a step in the right direction of fighting the epidemic. DeWine brought the first of many lawsuits against five top drug pharmaceutical companies.⁹ The five companies are, Purdue Pharma, Teva Pharmaceutical Industries, Cephalon, Inc., Janssen Pharmaceuticals, and Endo Health Solutions Inc.¹⁰ There are several counts being raised against the pharmaceutical companies, but only the counts for deceptive marketing practices are relevant for this Note.¹¹ This charge is particularly important here because Attorney General DeWine states that these deceptive marketing practices are one of the leading causes of this serious opioid epidemic.¹² This lawsuit has in turn prompted several other states to follow suit.¹³ The trend of bringing these lawsuits shows the willingness of states to recognize the problem and the want of these states to hold the correct entities accountable.¹⁴ New York Attorney General Eric Schneiderman stated, “For millions of Americans, their personal battle with opioid addiction did not start in a back alley with a tourniquet and syringe, they got hooked on medicine they were prescribed for pain or that they found in a medicine cabinet.”¹⁵ With law suits becoming more prevalent, it is showing the willingness of states to accept and want to hold those who are responsible accountable: the big drug pharmaceutical companies. In doing so, any entity bringing a lawsuit will have to overcome an exception, that exists under Products Liability Law, the Learned Intermediary Doctrine.

Under Federal and State law, there is an exception that exists, called the Learned Intermediary Doctrine. This exception is one which can absolve the drug manufacturers of liability from any misconduct that might be found and transfer that

OHIO DEPARTMENT OF HEALTH, *Drug Overdose Report* (in 2013, Ohio had 2,110 deaths unintentional drug overdoses), <https://www.odh.ohio.gov/-/media/ODH/ASSETS/Files/health/injury-prevention/odhnews-2013DrugOverdoseData.pdf?la=en>.

⁹ *Complaint, State of Ohio v. Purdue Pharma, et al., No. 17CI000261.*

¹⁰ *Id.*

¹¹ *Complaint at 66, State of Ohio v. Purdue Pharma, et al., No. 17CI000261.*

¹² *Id.*

¹³ Colin Dwyer, *Ohio Sues 5 Major Drug Companies For ‘Fueling Opioid Epidemic’*, NPR THE TWO WAY (May 31, 2017) (Ohio followed Alabama in filing a law suit), <https://www.npr.org/sections/thetwo-way/2017/05/31/530929307/ohio-sues-5-major-drug-companies-for-fueling-opioid-epidemic>; see also Jackie Borchardt, *Ohio Opioid Lawsuit against 5 Pharma Companies: 6 Things to Know*, CLEVELAND.COM (May 31, 2017) (Cherokee nation in Oklahoma also followed Ohio’s lead in filing a law suit), http://www.cleveland.com/metro/index.ssf/2017/05/ohios_opioid_lawsuit_against_5.html.

¹⁴ Yuki Noguchi, *41 States to Investigate Pharmaceutical Companies Over Opioids*, NPR THE TWO WAY (September 19, 2017) <https://www.npr.org/sections/thetwoway/2017/09/19/552135830/41-states-to-investigate-pharmaceutical-companies-over-opioids>.

¹⁵ *Id.*

liability to any treating physician.¹⁶ This exception is extremely relevant to this topic because it is the way many drug manufacturers were able to avoid being held responsible in the past. This Note proposes that with the current pending lawsuit in the State of Ohio, an exception to the Learned Intermediary Doctrine should be introduced. This Note will begin with a discussion of opioids and how these drugs have become such an aggressive problem in a very short amount of time in Ohio. Part II will talk about the role the government can play and the role the drug manufacturers have played and continue to play in the availability of opioids. It will discuss the effect these drug pharmaceutical companies have had on this problem and have had in increasing this problem. Part II will also discuss why this is a problem and why this problem matters. Further, it will talk about the steps that have already been taken by the Ohio Legislature to combat the opioid problems. Finally, it will delve into a discussion of what this current lawsuit means for fighting and decreasing the opioid problem and how it will directly affect the heroin epidemic in Ohio.

II. BACKGROUND

While this is a national problem, Ohio has been one of many states hit hard by this problem.¹⁷ In 2010, Ohio declared a public health emergency due to rising overdose deaths.¹⁸ “In 2016, unintentional drug overdoses caused the deaths of 4,050 Ohio residents, which was a 32.8% increase compared to 2015.”¹⁹ Although prescription opioid-related deaths have declined again, from 667 in 2015 to 564 in 2016,²⁰ the damage from the prescription pills has already been done and continues to ravage through the most unsuspecting homes and families. According to a study conducted by the Center for Behavioral Health Statistics and Quality, in August of 2013, three out of four new heroin users reported first abusing prescription opioids before beginning to use heroin.²¹ While these unintentional drug overdoses include heroin,²² the lawsuit brought by the state of Ohio relates the heroin epidemic directly to the misrepresentation of the effects of treating chronic pain with opioid pain killers.²³ The lawsuit intends to hold the drug manufacturing companies liable for these misrepresentations that were made, which in turn lead to the heroin epidemic that is faced by so many today.

¹⁶ Ohio Rev. Code Ann. §2307.76(C) (West 1988).

¹⁷ AMERICAN ADDICTION CENTERS, *supra* note 6.

¹⁸ Ohio Attorney General Complaint against Pharmaceutical Companies: The State of Ohio is suing 5 major drug pharmaceutical companies for allegedly misrepresenting their products and for false advertising, as a violation of the law under the products liability law in Ohio, and under Fraud in Ohio.

¹⁹ OHIO DEPARTMENT OF HEALTH, *Drug Overdose Report* (2016).

²⁰ *Id.*

²¹ Pradip K. Muhuri Et Al., *Association of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States*, SAMHSA (Aug. 2013), <https://www.samhsa.gov/data/sites/default/files/DR006/DR006/nonmedical-pain-reliever-use-2013.htm>.

²² *Id.*

²³ Complaint at 29, *State of Ohio v. Purdue Pharma, et al.*, No. 17CI00026.

This section will begin with a brief discussion of opioids and what they are, the epidemic that is happening, and why it is important for the government to step in and take action. Next, there will be a discussion on the main role the drug manufacturers play in this epidemic. Also, this section will discuss the steps taken to try and hold these pharmaceutical companies liable. Finally, it will end with why the proposed solution is the best way to begin to get this epidemic under control.

A. *What Are Opioids?*

Opioids are a class of drugs that are usually taken for pain relief.²⁴ There are natural opioids and then there are manmade synthetic opioids.²⁵ Natural opioids come from the poppy plant, while synthetic opioids are created in a lab.²⁶ Heroin, fentanyl and OxyContin are the three most commonly known synthetic opioids because they are manmade as opposed to being natural.²⁷ “Prescription opioids are powerful pain-reducing medications that include prescription oxycodone, hydrocodone, and morphine.”²⁸ Opioids work by interacting with the opioid receptors that are on nerve cells in the body and brain. People who take opioids for long periods of time are known to have a higher risk of becoming addicted to the pills.²⁹ These opioid addictions quickly lead to heroin addictions because heroin is more readily available.³⁰ Heroin is also far less expensive than any prescription opioids that individuals take.³¹ Heroin is also considered to be a better option because users and addicts no longer have to go to their doctor to get a prescription.³² The effects that opioids have are clear, but it is not always clear why these drugs are such a danger and so harmful to many people in society.

²⁴ NATIONAL INSTITUTE OF DRUG ABUSE, *Opioids*, (Nov. 2018), <https://www.drugabuse.gov/drugs-abuse/opioids>.

²⁵ Casa Palmera Staff, *What Drugs are Opiates?*, CASA PALMERA (Nov. 17, 2016), <https://casapalmera.com/blog/what-drugs-are-opiates/>.

²⁶ *Id.*

²⁷ *Id.*

²⁸ U.S. FOOD AND DRUG ADMINISTRATION, *Opioid Medications*, U.S. DEP’T HEALTH AND HUM. SERVICES (last updated June 14, 2018), <https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm337066.htm>.

²⁹ NATIONAL INSTITUTE OF DRUG ABUSE, *Opioids* <https://www.drugabuse.gov/drugs-abuse/opioids>.

³⁰ OHIO PRESCRIPTION DRUG ABUSE TASK FORCE; OHIO SUBSTANCE ABUSE MONITORING NETWORK (2008); *see also* AMERICAN SOCIETY OF ADDICTION MEDICINE (“94% of respondents in a 2014 survey of people in treatment for opioid addiction said they chose to use heroin because prescription opioids were ‘far more expensive and harder to obtain.’”), <https://www.asam.org/docs/default-source/advocacy/opioid-addiction-disease-facts-figures.pdf>.

³¹ OHIO PRESCRIPTION DRUG ABUSE TASK FORCE; OHIO SUBSTANCE ABUSE MONITORING NETWORK, *supra* note 30.

³² *Id.*

1. Why Are They Harmful?

Opiates are so harmful because of the way they interact with the brain. Opiates create endorphins in the brain, which in turn, lead to the user experiencing a rush of emotions.³³ This rush of emotions is due to endorphins releasing dopamine, what is often known as the ‘feel-good’ emotion.³⁴ This process does not become an issue unless these drugs are taken over a long period of time.³⁵ The brain eventually stops producing endorphins naturally, so once the drugs are no longer being taken, the user no longer experiences those positive feelings and emotions.³⁶ Without taking the drugs, the dopamine levels in the brain drop significantly, so the person taking the drugs is not experiencing this rush of emotion anymore.³⁷ “The body quickly builds up a tolerance to opioids, so it takes more and more of the drug to create the same pain-relieving and euphoric effects.”³⁸ Dr. Nora Volkow compared the effects of taking opioids with bad steering, “Your steering wheel does not work properly. So not only are you actually accelerating with intense desire and motivation to get the drug, you are not able to self-regulate and say, ‘If I take the drug, I will end up in jail.’”³⁹ This analogy helps to explain the dependency, because the brain is no longer producing these endorphins. A person who is addicted will do anything just to have that experience again, without considering the consequences.⁴⁰ The reactions that occur in the brain can help explain why people turn from opioids to heroin.

2. What Is Heroin, and Where Does it Come From?

The drug heroin is at the heart of this epidemic and is bringing light to this epidemic, so it is important for this Note to explain the role of heroin. Heroin is an opioid drug made from morphine.⁴¹ Heroin can come in different forms and can be ingested in different ways, but the main way people use heroin is by injecting it with

³³ Michael’s House, *Why Are Opiates so Addictive?* (2017), <http://www.michaelshouse.com/opiate-rehab/why-are-opiates-so-addictive/>.

³⁴ Katelyn Newman, *A Personal Look at a National Problem*, US NEWS AND WORLD REPORT (May 18, 2017), <https://www.usnews.com/news/national-news/articles/2017-05-18/the-opioid-epidemic-a-personal-look-at-a-national-problem>.

³⁵ *Id.*

³⁶ *Id.*

³⁷ Newman, *supra* note 34.

³⁸ *Id.*

³⁹ The Associated Press, *Science Say: Why are Opioids so Addictive?*, <https://www.apnews.com/7615878f9f40487593d99f02e68d96ee/Science-Says:-Why-are-opioids-so-addictive?>

⁴⁰ Michael’s House, *supra* note 33.

⁴¹ NATIONAL INSTITUTE ON DRUG ABUSE, *What is Heroin?* (2018) <https://www.drugabuse.gov/publications/drugfacts/heroin>; *see also* Medline Plus, *Morphine*, U.S. NATIONAL LIBRARY OF MEDICINE (June 15, 2017), (morphine is used to treat severe pain, and only used when there is no other way to treat the pain, morphine is highly regulated by the doctor or physician prescribing it because of how strong it is and how many side effects it causes), <https://medlineplus.gov/druginfo/meds/a682133.html#why>.

a syringe.⁴² The effects of heroin are very similar to that of the effects of prescription drug use; people using heroin typically report a feeling of euphoria.⁴³ Euphoria results because heroin affects the brain the same way prescription drugs do, which is binding to the opioid receptors in order to increase the feelings involved with pain and pleasure.⁴⁴

Heroin is not a drug that is prescribed by doctors, it is a drug that is found on the streets. More commonly, it is known to be found on the dark net's "black market." The dark net "is a constellation of sites and services that can be accessed through a special browser, which routes online traffic so it's much more difficult to identify where it originally came from."⁴⁵ In July 2017, one of the largest online black market drug websites, known as AlphaBay, was taken down by the FBI.⁴⁶ This website was being run not only nationally, but internationally, and was housing more than 250,000 listings for illegal drugs.⁴⁷ It was estimated that previous to AlphaBay being shut down, there were about 238 vendors advertising for the sales of heroin.⁴⁸ While these type of online black market sites are very common, there are also physical places that people can go to obtain drugs illegally. For example, in August 2017, a medical clinic was closed in California for sending dangerous and addictive pills to the black market.⁴⁹ While these are only a few examples, instances like these are happening all over the United States and even worldwide.⁵⁰

These kinds of statistics beg the question: how are these pills, which a patient needs a prescription to obtain, so readily available on the black market? Generally, there is one term that can describe this influx of prescription pills – diversion – which is most common at the patient level.⁵¹ Diversion at the patient level consists of patients who

⁴² *Id.*

⁴³ *Id.*

⁴⁴ *Id.*; see also NATIONAL INSTITUTE ON DRUG ABUSE, *What are the immediate effects of heroin use?* (Jan. 2018), <https://www.drugabuse.gov/publications/research-reports/heroin/what-are-immediate-short-term-effects-heroin-use> (abusers report a "rush" feeling, and this "rush" feeling generally controls how much of the drug is taken in by the user and how quickly they experience the rush).

⁴⁵ Kif Leswing, *The FBI just took down AlphaBay, Online Black Market for Drugs*, BUSINESS INSIDER (Jul. 20, 2017), <http://www.businessinsider.com/alphabay-online-black-market-taken-down-silk-road-2017-7>.

⁴⁶ *Id.* see also Joseph Goldstein, *Arrest in U.S. Shuts Down a Black Market for Narcotics* (Oct. 2, 2013), (Silk Road was another website run on the dark net, was home to more than 100,000 customers and was also responsible for the selling of black market drugs), <https://www.nytimes.com/2013/10/03/nyregion/operator-of-online-market-for-illegal-drugs-is-charged-fbi-says.html>.

⁴⁷ *Id.*

⁴⁸ *Id.*

⁴⁹ Thom Mrozek, UNITED STATES ATTORNEY'S OFFICE; CENTRAL DISTRICT OF CALIFORNIA (Aug. 3, 2017), <https://www.justice.gov/usao-cdca/pr/operators-bogus-medical-clinics-charged-conspiracy-divert-massive-amounts-prescription>.

⁵⁰ Leswing, *supra* note 45.

⁵¹ *Id.*

once needed pain medication but are no longer in need of it and are sitting on pills, family members who find the pills and dispose of them, or patients who do not actually need the pain medication but are “doctor shopping.”⁵² Doctor shopping is a commonly used term today to describe a situation where a patient will go from doctor to doctor, trying to get a prescription for pain medication filled.⁵³ Once they have obtained the prescription, they sell it.⁵⁴ As discussed below, part of stopping the epidemic is stopping the flow of prescription drugs illegally onto the black market.

3. Why This Issue is Important to the Government

This problem is important to the government because it is now not only affecting adults, but it is also reaching younger individuals each and every year. “After marijuana and alcohol, prescription drugs are the most commonly misused substances by Americans age 14 and older.”⁵⁵ The problems with addiction are soaring to unbelievable heights. While this is a vast problem throughout the United States, it would be best dealt with on the state level so that each state can make adjustments based on the specific problem in that state. There have been several attempts to remedy the problem, but nothing has been as influential as going directly to the source of the problem: holding the drug manufacturing companies, those responsible for the prescription drugs in the first place, accountable.

Specifically in Ohio, in 2015, House Bill 4 was passed, giving broader access to the drug Naloxone.⁵⁶ Naloxone is a drug known to reverse the effects from an opioid overdose, as long as it is dispensed in time.⁵⁷ A survey taken counting the administration of Naloxone found that there were about “11 administrations per day of the drug in 2003, and about 29 administrations of the drug per day in 2012.”⁵⁸ There is a clear correlation between the increase in the administration of naloxone and the increase in overdoses. Naloxone’s main use today is for the treatment of an overdose and to help reverse an overdose.⁵⁹ But, as previously noted, the overdose deaths have only continued to rise.⁶⁰ Even though Naloxone is helping to reverse specific incidences of overdoses, it is not substantially decreasing the overdoses, further

⁵² Eric Boodman, *Opioid Crisis Fueled by Prescriptions from Family Doctors and Internists*, STAT (Dec. 14, 2015), <https://www.statnews.com/2015/12/14/opioid-crisis-fueled-prescriptions-family-doctors-internists/>.

⁵³ *Id.*

⁵⁴ *Id.*

⁵⁵ NATIONAL INSTITUTE ON DRUG ABUSE FOR TEENS, *Prescription Drugs*, (March 2017), <https://teens.drugabuse.gov/drug-facts/prescription-drugs>.

⁵⁶ Ohio House Passes Legislation Expanding The Use of Naloxone | The Ohio House of Representatives.

⁵⁷ *Id.*

⁵⁸ OHIO MENTAL HEALTH & ADDICTION SERVICES, *Naloxone Administration in Ohio 2003-2012* (2012), <http://mha.ohio.gov/Portals/0/assets/Research/Reports/2013-no2-naloxone-epidemiological%20report.pdf>.

⁵⁹ Leswing, *supra* note 45.

⁶⁰ Dwyer, *supra* note 13.

illustrated by the continuing rise in annual overdose deaths.⁶¹ This is just furthering the need for the government to step in and help.

A Sheriff in Butler County has recently refused to allow his officers to carry Naloxone.⁶² Specifically, Sheriff Richard K. Jones, will not allow his officers to carry Naloxone due to the expense of the drug and due to the amount of repeated administration to the same individuals.⁶³ This has come across to many in the media as shocking because of the lives that Naloxone has helped save, however, Jones insists, “all we’re doing is reviving them, we’re not curing them.”⁶⁴ This is a belief that is held by many who are skeptical of the increased availability of Naloxone.⁶⁵

State governments, as well as the federal government, acknowledge that there is a growing problem, but none of the solutions proposed have gone far enough to put a significant halt on this epidemic we are seeing, as the overdose deaths are still steadily increasing.⁶⁶ For this reason, there needs to be stronger options in order to stop this epidemic from increasing.

4. The Role Of The Food And Drug Administration

The Food and Drug Administration (“FDA”), created in 1848, is the oldest consumer protection agency within the United States Government.⁶⁷ The FDA was broadly known as a consumer protection agency, much of how we think of it today, but it did not have only one specific area of focus.⁶⁸ As the times change throughout the nation, the FDA changes along the way.⁶⁹ Today, however, the FDA’s drug review

⁶¹ *Id.*

⁶² Corky Siemaszko, *Ohio Sheriff Says Officers Won’t Carry Narcan*, NBC NEWS (July 7, 2017), <https://www.nbcnews.com/storyline/americas-heroin-epidemic/ohio-sheriff-says-his-overdosing-ohioans-my-guys-have-no-n780666>.

⁶³ *Id.* (one dose of Narcan, which is costing about \$37.50 per dose); *see also* <http://radio.wosu.org/post/how-much-does-overdose-cost-ohio-it-adds-quickly#stream/0> (The city purchased over 7,000 doses of naloxone, which came out to be a total of \$243,560 in order to combat the overdose calls they will receive).

⁶⁴ *Id.*

⁶⁵ Siemaszko, *supra* note 62 (Board Member Debbie Walsh opposed allowing Narcan in Public schools in Akron; and was met with several others who agreed with her.); *see* The Associated Press, *Just Say No to Narcan?* CBS NEWS (September 26, 2016), (people have expressed frustration about rescuing addicts who often immediately resume using the potentially deadly drug). <https://www.cbsnews.com/news/just-say-no-to-narcan-heroin-rescue-efforts-draw-backlash/>.

⁶⁶ Dwyer, *supra* note 13.

⁶⁷ U.S. FOOD AND DRUG ADMINISTRATION, *The History of FDA’s Fight for Consumer Protection and Public Health* (March 7, 2018), <https://www.fda.gov/AboutFDA/WhatWeDo/History/>.

⁶⁸ *Id.*

⁶⁹ *Id.*

process ensures that drugs undergo very extensive safety, quality, and effectiveness evaluations before they are able to be sold to the public on the market.⁷⁰

Another reason it is important to the government is because the FDA is in charge of allowing these kinds of drugs into society, as well as determining the guidelines and precautions for certain drugs.⁷¹ The mission of the FDA is to protect the public health by assuring safety, among other things, of human and veterinary drugs.⁷² Further, in 2016, the FDA stated that opioids should only be used to treat pain as a last resort, which was the opposite of what drug manufacturers were advertising.⁷³ Since these drugs fall under the control of the FDA, which is a governmental agency, that is another reason the government is, and should be, involved in this growing problem.

B. *What Role Are Drug Pharmaceutical Companies Playing?*

The role drug pharmaceutical companies play in this problem is obvious: pharmaceutical companies have played a vital role in the increase of opioid related overdoses across the country.⁷⁴ Drug pharmaceutical companies have been falsely reassuring and representing not only to those in the medical field, but also to patients directly, that opioid pain relievers are safe to use for chronic pain, without risk of addiction.⁷⁵ As alleged in the lawsuit by Ohio Attorney General, Mike DeWine, each of the drug manufacturing companies have been promoting the utilization of opioids for chronic pain through their sales representatives.⁷⁶ Even after the problems were made public and continued to surface, DeWine alleges there was never an attempt to correct the falsely given information and that the drug pharmaceutical companies simply did nothing.⁷⁷ These companies increased their budget, spending, and the time their drug representatives were spending with doctors.⁷⁸ These practices have been going on since the late 1990s and have led to the epidemic we are faced with today.⁷⁹

⁷⁰ Michelle Meadows, *Promoting Safe & Effective Drugs for 100 Years*, FDA CONSUMER MAGAZINE, Jan.-Feb. 2006.

⁷¹ Douglas C. Throckmorton, M.D., *The Public Health Role of Drug Regulation in the US*, U.S. FOOD AND DRUG ADMINISTRATION (March 20, 2017), <https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM550079.pdf>.

⁷² *Id.*

⁷³ Complaint at 43, *State of Ohio v. Purdue Pharma, et al.*, No. 17CI000261 (From the early 1990's until today, regardless of any regulation put in place by the FDA, advertisements and selling points for drug manufacturers stated that opioids were safe for long-term use to treat chronic pain).

⁷⁴ NATIONAL INSTITUTE ON DRUG ABUSE FOR TEENS, *opioid overdose crisis* (June 2017), <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-crisis#one>.

⁷⁵ Complaint at 15, *State of Ohio v. Purdue Pharma, et al.*, No. 17CI000261; *see also Id.*

⁷⁶ Complaint at 15, *State of Ohio v. Purdue Pharma, et al.*, No. 17CI000261.

⁷⁷ *Id.*

⁷⁸ *Id.*

⁷⁹ *Id.*; *see also Opioid Addiction is the Biggest Drug Epidemic in U.S. History; How Did We Get Here?* PBS NEWS HOUR (September 29, 2017),

With this, several states are starting to point to the drug manufacturing companies as the ones to blame, and rightfully so.⁸⁰ While other options have been tried, and have failed, this is one more attempt to get this epidemic under control.

Recently, in September 2017, “41 state attorneys general announced they were expanding their investigation into companies that manufacture and distribute opioid pain killers.”⁸¹ Ohio, specifically, brought a lawsuit seeking damages from five major pharmaceutical companies that manufacture opioid pain pills.⁸² This lawsuit is seeking damages for the pain and suffering, loss of life, and overall punitive damages for the negative effects of the pharmaceutical companies’ advertising misrepresentations.⁸³ However, this is not the first time many of these companies are being questioned or even engaging in settlements for their misrepresentations.⁸⁴ Though there have been several settlements, the pattern of misleading advertising and false representations has not ceased.⁸⁵

In the past, Cephalon, one of the drug manufacturing companies named in the lawsuit by the state of Ohio, pled guilty to a violation of the Federal Food, Drug and Cosmetic Act (“FDCA”) for misleading the promotion of three (3) drugs.⁸⁶ Part of this misleading promotion that Cephalon was doing involved the drug Actiq. The company ordered sales representatives to try and convince doctors to use the drug for certain unapproved uses.⁸⁷ The manufacturing company agreed to pay \$425 million for the violation of the FDCA,⁸⁸ all the while still continuing to do what it pled guilty for in the past.⁸⁹ While the company ceased to use that sales strategy with Actiq after the settlement occurred in 2003, Cephalon was still pushing for the long-term use of

<https://www.pbs.org/newshour/show/opioid-addiction-biggest-drug-epidemic-u-s-history-howd-get>.

⁸⁰ State Attorneys General Expand Probe into Opioid Companies.

⁸¹ *Id.* (States including New York, Massachusetts, Tennessee and Vermont were among the states looking to increase and intensify their investigations into drug manufacturing companies following an announcement in June about the possible ties between the manufacturing companies and the national addiction epidemic).

⁸² Complaint, State of Ohio v. Purdue Pharma, et al., No. 17CI000261.

⁸³ *Id.*

⁸⁴ *Id.*

⁸⁵ *Opioid Addiction is the Biggest Drug Epidemic in U.S. History; How Did We Get Here?*, *supra* note 79.

⁸⁶ *Id.*

⁸⁷ PHILLIPS & COHEN, *Cephalon pay \$425 Million to Settle Unique off-label Marketing Case Brought by Whistleblower*, (Sept. 29, 2008), the lawsuit was filed, and a settlement reached because of a sales representative working for Cephalon who feared that the sales tactics they were being required to use were illegal and would bring about danger to patients), <https://www.phillipsandcohen.com/cephalon-pays-425-million-settle-unique-off-label-marketing-case-brought-whistleblower/>.

⁸⁸ *Id.*

⁸⁹ Complaint at 55, State of Ohio v. Purdue Pharma, et al., No. 17CI000261.

opioids to treat chronic pain. This exemplified how a settlement did not deter the behavior.⁹⁰

Purdue Pharma also reached a settlement agreement in federal court in the Western District of Virginia, paying upwards of \$600 million in fines for misleading regulators, physicians, and patients about the risks that are associated with taking OxyContin.⁹¹ Specifically, Purdue Pharma underestimated and underreported the “risk of addiction and the drug’s potential to be abused.”⁹² While these are only two examples, it is clear that these pharmaceutical companies have been aware and put on notice in the past that their misleading advertisements and misrepresentations have caused serious harm. This demonstrates the need for a more aggressive way of handling these companies.

Furthermore, in the past it has been hard for individuals to hold pharmaceutical companies responsible for the adverse effects they were receiving due to the use of opioids.⁹³ Generally, a state is going to be more sympathetic because a state can never be to blame for abusing pills, whereas individuals can be.⁹⁴ In many instances, people perceive that the abuse of opioids by the user as his or her problem because the user did not appropriately use the medication and thus caused their own problems.⁹⁵ This belief makes it very difficult to show the pharmaceutical companies’ responsibility and the role the pharmaceutical companies are actually playing.⁹⁶ Lars Noah, a professor of law at the University of Florida, has stated, “doctors, not consumers, were the ones targeted by the aggressive marketing campaigns undertaken by pharmaceutical companies, so it can be difficult to link consumer deaths with aggressive marketing.”⁹⁷ This will be discussed later in this Note, but this is essentially the reasoning behind the Learned Intermediary Doctrine since doctors are generally the ones being targeted by these pharmaceutical companies.

1. Drug Representatives Provide Information to the Medical Community

Drug representatives are employed by pharmaceutical companies to sell products, and they are also in charge of educating and informing physicians about their products.⁹⁸ Drug representatives also work on a commission basis, so the incentive to get a physician to purchase from them, over their competitors, goes beyond simply

⁹⁰ *Id.*

⁹¹ Barry Meiser, *Guilty Plea, OxyContin Maker to Pay \$600 Million*, THE NEW YORK TIMES, BUSINESS DAY (May 10, 2017), <http://www.nytimes.com/2007/05/10/business/11drug-web.html>.

⁹² *Id.*

⁹³ Alana Semuels, *Are Pharmaceutical Companies to Blame for the Opioid Epidemic?* THE ATLANTIC (June 2, 2017), <https://www.theatlantic.com/business/archive/2017/06/lawsuit-pharmaceutical-companies-opioids/529020/>.

⁹⁴ *Id.*

⁹⁵ *Id.*

⁹⁶ *Id.*

⁹⁷ *Id.*

⁹⁸ *A Day in the Life of a Pharmaceutical Sales Representative Med Reps*, MEDICAL SALES 101 (April 13, 2015), <https://www.medreps.com/medical-sales-careers/what-do-pharmaceutical-sales-reps-do/>.

promoting their products.⁹⁹ “These reps help to influence the physicians to prescribe their specific drugs to the physician’s patients.”¹⁰⁰ This also means that these drug representatives are giving the physicians the same information provided to the drug representatives about their own products, which is provided to them by their own companies.¹⁰¹ If the pharmaceutical companies are giving out information that is deceptive, that means their drug representatives are giving out that same misleading information to the physicians.¹⁰² As alleged in the Ohio lawsuit, all of the pharmaceutical companies were using deceptive advertising measures to get doctors, as well as patients, to believe these pills were safe for long-term use when in fact they were not.¹⁰³ These drugs were being pushed in the face of the medical community as a first option when in fact the FDA was pushing for these drugs to be used merely as a last resort.¹⁰⁴ The drug representatives are also responsible for getting physicians to choose their company and their drugs over their competitors.¹⁰⁵ It is no longer an easy task to get that job done, so it requires these representatives to get more creative in their selling tactics.¹⁰⁶ Selling tactics can and do involve making their specific product more appealing to the physician than that of their competitor.¹⁰⁷ Misleading information often comes from the need to make the product more appealing, more reliable, or better than that of the competitor.

However, the medical community still relies entirely on the information provided by the drug manufacturing companies’ drug representatives, so these creative selling tactics were simply just a way to overshadow the drug representatives putting their financial goals over their responsibility and duty owed to their consumers.¹⁰⁸ One study found that, in 2012, the pharmaceutical industry in the United States spent more than \$27 billion on drug promotion and more than \$24 billion of that overall spending went to marketing specifically to physicians.¹⁰⁹ The dynamic between drug

⁹⁹ MEDREPS; *2017 Pharmaceutical Sales Salary Report*, (2017), <https://www.medreps.com/medical-sales-careers/pharmaceutical-sales-salary-report>.

¹⁰⁰ *A Day in the Life of a Pharmaceutical Sales Representative Med Reps*, *supra* note 98.

¹⁰¹ *Id.*

¹⁰² Complaint at 66, *State of Ohio v. Purdue Pharma, et al.*, No. 17CI000261.

¹⁰³ *Id.*

¹⁰⁴ *Id.* at 43.

¹⁰⁵ Andrea Clement Santiago, *Pharmaceutical Sales Representative Career Overview*, VERYWELL, CAREER CHOICES (August 19, 2017), <https://www.verywell.com/pharmaceutical-rep-career-profile-1736168>.

¹⁰⁶ *Id.*

¹⁰⁷ *Id.*

¹⁰⁸ Complaint at 55, *State of Ohio v. Purdue Pharma, et al.*, No. 17CI000261.

¹⁰⁹ Prescription Project, *Persuading the Prescribers: Pharmaceutical Industry Marketing and its Influence on Physicians and Patients*, THE PEW CHARITABLE TRUSTS, RESEARCH AND ANALYSIS (November 11, 2013), <http://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2013/11/11/persuading-the-prescribers-pharmaceutical-industry-marketing-and-its-influence-on-physicians-and-patients>.

pharmaceutical companies due to this want and need to sell their product over others has raised questions over the years about whether or not this is in fact ethical.¹¹⁰

Attorney General DeWine also addresses the issue of “Key Opinion Leaders (“KOLs”).”¹¹¹ These are groups of doctors who are paid by the drug companies to be consultants on behalf of the drug companies and their products.¹¹² Often times, these KOLs are invited to speak at continuing medical education (CME) conferences, which are required for those in the medical field.¹¹³ Specifically, “KOLs have written, consulted on, edited, and lent their names to books and articles supporting chronic opioid treatment.”¹¹⁴ This becomes problematic because doctors are relying on the information given by their peers as KOLs, when in fact, the KOLs’ support of the drugs is due to receiving payments instead of actually promoting the health and well-being of patients.¹¹⁵ This is similar to the paid endorsements we see each and every day with athletes. They are promoting the product because they are being paid to do so, not because they truly believe that the product is the best one on the market. Another example we see of this is with lobbying within the government. Lobbyists are fighting for their own interests, not because the interest they want is for the greater good. The analogy is simple yet frightening. It has become even more obvious that there is a problem with the relationship between drug representatives, drug pharmaceutical companies, and physicians; it is time something is finally done. However, with such challenging allegations already set forth, states are even further challenged to try to hold drug pharmaceutical companies liable due to an exception written within products liability law.

C. *The Learned Intermediary Doctrine*

Products liability law nationally, as well as in the state of Ohio, allows consumers to bring a claim against a company or a manufacturer for injury or death resulting from the way the product was designed or made, lack of warning, or lack of warranty.¹¹⁶ While products liability laws apply to just about all products on the market, these laws have recently been expanded to include medications as well as medical devices.¹¹⁷ However, when it comes to medical drugs and medications, there is a special exception that exists when it comes to holding drug manufacturers liable for prescription

¹¹⁰ Hneine Brax, et al., *Association Between Physicians’ Interaction with Pharmaceutical Companies and Their Clinical Practices*, 4 PLOS 12 (2017) (of 19 studies done to look at the different types of interactions between pharmaceutical companies and drs. found a consistent association between interactions promoting a medication & increased proscribing rates inappropriately), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5391068/>; see also Birendra Kumar Mandal, et al., *Relationship Between Doctors and Pharmaceutical Industry: and Ethical Perspective* 3 INT. J. PHARMACEUTICAL & BIOLOGICAL ARCHIVES 415-417 (2012), <file:///Users/lacyleduc/Downloads/2.Relationshipbetdoctorsandpharmaceuticalindustry.PDF>.

¹¹¹ Complaint at 18-19, *State of Ohio v. Purdue Pharma, et al.*, No. 17CI000261.

¹¹² *Id.*

¹¹³ *Id.*

¹¹⁴ *Id.*

¹¹⁵ *Id.*

¹¹⁶ Ohio Rev. Code Ann. §2307.71 (West 1988).

¹¹⁷ See Tracy, 58 Ohio St. 3d 147, *infra* note 129.

drugs.¹¹⁸ This exception is known as the Learned Intermediary Doctrine.¹¹⁹ The Learned Intermediary Doctrine has been recognized for almost 50 years and is now recognized and applied in almost every jurisdiction nationwide.¹²⁰ The Learned Intermediary Doctrine was first recognized in case law.¹²¹ The case is from the 8th Circuit in 1966, *Sterling Drug, Inc. v. Cornish*, where an action was brought against a drug manufacturer for eye damage, and the plaintiff alleged that the damage was due to the drug that was being taken.¹²² The issue before the court was to determine whether the drug manufacturer had a duty to warn the doctor of the potential side effect of the drug.¹²³ The lower court ultimately found that drug manufacturer did have a duty to warn the doctor since they were aware of the potential side effect of this drug.¹²⁴ The court stated,

In this case, we are dealing with a prescription drug rather than a normal consumer item. In such a case the purchaser's doctor is a learned intermediary between the purchaser and the manufacturer. If the doctor is properly warned of the possibility of a side effect in some patients and is advised of the symptoms normally accompanying the side effect, there is an excellent chance that injury to the patient can be avoided.¹²⁵

The learned intermediary doctrine applies to manufacturers who normally would owe a duty to the consumer but instead are precluded from liability because the "learned intermediary" or the general physician has been given adequate warning about the consequences.¹²⁶ This exception exists specifically when it comes to medical drugs because a physician is said to be in the best position to discuss their patients' needs and to give them the necessary warnings about prescriptions and treatment options associated with them.¹²⁷ However, this again causes a huge problem that this exception does not cover, which is when intentional incorrect information is being provided to the physician. As shown in the examples stated above, Cephalon and Purdue Pharma were able to reach settlements instead of properly being held accountable for their misrepresentations.¹²⁸

¹¹⁸ Ohio Rev. Code Ann. §2307.76(C) (West 1988).

¹¹⁹ *Id.*

¹²⁰ Richard B. Goetz & Karen R. Growdon, *A Defense of the Learned Intermediary Doctrine*, 63 FOOD & DRUG L.J. 421 (2008).

¹²¹ *Id.*

¹²² *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82 (8th Cir. 1966).

¹²³ *Id.*

¹²⁴ *Id.*

¹²⁵ *Id.* at 85.

¹²⁶ FBT Health Law Advisory, *Duty to Warn: Expanding Application of the Learned Intermediary Doctrine to Pharmacists* (May 2005), <http://www.frostbrowntodd.com/resources-374.html>.

¹²⁷ *Id.*

¹²⁸ Meiser, *supra* note 91.

The Ohio Supreme Court held in *Tracy v. Merrell Dow Pharmaceuticals Inc.*, that “the physician has the duty to know the patient’s condition as well as the qualities and characteristics of the drugs or products to be prescribed.”¹²⁹ In this case, the Estate of Larry Tracy sued Merrell Dow Pharmaceuticals for the death of Tracy and alleged that it was due to a known side effect of the Nicorette.¹³⁰ The Court found that the physician in this case was participating in the study and was aware of the potential side effects as well as the potential effect that they would have on certain patients.¹³¹ Because the physician was aware of the potential side effects, it was enough to establish him as the learned intermediary, and thus, shifting the blame from the drug company to the physician.¹³² In Ohio, manufacturers of prescription drugs are precluded from liability for failure to instruct or warn consumers so long as they instruct and warn the physician that is responsible for prescribing the medication to the consumer.¹³³ There is no line drawn in Ohio that determines whether or not the information being provided must be accurate but only that if the information is provided, the drug companies cannot be held liable.¹³⁴

The Learned Intermediary Doctrine becomes an issue when specifically trying to hold drug companies liable because they are able to pass along the liability.¹³⁵ In *Tracy v. Merrell Dow Pharmaceuticals Inc.*, the Ohio Supreme Court refused to allow recovery for a death that resulted from nicotine chewing gum that was prescribed by the family doctor.¹³⁶ However, it also raised the question of what happens when these drug companies engage in deceptive marketing tactics and the warnings are not considered adequate.¹³⁷ The Ohio Supreme Court has yet to address an issue as to what should happen when the warnings provided to the ‘learned intermediary’ are inadequate. As shown by Attorney General DeWine, these pharmaceutical companies have not been honest and forthcoming about the side effects that can, and almost certainly will, arise from the long-term use of these prescription drugs.¹³⁸ This is where the need for accountability comes. An exception to the Learned Intermediary Doctrine is needed because there were not adequate warnings being provided, and it has since led to a nationwide epidemic.¹³⁹

¹²⁹ *Tracy v. Merrell Dow Pharmaceuticals Inc.*, 58 Ohio St. 3d 147 (1991).

¹³⁰ *Id.* at 147.

¹³¹ *Id.* at 150.

¹³² *Id.*

¹³³ *In Re Meridia*, 328 F.Supp.2d 791, N.D. Ohio, 07-07-2004.

¹³⁴ *Id.*

¹³⁵ *See also* *Howland v. Purdue Pharma*, 104 Ohio St.3d 584 (2004) (holding that the learned-intermediary doctrine precludes manufacturer liability for failure to warn the consumer when an adequate warning has been given to a ‘learned intermediary,’ e.g., the consumer’s physician).

¹³⁶ *Tracy v. Merrell Dow Pharmaceuticals Inc.*, 58 Ohio St. 3d 147 (1991).

¹³⁷ Diane Schmauder Kane, *Construction and Application of Learned-Intermediary Doctrine*, 57 A.L.R.5th 1 (1998).

¹³⁸ Complaint at 30, *State of Ohio v. Purdue Pharma, et al.*, No. 17CI000261.

¹³⁹ *Id.* at 18-19.

III. ANALYSIS

As the heroin epidemic continues to surge throughout the country, and specifically in Ohio, the steps being taken by the government need to be more aggressive and serious. Reaching agreements with drug pharmaceutical companies and allowing them to pay only a fine, without requiring them to do something in return, is not enough.¹⁴⁰ As shown by the past, these pharmaceutical companies have entered into settlements more than once but have still continued their deceptive practices.¹⁴¹ The Learned Intermediary Doctrine is being used to allow drug manufacturing companies to absolve liability and place all of their liability on physicians.¹⁴² To slow the epidemic, there needs to be a way for states to hold the drug manufacturing companies liable.

Drug manufacturing companies are the main source of information regarding the opioid drugs that the medical community is prescribing.¹⁴³ But, these same drug manufacturing companies are also the primary source of funding for the CME conferences as well as medical journals that were established and sent around for physicians to spread information.¹⁴⁴ Now, in recognizing that there is a problem by allowing these companies to fund everything, independent sources are coming forward to do so as well as doctors' offices and hospitals. They are agreeing to step away from such close interactions with these companies.¹⁴⁵

While this idea has been prompted in many states, the biggest question that arises is, "who is going to pay for these continuing education programs?"¹⁴⁶ The next question is, "why should tax payers be responsible for any charges brought where these drug manufacturing companies have been using misleading and deceptive schemes in order for them to make more money?" Among many settlement talks happening surrounding several hundred opioid lawsuits, Federal Judge Dan Polster is suggesting that the money from these settlements goes toward treatment for individuals who have already been affected by this and to have doctors educated on the effects of these drugs and ways to prescribe fewer of them.¹⁴⁷ While these

¹⁴⁰ OHIO MENTAL HEALTH & ADDICTION SERVICES, *supra* note 58.

¹⁴¹ *Id.*; see also Tracy Staton, *Pharma's Top 11 Marketing Settlements*, FIERCEPHARMA, <https://www.fiercepharma.com/special-report/pharma-s-top-11-marketing-settlements> (showing settlements from several big pharmaceutical companies over the past years for deceptive marketing practices and failing to properly warn the public).

¹⁴² See *Tracy*, 58 Ohio St. 3d 147; see also *Vaccariello v. Smith & Nephew Richards Inc.*, 94 Ohio St.3d 380 (2002).

¹⁴³ *A Day in the Life of a Pharmaceutical Sales Representative Med Reps*, *supra* note 98.

¹⁴⁴ Complaint at 19, *State of Ohio v. Purdue Pharma, et al.*, No. 17CI000261.

¹⁴⁵ *Independent Medical Education Funding and Application*, AMGEN GRANTS AND GIVING (2017), (using Independent Medical Education (IME) completely separate from the company to educate the medical community), <http://www.amgen.com/responsibility/grants-and-giving/independent-medical-education-funding/>.

¹⁴⁶ *Id.*

¹⁴⁷ Eric Heisig, *Settlement Talks Begin in Cleveland between Drug Companies and Governments over Opioid Epidemic*, CLEVELAND.COM (Jan. 31, 2018), http://www.cleveland.com/court-justice/index.ssf/2018/01/settlement_talks_begin_in_clev.html.

settlement talks currently do not involve Ohio's lawsuit versus the five big drug companies, it would include several lawsuits that have been brought by cities and municipalities in Ohio and involve the settlement money to be distributed in hopes of helping people who are currently being affected by this epidemic.¹⁴⁸

A. The Solution: An Exception to the Learned Intermediary Doctrine

This epidemic is so widespread that it is time for something constructive to be done.¹⁴⁹ It is time to hold the correct people accountable, open up the ability to slow it down, and get these severe issues under control. The reason this solution is the best is because it goes to the root of the problem. The drug companies are responsible for producing and making the drugs available to physicians as well as to consumers.¹⁵⁰ If the deceptive marketing strategies are the same, it is going to be the sole responsibility of the physicians to ensure that what they are being told by the drug representatives is credible and in the best interest of the patients.¹⁵¹ Since there have only ever been monetary settlements against these drug companies, some form of accountability needs to attach to the companies.¹⁵² Part of this solution and promoting accountability rests in educating the doctors the correct way, without the influence of the drug companies, and encouraging safe practices in writing and delivering prescriptions. Many states, including Ohio, have been reluctant to bring such a suit because it is considered such a stretch to hold these companies liable, due to the Learned Intermediary Doctrine.

This Note proposes that an exception to the Learned Intermediary Doctrine should be introduced. Since the doctrine was originally established through case law, any exceptions or abolishment of the doctrine will be able to be effectuated through case law as well. Therefore, it is left up to the courts to settle this matter based on law suits that are brought revolving around this issue.

This exception will include two prongs. The first prong will address whether a drug manufacturing company is going to try and absolve itself from a duty owed to consumers through the Learned Intermediary Doctrine. If the company should want to use this, then they must be required to prove that they have done everything in their power to stop the drugs from going to the black market. As stated earlier, diversion to the black market is most common at the patient level.¹⁵³ Without providing the information that is necessary to the medical community that is responsible for writing these prescriptions, it can cause an influx of prescriptions, which then leads to these drugs showing up on the black market.¹⁵⁴ When the drug manufacturing companies are providing information to the medical community that these drugs are safe for long-term use, without leading to addiction, it can lead to the over-prescription of pain

¹⁴⁸ *Id.*

¹⁴⁹ Armstrong, *supra* note 2.

¹⁵⁰ Complaint at 10, State of Ohio v. Purdue Pharma, et al., No. 17CI000261.

¹⁵¹ *A Day in the Life of a Pharmaceutical Sales Representative Med Reps*, *supra* note 98.

¹⁵² Borchardt, *supra* note 13 (Kentucky settled with Purdue for \$24 million, also with Janssen for \$15.5 million, but, neither company admitted wrongdoing).

¹⁵³ Boodman, *supra* note 52.

¹⁵⁴ *Id.*

medication under the belief that it is safe to do so.¹⁵⁵ By enforcing this prong of the exception, it will ensure that doctors are aware of their prescribing habits and are being much more conscious to that respect because the information is being provided to them directly from the drug representatives and the drug manufacturing companies.

Under this first requirement, this Note proposes that the duty should rest with the drug manufacturers to provide information to the prescribing medical community on how to responsibly prescribe opioids. The duty of a drug manufacturer cannot be absolved if the information that is provided is knowingly wrong. Under this proposal, the standard applied would be that of strict liability. For example, if the drug manufacturing company is found to have been providing false or misleading information, whether intentionally or not, they will not be able to utilize the Learned Intermediary Doctrine as a defense. This will provide an another incentive to ensure that the drug manufacturing companies are doing all that they can to conduct research, educate, and inform their drug representatives and the medical community.

A second prong of this exception will include the requirement that drug manufacturing companies fund continuing education programs for the medical community to whom they provide information. Since the medical community that is in charge of prescribing these opioid pain pills is relying on the information provided from the manufacturers and their representatives, the only way to absolve the manufacturer's duty entirely is to provide another outlet for education. Part of this education plan will be to include education for dealing with chronic pain and pain management without the prescription of opioid pain killers. However, the pharmaceutical companies will be required to bring in independent speakers, so as to ensure they are not giving biased information.¹⁵⁶ As previously discussed, when the pharmaceutical companies are bringing in their own KOLs, they are able to pay these doctors as well as provide them with the information they want to be given out to doctors.¹⁵⁷ This is further problematic because it gives an incentive for these doctors to state opinions based on the amount of money they are being paid instead of what is actually safe for the medical community and their patients.¹⁵⁸

If both of these prongs are adopted and accepted on a federal level as well as in the state of Ohio, this will be the first of many successful steps towards effectively fighting this epidemic.

While some may make the argument that you cannot completely eradicate drug sales on the black market, my first prong would significantly decrease the diversion because the drug companies and the medical community would be working together. In previous years, it has been the drug companies providing information to the medical community and the medical community acting in unison with that information.¹⁵⁹ However, with my first prong being implemented, it would promote true and correct information as well as information that is in the best interest of the patients.

¹⁵⁵ Complaint at 66 State of Ohio v. Purdue Pharma, et al., No. 17CI000261.

¹⁵⁶ Complaint at 19, State of Ohio v. Purdue Pharma, et al., No. 17CI000261.

¹⁵⁷ *Id.*

¹⁵⁸ *Id.*

¹⁵⁹ Santiago, *supra* note 105.

B. The United States Supreme Court has the Authority to Make this Exception

Under federal law, the Learned Intermediary Doctrine provides the same defense to liability that it does under Ohio law. A prescription drug manufacturer does not have a legal duty to warn a consumer of the dangers of a drug as long as adequate warning has been provided to the physician.¹⁶⁰ Since the Supreme Court established this doctrine under case law, the ability to abolish the doctrine or make changes to it is also rests within the courts.

However, the Supreme Court has created several exceptions to this doctrine. Specifically, the Court created an exception in *Edwards v. Basel Pharmaceuticals*, a case where a man had a heart attack when he was wearing two nicotine patches.¹⁶¹ The widow of the man sued the pharmaceutical company that manufactured the nicotine patch under products liability law.¹⁶² The court in this case held that the Learned Intermediary Doctrine did not apply because the manufacturers were required to provide certain warnings to consumers of certain products.¹⁶³ The court further stated that, the learned-intermediary doctrine should not be used to preclude liability, even if the manufacturer had provided adequate warnings to the physician.¹⁶⁴ This ruling by the Supreme Court should reflect overall rulings in products liability cases. If a drug is believed to be one that carries such dangerous side effects that it requires the manufacturer to ensure adequate warning has been given to the consumer, then the manufacturing company should not be able to absolve liability by only providing adequate warning to doctors.

C. The Role of the FDA

The FDA could also be responsible for allowing any changes to be made to the doctrine. Since the FDA is the federal agency charged with consumer protection, it is the front runner to be able to establish regulations for prescribing as well as manufacturing prescription pain pills.¹⁶⁵ The FDA decides whether certain products that will be used by consumers are safe for consumption and if any further regulation needs to be created once the products are approved.¹⁶⁶ If the FDA enforced a regulation on drug manufacturers that mandated the manufacturers to go further than just providing adequate warnings to the physicians, then that would eliminate the Learned Intermediary Doctrine altogether in these instances.

The FDA requires manufacturers of nicotine patches and/or nicotine gum to provide adequate warnings not only to physicians but also to the consumers that will be consuming the products.¹⁶⁷ If this were to be applied to prescription drug manufacturers as well, then the drug manufacturers would be responsible for

¹⁶⁰ Kane, *supra* note 137.

¹⁶¹ *Edwards v. Basel Pharmaceuticals*, ALR 57 A.L.R.5th 793 (1997).

¹⁶² *Id.*

¹⁶³ *Id.*

¹⁶⁴ *Id.*

¹⁶⁵ U.S. FOOD AND DRUG ADMINISTRATION, *supra* note 67.

¹⁶⁶ *Id.*

¹⁶⁷ Goetz & Growdon, *supra* note 120.

providing adequate warnings to consumers that could possibly be prescribed these prescription drugs as well as the physicians that would be prescribing them. If this were to be implemented, it would lead to a decrease in the number of drug related deaths. While it may not happen overnight, and could take some time to develop, it is ultimately encouraging and would result in a cost-benefit analysis that would come out on the side of the consumer. This is what the FDA is charged with doing as the only and oldest consumer protection agency within the United States Federal Government.

D. The Ohio Supreme Court has the Authority to Make this Exception

The Ohio Supreme Court has made several adjustments to the overall application of the Learned Intermediary Doctrine.¹⁶⁸ One exception, which is especially applicable here, gives the defendant a chance to rebut the presumption of inadequate warning.¹⁶⁹ If the drug company can show that an adequate warning would not have made any difference in how the physician decides to prescribe a drug, then proximate cause cannot be met.¹⁷⁰ In this case, the drug company will be absolved of liability for being able to show that whether or not there was adequate warning given, it would have made no difference.¹⁷¹ The case that set out this exception is different from the current Ohio lawsuit because the physicians were being told that there was no long-term addiction consequences for prescribing these pain pills for chronic pain.¹⁷² If these physicians were aware of the addictive nature and the potential for addiction at the time, it is a likely conclusion that they would have done things differently.

This is another way of showing how the Ohio Learned Intermediary Doctrine has been expanded. Specifically, here, if the manufacturers are able to show the physicians would not have done anything different, then the doctrine can apply. However, if they are not able to do so, then the Learned Intermediary Doctrine should not apply, unless the manufacturers are willing to accept responsibility by providing funding for CME's for physicians and taking the extra steps to ensure the physicians are properly and adequately given information.

Another exception, in *Vaccariello v. Smith & Nephew Richards Inc.*, the Ohio Supreme Court expanded the Learned Intermediary Doctrine to include medical devices as well as prescription drugs.¹⁷³ The court reasoned that while the statute specifically defines "ethical drug" and "ethical medical device" separately, there is no indication based on the language of the doctrine itself, and it cannot apply to prescription medical devices.¹⁷⁴ This exception, however, was mainly an expansion of the doctrine in favor of the drug companies, but the Ohio Supreme Court did not extend any procedural protections as this note is suggesting. Even though the doctrine

¹⁶⁸ *Vaccariello*, 94 Ohio St.3d 380.

¹⁶⁹ *Monroe v. Novartis Pharmaceuticals Corp.*, 29 F. Supp. 3d 1115 (S.D. Ohio 2014).

¹⁷⁰ *Id.*

¹⁷¹ *Id.*

¹⁷² Complaint at 66, *State of Ohio v. Purdue Pharma, et al.*, No. 17CI000261.

¹⁷³ *Id.*

¹⁷⁴ *Id.*

was expanded here, it was not in a substantive way, and therefore, the court could and should still carve out the exception that this Note proposes.

In order to allow this solution, the Ohio Supreme Court would again have to find that an exception is warranted. The court has expanded the Learned Intermediary Doctrine and would be able to do so here because it is within the same scope of the language. The court should expand the doctrine to include the exception that while the drug may not be considered defective, in order for the learned intermediary doctrine to apply, the manufacturer must have to show the steps they took.¹⁷⁵

1. Repealing The Learned Intermediary Doctrine

One possible counter argument to this proposed solution is: rather than creating an exception to the learned intermediary doctrine, it could be repealed entirely. This argument has been addressed but has not been accepted in jurisdictions nationwide, as they all still follow and apply the Learned Intermediary Doctrine.¹⁷⁶

The rebuttal to this argument is the fact that this doctrine under products liability law has been recognized nationwide, as well as on a state by state basis.¹⁷⁷ Every state has some form of the Learned Intermediary Doctrine under their products liability law.¹⁷⁸ Due to its extensive history, repealing this doctrine would be very difficult. The Learned Intermediary Doctrine is also centered in protecting those manufacturers who do in fact provide adequate warnings to consumers, as well as physicians, but somewhere in the chain of communication, something is lost. It is not a bad doctrine that needs to be repealed, but simply needs to be applied in a way that is ensuring the right companies are being held liable and the right companies are being absolved of liability. While this argument certainly makes sense given the context of this Note, this would not be as successful because of the extensive legislative history given to this doctrine and acceptance throughout the United States.

Another reason that appealing this doctrine would not be effective is because of the new Direct to Consumer advertising (“DTC advertising”). DTC advertising is an up and coming form of advertising that eliminates the need to warn physicians, which would eliminate the need for the learned intermediary doctrine altogether.¹⁷⁹

2. Punishment this Late would be Ineffective

Presumably, drug manufacturers might say that they should not be punished at this point because the damage has already been done. Without any further negative acts continuing to add to the problem, what is punishing them going to do? Also, it has already been shown that at least one of the pharmaceutical companies involved in Ohio’s lawsuit and several of the other state lawsuits, Purdue Pharma, has made settlements with the federal government.¹⁸⁰ Purdue Pharma has also put a drug onto

¹⁷⁵ Ohio Rev. Code Ann. §2307.76(C) (West 1988).

¹⁷⁶ Goetz & Growdon, *supra* note 120.

¹⁷⁷ *Id.*

¹⁷⁸ *Id.*

¹⁷⁹ *Id.*

¹⁸⁰ Alana Semuels, *Are Pharmaceutical Companies to Blame for the Opioid Epidemic?* THE ATLANTIC (November 11, 2013),

the market that is less-addictive than Oxycodone and has the same effect as far as pain relief.¹⁸¹

Although these companies have already created the danger and it is living out in society as we speak, there has yet to be a response from them.¹⁸² While it is also in the hands of the physicians and the medical community who prescribe these opioid pain pills, in holding the drug companies liable for deceptive practices, it will force them to act in a positive way. It will require them to ensure that the physicians and the medical community they are in fact contacting are not prescribing in a way to allow excess pills to end up on the streets or in the hands of addicts.¹⁸³ It will ensure that if these physicians are to be held responsible and the duty falls to them, they are being provided the adequate and correct information about what the effects of these opioid pills have.¹⁸⁴ Furthermore, it will ensure that they be provided that information from an independent third party.¹⁸⁵ Finally, CME programs are very relevant and necessary in the medical community, but it is not reasonable to suggest taxpayers bear the burden to fix a public health problem when it is caused by these billion dollar companies.¹⁸⁶

IV. CONCLUSION

There is no doubt that the Country as a whole is suffering from this severe and debilitating epidemic. States like Ohio are complicated, deeply intertwined, and continuing to get worse, not better. What is very clear within this ongoing epidemic, is that something more needs to be done, and it needs to be sooner rather than later. When large pharmaceutical companies are preying on consumers and their physicians through deceptive tactics¹⁸⁷ and they are able to avoid the blame for their actions,¹⁸⁸ there needs to be consequences. These deceptive marketing practices not only led to the opioid epidemic but have also been the background for rapidly increasing the seriousness of the epidemic. This Note has discussed the ways that have already been proposed, from allowing Narcan to be carried and bringing awareness to the epidemic. Even after these proposals have been implemented though, they are still not successful in stopping or even decreasing the amount of deaths from overdoses we are seeing each and every year. With several states now realizing that the drug pharmaceutical companies are at the core of this problem, more and more states are bringing law suits against them in an attempt to hold them accountable.

<https://www.theatlantic.com/business/archive/2017/06/lawsuit-pharmaceutical-companies-opioids/529020/>.

¹⁸¹ *Id.*

¹⁸² Borchardt, *supra* note 13.

¹⁸³ *A Day in the Life of a Pharmaceutical Sales Representative Med Reps*, *supra* note 98.

¹⁸⁴ *Id.*

¹⁸⁵ *Independent Medical Education Funding and Application*, *supra* note 145.

¹⁸⁶ *Id.*

¹⁸⁷ Complaint at 66, *State of Ohio v. Purdue Pharma, et al.*, No. 17CI000261.

¹⁸⁸ Ohio Rev. Code Ann. §2307.76(C) (West 1988).

Since the learned intermediary doctrine was established through case law,¹⁸⁹ any changes that can be made to it can be established through case law. This means that exceptions can be carved out through case law under the United States Supreme Court¹⁹⁰ and the Ohio Supreme Court.¹⁹¹ Also, because the Food and Drug Administration is tasked with providing consumer protection, regulations could be laid out that require drug manufacturers to warn consumers when there are specific drugs that are being tested. Further, the FDA could establish the requirement that if the warnings are not provided to the consumer, then the drug manufacturing company could and will be held liable for any damages that result.

The answer to decreasing this serious drug epidemic across the nation is to hold the pharmaceutical companies accountable and to not allow them to misplace the blame. In making these companies understand the capacity of their deceptive marketing to doctors and in turn to consumers, they will be forced to make changes and to start to remedy their bad practices. This Note proposes a solution that would require two separate actions from any company trying to use the Learned Intermediary Doctrine. The first prong addresses when a drug manufacturing company is going to try and absolve itself from a duty owed to consumers through the learned intermediary doctrine. If the company should want to use this, then they must be required to prove that they have done everything in their power to stop the drugs from going to the black market. The black market is a hot spot for drug addicts to get their hands on drugs illegally, and part of the reason behind this is due to the influx of illegal prescription drugs into the black market. By ensuring proper prescription methods through giving the physicians the information and knowledge they need, it is ensuring that less drugs will illegally end up being sold on the black market and ultimately falling into the wrong hands.

The second prong of this exception will include the requirement that drug manufacturing companies fund continuing education programs for the medical community to whom they provide the information. Since the medical community that is in charge of prescribing these opioid pain pills is relying on the information provided from the manufacturers and their representatives, the only way to absolve the manufacturer's duty entirely is to provide another outlet for education, instead of allowing for the KOLs, which are paid for and provided by the manufacturing companies themselves. This will ensure unbiased information as well as correct information. Further, this will ensure that the consumer's best interests are always the first consideration.

It is never too late for a solution, and this would be a strong push in the direction of showing the care for the consumers whose lives have been flipped upside down because of the deceptive tactics. There needs to be a collective effort across all actors involved in order to bring this to an end. Lives are being taken across all age ranges, races, income levels, cities and rural areas, without any discrimination, and something needs to be done. The proposals set out in this Note will begin to put an end to the epidemic and be a giant step in the right direction toward slowing and ultimately ending this awful epidemic.

¹⁸⁹ Goetz & Growdon, *supra* note 120.

¹⁹⁰ *Sterling Drug*, 370 F.2d 82.

¹⁹¹ *Monroe*, 29 F. Supp. 3d 1115.