INTRODUCTION

The opioid overdose crisis is a knife that has been at the throat of this country for quite some time. Attempting to address this issue is a task that has been more than a handful for policy makers over the years. According to Business Insider, there were around 47,055 overdose deaths in the United States in 2014.
alone, 60% of which involved opioids.1 In addition, the opioid crisis is affecting newborns as many are being born with Neonatal Abstinence Syndrome.2 This syndrome occurs when babies become dependent on opioids in the womb, and, after they are born, suffer from withdrawal symptoms.3 This issue, as well as the many others surrounding the opioid crisis, has led to many attempts at multidistrict litigation around the country, making this issue massive and extremely far reaching.4 The expansion of access to Naloxone, an opioid overdose reversal antidote, is the newest proposed solution to this issue. All fifty jurisdictions have passed, or are in the process of passing, legislation that substantially expands access to the antidote in hopes that its short term, life-saving capabilities will reach as many as possible in order to save more lives from overdose.5

This legislation expands Naloxone access to law enforcement officers, emergency response personnel, and general laypeople in order to cover as much ground as possible in an attempt to substantially increase general life-saving capabilities and to prevent more overdoses as the years progress.6 The hope is that by enabling emergency response personnel to carry the antidote on hand, they will be able to revive people who are overdosing on the scene instead of having to rush them to a hospital, wasting valuable life-saving time. The dialogue surrounding the opioid overdose epidemic is absolutely vital as it has been a major issue

3. Id.
over the years, and continues to claim the lives of many to this day. However, on top of understanding this issue at its roots and furthering the dialogue, it is important to address a major component that appears to be absent from the conversation: the long-term legal implications of the administration of Naloxone, the opioid reversal antidote.

This note will attempt to do just that. It analyzes (I) what makes opioids so addictive; (II) the opioid antidote, Naloxone: what it is and how it works; (III) the effectiveness, fairness, and potential legal ramifications surrounding the legislative expansion of access to emergency response personnel and the general public; and (IV) proposes a solution to addressing future potential side effects. Furthermore, within the confines of addressing potential legal concerns, this note will: (A) analyze some of the legislative history of the Naloxone expansion movement, as well as some different forms of legislation, directly comparing them to one another; and (B) assess the effectiveness of the immunities they grant, long-term side effects, and some approaches to an unaddressed short-term issue with allergies.

I. OPIOID ADDICTION

Before being able to fully dive into the issue of addressing the potential legal ramifications of the legislative expansion to access of Naloxone, it is first necessary to understand the big picture crisis, which has lead to the research, development, and ultimately the use of overdose reversal compound to combat it. Having this background understanding of the issue as a whole is vital before attempting to unpack the rest.

First it is important to understand that the mention of “opioid crisis” does not just refer to illegal purchase and use of heroin, as that is what likely comes to mind for most when they hear it. Rather, according to the National Institute on Drug Abuse, in many instances the addiction begins from a simple, routine prescription from a doctor.7 Many users are prescribed opioids directly for pain suppression, whether it is to manage an

7. Id.
injury or for post surgery recovery. A short list includes Hydrocodone, Oxycodone, Codeine, and Morphine; all pain killers that are legally prescribed in the United States. This, unfortunately, for many of the addicts is where it all begins, because often times from there, minor use progresses to a serious, seemingly unstoppable addiction to the prescription opioids, and far too often leads to a transition to something a bit worse: Heroin. That idea, of course, fails to account for the many people who intentionally or unintentionally share their opioid prescriptions with others who are not supposed to be using them at all. This shows just how fast the epidemic can spread and explains how it has become such a major crisis over the years.

Understanding why opioids are so addictive is also important for purposes of understanding the bigger picture. According to the National Institute for Drug Abuse, opioids are derived from the poppy plant and work by attaching to certain receptors located in the body and the brain. When the opioid attaches to the receptors in the body and the brain, it blocks them from sending and receiving pain messages, hence the virtual disappearance of all perceived physical pain. Upon attachment to the receptors, the opioid also stimulates them, causing the body to release large amounts of Dopamine. The large release of Dopamine causes the person to enter an intense state of euphoria. That euphoric sensation brought on by opioid use essentially reinforces the act of using them over and over again.

9. Id.
10. Id.
12. Id.
13. Id.

316
until it is too late and an addiction has set in.\textsuperscript{15} Beyond that, the withdrawal symptoms from an attempt to cease opioid use after becoming addicted are extremely harsh making the quitting process a long and arduous one—impossible for some.\textsuperscript{16} All in all, opioid users feel nothing short of amazing when using them, after all that is their intended purpose. The problem is that they feel just a little too amazing, and that is where the issue begins.

Chasing that amazing, extremely euphoric sensation is something that has consumed the lives of far too many across the nation. Some basic estimates of national numbers show that around 29 percent of people that are prescribed opioids, legally, go on to misuse them.\textsuperscript{17} From there, around 12 percent of all users go on to become fully addicted to the drugs, six percent of which transition to using Heroin.\textsuperscript{18} Around 80 percent of all Heroin users first misused and were addicted to other opioids, in other words, they started with simple prescription painkillers, medication that we have all likely taken ourselves for one reason or another.\textsuperscript{19} Some of these numbers may seem small, but these percentages represent far too large of a sample of the population given the fact that they are in regards to a massive drug addiction. In modern times, it would seem that almost everyone has been prescribed some sort of opioid for one reason or another, and the fact that a whopping 29 percent of those people become addicted to them speaks loudly to how incredibly addictive they truly are. To hammer home just how significant and relevant this issue is, around 115 people die from an opioid overdose every single day.\textsuperscript{20} Opioid addiction and overdose is a massive killer, so the national effort to combat overdose is well warranted. However, no solution is perfect, so attempting to address those imperfections is essential, as this critical situation continues to develop. The current national effort to combat the opioid epidemic centers around Naloxone, the overdose reversal

\textsuperscript{15} Id.
\textsuperscript{17} Id.
\textsuperscript{18} Id.
\textsuperscript{19} Id.
\textsuperscript{20} Id.
antidote, and its life-saving capabilities.

II. NALOXONE: WHAT IT IS AND HOW IT WORKS

Understanding the antidote and how it works is essential to understanding legislative efforts to incorporate it into a solution. The antidote’s formal name is Naloxone, but there are a few different brand names, most notably Narcan and Evzio. When it comes to Naloxone, the major focuses lie in the varying methods of application, as well as price.

A California based company called Opiant Pharmaceuticals is responsible for manufacturing Narcan, one version of the opioid reversal antidote.\(^\text{21}\) The FDA approved Narcan in 2015 and the company’s sales partner, Adapt Pharma, began generating sales of the antidote by 2016.\(^\text{22}\) Including Narcan, six different manufacturers, who produce a total of eleven different Naloxone products, share the market for Naloxone sales.\(^\text{23}\) However, only two are widely available and used largely within the confines of this expansive legislative movement to combat addiction and overdose: Narcan and Evzio.\(^\text{24}\) This is due to the fact that Narcan and Evzio are both the easiest versions of the antidote to administer as Narcan is a nasal spray and Evzio is an injection.\(^\text{25}\) Narcan is more often used then all of them including Evzio because, in addition to being user-friendly, it is also currently the least expensive option.\(^\text{26}\) Narcan currently costs around $150 for a two-pack containing two doses versus Evzio, who currently has its price hiked all the way up to $4,500 per two-pack.\(^\text{27}\) That price comparison is an obvious illustration of


\(^\text{22}\) Id.

\(^\text{23}\) Id.


\(^\text{25}\) Id.

\(^\text{26}\) Id.

why Narcan is the most common. If Narcan joins the others in hiking its prices, then maintaining a steady Naloxone supply for law enforcement and first responders, as required by some proposed legislation throughout the states, is going to prove extremely challenging.

Narcan is packaged into a small device to be administered as a nasal spray into the nasal cavity of anyone who is experiencing an opioid overdose. It comes in packs of two doses, typically containing roughly four milligrams of Naloxone inside. It is made for use in emergency opioid overdose situations, as it does nothing to people who are not using opioids. However, the presently known, short term side effects that it does have on people who are overdosing is a fairly harsh list, which contains: flushing, dizziness, tiredness, weakness, nervousness, restlessness, irritability, body aches, diarrhea, stomach pain, nausea, fever, chills, goose bumps, sneezing, shortness of breath, and a runny nose. Other, more severe side effects that result from improper dosage are simply nasty and typically consistent with those of opioid withdrawal. That list that can contain things like: agitation, high or low blood pressure, cardiac arrhythmia (abnormal heartbeat), shortness of breath, pulmonary edema, encephalopathy (abnormal brain function), seizures, coma, and death. When it comes to Naloxone administration, getting the dosage right is a huge deal for those reasons. Ultimately, aside from those harsh side effects, Naloxone works as an opioid antagonist by binding to the opioid

29. Id.
32. Id.
33. Id.
34. Id.
receptors and pushing any opiates off, all while having no effect on the receptors themselves.\textsuperscript{35} There is no doubt that the antidote is extremely effective at performing its intended purpose, however it still carries with it some mystery. When it comes to compounds like Naloxone, which are intended to enter into the body without all things being known for certain, potential for future legal battles is extremely large. It is important to prepare for those potential legal consequences and to examine the history of the legislation used to expand the access and use of this antidote.

III. NALOXONE LEGISLATION: HISTORY AND ADDRESSING POTENTIAL LEGAL CONSEQUENCES

A successful effort to properly expand access and use of Naloxone via legislation requires (A) an understanding of the legislative history and (B) an analysis of the effectiveness and fairness of the current legislation in addressing potential future legal consequences. Any pitfalls in legislation that subtract from its effectiveness or fairness need to be addressed and amended.

Attached to this rather new opioid overdose reversal antidote is a rather large potential for litigation both in the near and far future. The nature of administering the antidote is a little bit of an invasive action for a person to take on another. With the most common delivery method being Narcan, administration requires a device to be inserted into the overdosing person’s nose to release a spray into his or her nasal cavity.\textsuperscript{36} Beyond that, it is unlikely that most regular laypeople will be sufficiently trained to properly administer Narcan. Even if properly trained, whether it be a regular person, law enforcement officer, or emergency response personnel, the potential for sheer negligence in the application of the opioid antagonist remains large, just as it does with most other activities. When it comes to putting substances into the body, any number of complications could occur from administration to how any one individual’s body reacts to it. Depending on the substance and circumstances, the reaction

\textsuperscript{35} Highlights of Prescribing Information, supra note 30.
\textsuperscript{36} Id.
could be quickly realized, or it may take time. That principle of the unknown generally applies to all substances entered into the body, especially those that have not been around long enough for side effects to be thoroughly studied and understood. With Narcan, the short-term side effects are generally known. However, Narcan is one of those substances that has not been around long enough to truly know the long-term side effects, if they exist. There may be no side effects in the end, however given the track record of other unnatural substances entered into the body, it would seem highly unlikely for that to be the case.

Everyone has seen those commercials for other well-known medications that always end with a nasty laundry list of unpleasant side effects. Following those commercials years down the line is often another commercial reaching out to anyone who took that medication and suffered some sort of unforeseen harm in order to try and help them recover damages for it. Keep in mind: those are often substances that were not distributed on a mass scale in order to fend off an epidemic. Naloxone, on the other hand, is an antidote being legislatively implemented as a mass epidemic combatant. For that reason, for something on this grand of a scale, it is important to address potential legal immunities that are not already in place, both short-term and long-term.

In assessing how to approach future legal battles over the unknown potential side effects of the antidote, it is vital to strike a viable balance between protecting the parties prescribing and administering the antidote and protecting the party being saved from an overdose. This balance must be well struck both in the short-term and the long-term. Most states have recognized this need for balance, at least in the short-term, and have formulated language to extend a form of immunity from liability to health care providers who are tasked with prescribing the drug. They have also, to some extent, enacted some form of immunity protection for those who take to administering it in emergency

situations.\textsuperscript{39} In most states with naloxone expansion legislation, the short-term protections share some commonalities for both prescribers and administers.\textsuperscript{40} These commonalities, however, are not where the big picture issue lies with regards to the legislation. Instead, the big issue is the fact that potential long-term legal ramifications have not been addressed at all, and it must be at least contemplated. Nonetheless, striking the proper balance all begins with assessing the legislative history.

A. Legislative Expansion and History

When it comes to opioid overdose, it is important to realize that it is most often going to be the case that an average person is going to be first on-scene to witness another person overdosing, whether it is a friend, family member, or bystander stranger.\textsuperscript{41} In the instance when none of the ordinary people present have the ability to save the overdosing party, then they will likely make an immediate call to 911 for help. Then, in will come the emergency response personnel and law enforcement officers to try and save the day, not necessarily in that order. Given the fact that access to Naloxone has historically been more restricted prior to this new legislative expansion, even to emergency response personnel, lives were continuously lost. With an effective antidote in existence, continuing to allow lives to be lost due to untimely assistance is simply something that did not make sense to legislatures all across the country. There is a solution, so why not use it?

Thus, the legislative expansion of access to Naloxone began in 2001 in the state of New Mexico, as they were the first state to enact it.\textsuperscript{42} This access expansion approach to preventing overdose has arguably been the most successful stand against the opioid overdose epidemic to date because, as of 2018, it has successfully

\begin{flushleft}
\textsuperscript{39} Id.\textsuperscript{.} \\
\textsuperscript{40} Id.\textsuperscript{.} \\
\textsuperscript{42} Id.\textsuperscript{.}
\end{flushleft}
decreased the total number of opioid related deaths by 9% to 11%. Even though New Mexico was first to expand Naloxone access all the way back in 2001, most states did not follow suit until around a decade, or more, later. It was not until 2017 that all fifty states had passed Naloxone expansion legislation. It is unspecified in the states’ legislative history why a lot of states waited to join in the trend, however if one were to speculate, it was likely due to the fact that they wanted to observe to see if New Mexico’s experiment worked and what unintended consequences they endured. Further, it is also likely due to the fact that the user-friendly versions of Naloxone including Narcan and Evzio had not been placed on the market yet, so states probably did not want to expand access to third party laypeople just yet. Now, with legitimate means to combat an overdose being so readily available and backed by FDA approval, a movement to significantly expand access to Naloxone has officially swept the nation. Most of the fifty states go far enough to address immunity, however most is not good enough. Most also fail to account for some long-term issues and that needs to be addressed as well. It is important to compare the different, common types of Naloxone legislation and to analyze their strengths and pitfalls regarding the granting of immunity and how they prepare for future legal consequences.

i. Examples and Comparisons of Different Naloxone Legislation

As previously mentioned, every state has passed, or is in the process of passing, some form of legislation intended to expand access to Naloxone. The following are some examples from different states, which read verbatim:

44. US Map for Naloxone Administration Laws and The Good Samaritan Law, supra note 38.
45. Parker, supra note 43, at 373.
46. Faulkner, supra note 21.
47. Parker, supra note 43, at 373.
New Mexico (The First):

A. A person authorized under federal, state or local government regulations, other than a licensed health care professional permitted by law to administer an opioid antagonist, may administer an opioid antagonist to another person if:

1. He, in good faith, believes the other person is experiencing a drug overdose; and
2. He acts with reasonable care in administering the drug to the other person.

B. A person who administers an opioid antagonist to another person pursuant to Subsection A of this section shall not be subject to civil liability or criminal prosecution as a result of the administration of the drug. A licensed health care professional, who is permitted by law to prescribe an opioid antagonist, if acting with reasonable care, may prescribe, dispense, distribute or administer an opioid antagonist without being subject to civil liability or criminal prosecution.\(^48\) It is strongly recommended that any person administering an opioid antagonist to another person immediately call for emergency medical services.

C. Lists guidelines for opioid antagonist administration programs. Such programs must, among other things, have a program director and physician medical director. Each program must “promptly” notify local EMS of the “activation and existence” of the program and if it stops or cancels its operations. Defines “trained targeted responders.” Must also keep certain records and submit an application for registration before beginning operations, and report any use of Naloxone by trained responders, among other requirements.\(^49\)

New Mexico’s legislation, being the first by quite a few years, served as the framework for much of the legislation to follow, in some form or another. A notable, non-exhaustive list of states that have, in some fashion, followed the New Mexico Framework are Connecticut, Colorado, Alabama, California, Florida, and


\(^{49}\) N.M.A.C. § 7-23-7 (2001).
Georgia. Over the years, there have also been some variations, with some states leaving out certain immunities that are granted in the New Mexico Model, or that alter them in some fashion. An exhaustive list of states that do not have some form of Good Samaritan law in application to Naloxone administration and calling emergency responders for an overdose are Arizona, Texas, Oklahoma, Kansas, Missouri, Iowa, Wyoming, Idaho, South Carolina, and Maine. This means that unlike the rest of the states, these ones do not extend full legal immunity to bystanders who step in to administer Naloxone, or call 911 for help in order to try and save someone experiencing an overdose. The degree to which that immunity is limited varies among that small list of states, but nonetheless they come up short of the rest of the states. An example of a state that strayed a little bit from the New Mexico Model in another way is Delaware.

Delaware:

Doctors prescribing naloxone who, acting in good faith, directly or by standing order, prescribes or dispenses the drug naloxone to a person who completes an approved-training program who, in the judgment of the health-care provider, is capable of administering the drug for an emergency opioid overdose, shall not be subject to disciplinary or other adverse action under any professional licensing statute, criminal liability, or liable for damages for injuries or death sustained to the individual in connection with administering the drug, unless it is established that such injuries or death were caused willfully, wantonly, or by gross negligence on the part of the doctors who signed the standing order and protocol.

Delaware strayed from the New Mexico Model by mandating that a person to whom Naloxone is prescribed first complete a training program before he or she is covered by Good Samaritan

51. Drug Overdose Immunity And Good Samaritan Laws, supra note 41.
52. Id.
53. Id.
55. Id.
immunity. Under the New Mexico model, a third party does not need training to administer Naloxone in good faith and be immune from suit in connection with the act of administering it. Also, unlike the New Mexico legislation, Delaware expressly stated that the doctor's immunity from suit only goes so far, as it can be stripped away if he or she acted “willfully, wantonly, or by gross negligence” caused the injury or death of the person to whom the antidote was administered. In essence, Delaware made it clear that they were not willing to extend total immunity; rather they wanted to ensure that the victim of an improper administration of Naloxone could recover if properly warranted. There are other states that committed to the same, notably, Washington D.C., which applies the “gross negligence” standard.

Another state with noticeable differences in its legislation is Louisiana. Louisiana lays out requirements that must be met before it permits licensed medical practitioners to prescribe Naloxone. The state requires that the medical professionals train and advise the people they are prescribing Naloxone to on its proper use, how to recognize signs of an overdose, how to properly store the antidote, and on proper emergency procedures in an overdose situation. Those are the express rules before a medical practitioner can even prescribe the antidote. Aside from that, Louisiana's legislation mirrors that of Delaware with the “willful, wanton, or gross negligence” standard for the maximum extent of immunity to those prescribing medical professionals.

A couple of other notable mentions, as far as states that have done something different, are that the states of Arizona and Rhode Island have both passed legislation which address the co-preservation of Naloxone along with their prescription opioids, something left out of all of the others. An interesting addition,

56. Id.
61. Id.
62. Id.
63. Kate Blackman, Opioid Policy Trends Continue in 2018 Legislative
which introduces an attempt to ensure that Naloxone is on-hand any time a person possesses prescription opioids; simply pairing the two together from the start.

All in all, a lot of states generally either follow a broader, more lightly worded framework like the original New Mexico model, or they follow a more descriptive legislative framework such as the ones native to places like Delaware, Washington D.C., and Louisiana. Some states, like New Mexico, require nothing more than a “good faith, reasonable” effort to prescribe and administer the antidote to receive immunity. The others are a little more strict and attempt to ensure that parties administering the antidote are well-trained and educated on how to properly do so, they expressly describe their requirements of the medical professionals, and ensure that they cannot get away with grossly negligent, willful, and wanton behavior by simply claiming they made a “good faith” effort in prescribing the antidote. Those states are just a little bit more specific and intentional with their legislative language.

Nonetheless, even with the presence of a couple of standard frameworks to go by, the result of what has been legislatively enacted across the states, as far as immunity, still varies in quite a few ways. To paint as clear of a picture as possible, as to the reality of the situation, all fifty states and D.C. have expanded access to Naloxone, forty states and D.C. have Good Samaritan laws, and thirty seven states protect prescribers criminally when they prescribe Naloxone to laypeople. Additionally, forty one states protect prescribers civilly when they prescribe Naloxone, thirty five states protect prescribers from professional sanctions when they prescribe it, thirty six protect distributors from criminal sanctions when they distribute it, forty one states protect distributors civilly, thirty five do so professionally, and

65. Id.
66. Mahoney, supra note 8, at 544; see generally Parker, supra note 43, at 372.
fifty permit distributors to do so over-the-counter without a patient-specific prescription.\textsuperscript{67} Furthermore, thirty eight states protect laypeople from criminal sanctions, forty six protect them from civil sanctions, and lastly, fifteen remove criminal charges for possession of Naloxone without a prescription.\textsuperscript{68} Ultimately, as it rests today, most states extend protections and Good Samaritan immunity in some capacity to the medical professionals on the prescription side, as well as the parties administering the opioid antagonist.\textsuperscript{69} Regardless, the legislative attempts to expand access to Naloxone all contain pitfalls with regards to their effectiveness at fairly extending certain immunities and addressing potential future side effects, both short and long-term. The upside is that these flaws in the various pieces of legislation can be repaired through minor amendments.

B. Effectiveness and Fairness of the Existing Legal Immunity Framework

The massive exposure for potential liability in both the prescription and administration of Naloxone stems largely from the inability to eliminate human error from the process. Human beings, albeit sophisticated, are far from perfect, and therein exists the problem.

For that reason, as addressed, most states have included language in their legislation to implement some sort of immunity and protection for healthcare professionals who are tasked with prescribing Narcan, as well as parties who seek to administer the antidote and call 911.\textsuperscript{70} All of the states permit healthcare professionals to prescribe Narcan to patients who are addicted to opioids, or who are at high-risk of overdose.\textsuperscript{71} Now, as mentioned

\begin{itemize}
\item \textsuperscript{67} Id.
\item \textsuperscript{68} Id.
\item \textsuperscript{69} US Map for Naloxone Administration Laws and The Good Samaritan Law, supra note 38.
\item \textsuperscript{70} Mahoney, supra note 8, at 544.
\end{itemize}

328
above, in an effort to vastly expand access to Narcan, most states also provide that healthcare professionals can prescribe under a non-patient-specific model. This model essentially allows states to make it vastly more available by lowering the threshold for receiving Narcan, meaning the party to whom the doctor is prescribing it to does not necessarily need to be the addict themselves. This turns the idea of prescription into more of a mass-distribution model. Under this model, Narcan can be distributed to and by third party laypersons that are not addicted, or at-risk for opioid overdose, but will, at some point, take it upon themselves to administer the antidote to parties whom they believe to be overdosing. This model makes the antidote much more available to emergency responders, friends, and family members of overdosing parties, which is, most likely, a good thing because, again, they are the ones most likely to need the antidote on hand at any given moment. The health care professionals, in most states, can essentially prescribe Narcan to just about anyone on a good-fait basis. This legislatively expanded access to Narcan leads to more prescriptions being written daily to parties who may not be qualified to administer it in some states, and therefore exposes the health care professionals and administrators of the antidote to even more potential liability, liability they need protection from. The states know this and most have acted on it.

i. Healthcare Professionals.

The opportunity for mistakes in the process of administration of the antidote by unqualified laypeople, after the prescription is written and distributed, directly exposes the prescribing healthcare professionals to potential liability. In order to address this enormous exposure to liability for the health care professionals, most states have included language in their Naloxone expansion legislation to protect them, and another example of how the language may read is as follows:

72. Id.
73. Id.; Mahoney, supra note 8, at 544.
74. Id.
75. Drug Overdose Immunity And Good Samaritan Laws, supra note 41.
A person who is permitted by law to prescribe or dispense an opiate antagonist shall be immune from criminal prosecution for: such prescribing or dispensing; or any outcomes resulting from the eventual administration of the opiate antagonist by a layperson. A prescriber or dispenser who dispenses an opiate antagonist is strongly encouraged to educate persons receiving the opiate antagonist on the use of an opiate antagonist for overdose, including but not limited to instruction concerning risk factors for overdose, recognition of overdose, calling emergency medical services, rescue breathing, and the provisions of this section shall not be interpreted to establish any duty or standard of care in the prescribing, dispensing, or administration of an opiate antagonist.\textsuperscript{76}

That is the language of Colorado’s Naloxone access expansion legislation. The reason that serves as a good example is because it not only follows the New Mexico model to some extent, but it also mimics the Delaware statute to an extent as well. This piece of legislation, however, only protects prescribers from criminal prosecution, while failing to protect them from civil liability associated with the administration of the antidote.\textsuperscript{77} This language leaves medical professionals tasked with prescribing Naloxone directly exposed to civil liability, which seems like a flood gate left wide open to the courts. It is likely the reason that New Mexico and other states that provide civil protection for medical professionals who prescribe the drug: to seal that floodgate. Beyond that, however, in order to be fair to the injured, it would seem sensible to also include the “willful, wanton, and gross negligence” loophole to the protections included in the Delaware statute.\textsuperscript{78} It makes sense for the states to build up a solid wall of immunity protection for these medical professionals prescribing Naloxone because the long-term side effects are not generally known, and negligence is always afoot. However to make that wall impenetrable and allow healthcare professionals to get away with gross negligence and to cause pain willfully and wantonly simply seems wrong and unfair.

Providing total insulation from criminal prosecution and civil

\textsuperscript{76} Colo. S.B. 13-014 (2013).
\textsuperscript{77} Id.
\textsuperscript{78} Del. Code § 6-3001D (2014).
suit for healthcare professionals in prescribing Narcan is the proper avenue for the states to take because it provides the most fair situation for them given the circumstances and provides the most beneficial route for society as a whole. This is the most fair to the healthcare professionals because in order for them to fully act in compliance with the standing orders in certain states and the legislation aimed at expanding access to the antidote, they simply need to get it into the hands of as many people as possible. This rapid distribution needs to be done despite the fact that a lot can go wrong, and what that entails can often be completely out of their hands. Nonetheless, they would be considered for purposes of liability if somebody were to get hurt or die as a result of their prescription and mass distribution. What they are prescribing to people is, at the moment, merely an antidote, and a problem solver to one of the country’s biggest problems that it has ever faced. The healthcare professionals are merely attempting to assist the government in addressing that massive problem and demand is high. They are not necessarily the ones making the executive decisions anymore; rather they now seem to merely be trying to manage pressures coming from the top down with all of this new legislation.

On top of that, however, it is necessary that their vast protections have limits and boundaries set somewhere. That is where the language from the Delaware legislation comes into play. In the end, protection of any sort for these medical professionals is a good thing, since they are merely facilitating and following orders. For that reason, the states that do protect them, which is most, are effectively on the right track. However, the most effective form of legislation would be a hybrid between the New Mexico Legislation and the Delaware legislation. The closer a state moves their legislative policy to that, the more effective they will be at best serving the prescribers in this situation, while also being fair to others. Again, it is simply a game of balancing the interests of all parties involved, as best as possible, and that hybrid model would be quite a nice solution. This inherently means considering protecting the interests of the parties tasked with administering Naloxone.
ii. Parties Administering Naloxone

As mentioned before, pursuant to the language in some states’ Naloxone expansion legislation, parties who administer Narcan in the event of an overdose do not necessarily reap the benefit of complete insulation like healthcare professionals do. However, most states that do address liability for parties administering the opioid antagonist, include language, which typically reads as follows:

Any person, other than a healthcare professional, who in good faith believes that another person is experiencing an opioid-related drug overdose may, if acting with reasonable care, administer an opioid antagonist to such other person. A person administering an opioid antagonist pursuant to this subsection shall not be liable for damages in a civil action or subject to criminal prosecution with respect to the administration of such opioid antagonist.

This is the language from Connecticut’s Naloxone legislation and it is a good example of a state extending immunity to parties who administer the antidote in the case of an emergency, so long as they act in good faith and with reasonable care. This is also a good example of a state that does not expressly extend Good Samaritan immunity to a third party who calls 911 for help. While including language to extend the 911 Good Samaritan protections to third party bystanders would be a good idea, failing to do so is not necessarily a fatal mistake. It would be an easily implemented, good idea because a study report once found that 33% of people surveyed said that they would not call the police in the case of an opioid overdose for fear that they would get in trouble themselves. The reason that omitting such an express protection is not vital in that type of situation is because it is unlikely that law enforcement officers are going to spend time punishing people for opioid, illegal Naloxone or other drug

79. Parker, supra note 43 at 372-73.
80. CT H.B. 5487 (2014) (emphasis added).
81. Id.
82. Id.
83. Parker, supra note 43, at 373.
possession, but instead will be focused on saving the overdosing individual. This notion is supported in a survey to which 62% of the police officers in the sample responded that such a protection would not have changed the outcome, as they would not have made arrests for illegal activity immediately collateral to exigent circumstances created by the ongoing overdose. The language is a good idea because 62% is not 100%, however that is still a majority. The language from Connecticut, as well as the language in most other states, is typical of a negligence standard, as it requires good faith and acting with reasonable care. That means that the party who takes to administering the Narcan to another whom they reasonably suspect of suffering an opioid-related overdose must act reasonably in doing so under the given set of circumstances.

This standard and the manner in which it applies appear comparable to the standard set out in the Third Restatement of Torts on cardiopulmonary resuscitation (“CPR”). Under tort law, no duty exists for people to rescue others in need, aside from when that person’s professional title vests them with a formal duty to act. However, when a person carries out an act that creates potential risk of physical harm to another, a duty is created and that duty is for him or her to act using reasonable care. This means that bystanders have no duty to administer CPR to someone whom they reasonably believe needs it, however, once they commit to assisting they must execute it using reasonable care under the given set of circumstances. All that means is that the person administering CPR must do so in “good faith.” Anything other than a good faith effort falls short of exercising reasonable care, which then exposes that person to liability for creating and causing physical harm to the person they were trying to save; however, that is an incredibly high

84. Id.
85. CT H.B. 5487 (2014); see Restatement (Third) of Torts: Liability for Physical and Emotional Harm § 7 (2010).
86. Id.
87. Id.
88. Id.
89. Id.
90. Id.
threshold and is nearly impossible to successfully reach for any plaintiff.\textsuperscript{91} The people who voluntarily administer CPR in good faith, using reasonable care are considered “Good Samaritans” and are legally protected in all 50 states as such.\textsuperscript{92} It seems to be the exact same standard that the majority of state legislatures intended to adopt for the administration of Naloxone and the subsequent calling for emergency assistance. This seems to be an extremely fair standard because, ideally, it encourages bystanders to voluntarily try and administer Naloxone to rescue others from overdose without fear of having it legally backfire on them.

Currently, only two states mandate training in order to be protected as a Good Samaritan for the purposes of administering Naloxone, however those states should repeal that language because requiring it would have a reverse effect as far as human life saving capacity.\textsuperscript{93} Instead, they should replace it with language similar to the Colorado legislation that “strongly encourages” medical professionals prescribing Naloxone to thoroughly inform and train the people that they are prescribing it to.\textsuperscript{94} At a minimum, this would require the prescribers to at least try and inform the party receiving the prescription face-to-face. It is also a chance for them to potentially supply those people with pamphlets or brochures to take with them in case they forget what they are told. Most importantly, it better ensures that the people carrying Naloxone are, in fact, somewhat educated on how to administer the antidote and how to spot overdose symptoms indicating when they need to use it. However, even with the training programs in the community, which all provide great benefit, a lot of people are living busy lives. They may plan to take time out of their busy schedules in order to take care of those minor details, but by the time they get

\begin{thebibliography}{99}
\bibitem{91} CPR: Legal and Ethical Issues, \textsc{American Heart Ass'n} (2006), http://www.life1st.com/files/CPR-Legal_and_Ethical.pdf.
\bibitem{92} Id.
\bibitem{94} Colo. S.B. 13-014 (2013).
\end{thebibliography}
around to it, the situation to save a life from an overdose may have already presented itself, or they may just forget. This standard ensures that they are informed, at least to some extent, right when they gain control of the antidote, so it better increases the chances of it being used correctly and effectively.

As for the parties administering the antidote, the states should continue to apply the good faith standard protecting them as Good Samaritans. Going beyond that simply requires too much of an ordinary layperson when it comes to making a split-second decision to try and save a life. It is important that the act of saving a life be executed correctly, but often times, failing to take action at all is not an option. Some effort is better than none. Nonetheless, receiving training in Naloxone administration, whether it is by Evzio injection or by Narcan nasal spray, has been heavily encouraged across the various states, and that is good enough.95 Up to 30 states have ramped up training programs for all parties including mere laypeople in order to ensure that they are receiving all necessary information to try to live up to their ultimate end goal: saving as many lives from overdose as possible.96

This good faith, reasonable care standard seems perfectly fair in application to parties who administer Narcan. The reason is because unlike the healthcare professionals in this situation, the parties administering the antidote have someone else’s life in the palm of their hands, and even with sufficient, state-certified training, they are nowhere near the level of knowledge and experience of those medical professionals. Saving the lives of others is a complex and dangerous task and one that society takes very seriously. Therefore, ensuring that life-saving situations are being handled correctly is important, however creating too harsh of a standard for laypeople to meet would undermine the purpose behind expanding access to the antidote. For the purposes of Naloxone, these laypeople are only acting in emergencies, so it is best to be fair and reasonable to them, and

95. Todd Kerensky & Alexander Y. Walley, Opioid overdose prevention and naloxone rescue kits: what we know and what we don’t know, 12 ADDICTION SCI. & CLINICAL PRAC. 1, 2 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5219773/.
96. Id.
that is exactly what the good faith standard provides. The only addition that could potentially be quite beneficial is to add in the “willful, wanton, and gross negligence” language form the Delaware statute and apply it to the people administering the drug.\footnote{Del. Code § 6-3001D (2014).} This would be sound from a policy standpoint because it completes the process of striking a fair balance between the parties involved by ensuring that the overdosing party has a right to pursue recovery for harm resulting from an improper administration of Naloxone under the legislation, while maintaining the administering party’s ability to defend themselves for making a reasonable, good faith effort to save a life. It maintains the solid protection set forth by the good faith standard, while prohibiting gross misconduct, and that is ideal. That language couples a firm reminder of how serious the situation is with a fair standard of good faith. It provides them a vital avenue of relief in the instance someone acted without good faith.

For that reason, the few states, such as New Hampshire, that do not include that exact “good faith and reasonable care” language in their standard of care for administrators of Naloxone should improve their legislation by amending it to expressly include it.\footnote{N.H. H.B. 271 (2015).} The states that do already apply that standard in their legislative language are well situated. Nonetheless, all of the states need to reach the point where they achieve that proper balance. Aside from this balancing attempt, there is still a vital need to effectively consider and prepare an approach for the potential of unknown future side effects that may surface as a result of the wide spread administration of Naloxone in its various forms.

iii. Approaching Potential Unknown Future Side Effects

As with any product, especially those that enter the body, consequences and side effects represent a great unknown. As listed before, the short-term side effects are known and are quite harsh.\footnote{Cunha, supra note 31.} With the antidote, in its newly FDA-approved forms, in
combination with those nasty potential short-term side effects, the potential for long-term damage, albeit unknown at the moment, carries the potential to be even more dangerous. All effects contained within that list of short-term side effects do not include an analysis of the potential for havoc stemming from possible allergic reactions. Beyond that, in the instance that awful adverse side effects begin to appear in the long-term future, whether it is a year or a decade after receiving a dosage, Congress and the courts need to be equipped to effectively address them, as unknown future side effects alone create a massive potential for litigation. Due to the wide range of possibilities of things that could potentially go wrong in the long-term, it makes sense to try and address it with as blanket ed of an approach as possible in order to bring judicial predictability and efficiency to a matter that carries the potential to create just the opposite. Luckily, there may be a fitting solution that already exists. That potential solution, which may best accomplish that, could be to treat Narcan and its known and unknown side effects in the same way that the law treats vaccines and their side effects. Nowhere in any of this legislation are the various manufacturers of Naloxone protected from lawsuit.\textsuperscript{100} They clearly warn of all of the short-term side effects, however warnings of long-term effects are absent given their unknown nature. They also do not list out what happens when a person has an allergic reaction to Naloxone, rather it is simply stated not to use Narcan if allergic.\textsuperscript{101} That ambiguous instruction completely fails to address allergies and therefore potential liability for them remains. Allergic reactions need to be addressed and the courts need to be ready to manage long-term side effects if they appear at some point.

iv. Allergic Reactions

With Naloxone allergies virtually unaddressed in the products’ warning labels, the manufacturers are exposed to liability. What is most confusing about the Naloxone

\textsuperscript{100} US Map for Naloxone Administration Laws and The Good Samaritan Law, \textit{supra} note 38.

\textsuperscript{101} Highlights of Prescribing Information, \textit{supra} note 30.
manufacturers’ failure to describe what happens in the case of an allergic reaction is the fact that some common reactions are known.\textsuperscript{102} It is common for people who are allergic to experience hives, shortness of breath, and swelling of the face, lips, tongue, or throat.\textsuperscript{103} All of these reactions seem like fairly common, straightforward allergic reactions. The issue, however, is that these reactions could happen to someone who is unconscious, suffering from an overdose, and on the verge of death. People suffering from an opioid overdose are already struggling to breathe properly, so the fact that a person who administers Naloxone to them may do so without knowledge of a potential allergic reaction, or what to look for, is extremely concerning. Unsuspecting third parties administering the antidote could very well be exacerbating the health-compromising effects of the overdose without realizing they are doing so. That is why the proposed standard and immunity mentioned above for parties administering the antidote is appropriate. The manufacturers need to adjust their warnings to include allergy descriptions because it is a matter of life and death. If they fail to do so, then they will likely, and should, be held accountable in court for a failure to warn under products liability law. It is such an easy fix for the manufacturers. It is essential for people to be aware of such valuable information, especially when they need to utilize it in emergency situations.

Under products liability law, any seller, including the manufacturer that sells a product in a defective condition that is unreasonably dangerous to the consumer is liable for any harm to the consumer resulting from a reasonable use of the product.\textsuperscript{104} In situations where a product like a drug is sold and is conditionally safe in some circumstances, but not in others, posing conditional dangers, the manufacturer must provide adequate warning of the danger.\textsuperscript{105} Failure to include an adequate warning makes the product defective.\textsuperscript{106} As it pertains

\begin{footnotesize}
\begin{enumerate}
\item[102.] Cunha, \textit{supra} note 31.
\item[103.] \textit{Id.}
\item[104.] Restatement (Second) of Torts § 402A (1979).
\item[105.] \textit{Id.} at cmt. h.
\item[106.] \textit{Id.}
\end{enumerate}
\end{footnotesize}
to common allergies, a seller is not required to warn against them. However, uncommon allergies not generally known do require a warning if the manufacturer has knowledge of them. If they fail to do so, the product is considered unreasonably dangerous. Naloxone is an allergen to enough people, given its widespread use as an epidemic combatant, but whether or not any individual is allergic to it is something most are subjectively unaware of. Its allergen capabilities are, however, well known by the manufacturers. Their simple advisory to not use the antidote if one is allergic is not enough. Even if someone happened to know that he or she was allergic to Naloxone when receiving a dose, he or she is almost surely going to be unconscious and unable to communicate that to the person administering it, who is almost surely unaware of the allergy. For those reasons, if the manufacturers do not change their allergy warnings to be adequate, then they should be strictly liable for any harm that results. Allergies are yet just another short-term side effect, but it has been insufficiently addressed and continues to leave manufacturers exposed. Aside from an unaddressed short-term side effect such as allergies, the potential for unknown long-term side effects remains. Courts need to be prepared with an effective solution for handling litigation stemming from the appearance of those potential future side effects.

IV. SOLUTION: TRANSLATING VACCINE LAW TO NALOXONE

In preparation for a future that is highly unknown and unpredictable, it is always best to be prepared for the worst. If the situation were to play out in the absolute best-case scenario, there would be no long-term side effects whatsoever. The people who are subjected to Naloxone and all of its brands wind up being completely fine and the antidote has no detrimental effects on them, or any offspring they may have. In that scenario, there is nothing to worry about because everyone is fine. Obviously, there would be no liability for anyone. However, relying solely on

107. Id. at cmt. j.
108. Id.
109. Id.
the best possible scenario is a huge mistake. Getting ahead of any issue is always a good idea. Even though predicting future unknown side effects could be impossible and unreasonable at the moment, preparing to deal with them if they do surface would be extremely beneficial to Congress, the legal professionals, and the courts. The most fitting manner would be to treat Naloxone manufacturers and their versions of the antidotes like the law treats vaccine manufacturers under the childhood vaccine laws.

In the mid 1900's this country began its national vaccination efforts and as a result saw a dramatic drop in the number of "communicable diseases." Due to the fact that vaccines had proven so effective at their intended purpose, every state began instituting laws to have children vaccinated. Every state required children to have at least some sort of vaccination before they could attend school. Even with the undeniable success that vaccines had in eradicating all of those communicable diseases, the public began focusing on the harm these vaccines might have had and suing the manufacturers over it. In response and out of fear that these suits would make it unfeasible for the manufacturers to stay in business, Congress created the National Childhood Vaccine Injury Act (NCVIA).

Within the confines of the NCVIA, a vaccine injury table was created, which details out all of the different types of vaccines, known potential side effects, and a timeline for which people might commonly experience them. If a party suffers a side effect or injury listed on the table he or she may be owed some sort of compensation for it, and the burden of proving some sort of defect or causation falls on the government. If the injury or harm suffered is not on the table, then the injured party must


111. Id.

112. Id.

113. Id.

114. Id.; 42 USCS § 300aa 1-34 (2007).

115. 42 USCS § 300aa 14 (2007).

prove it as a normal lawsuit.\textsuperscript{117} The NCVIA caps damages, and then pays them out from a fund formed through taxes on vaccines.\textsuperscript{118} The NCVIA also protects manufacturers from liability, so long as they abide by their regulatory requirements, avoid fraudulent behavior and criminal activity, and avoid withholding material information from consumers.\textsuperscript{119} That means that if they do engage in that kind of activity, or in other words, are “willful, wanton, or grossly negligent”, then they will be exposed to suit.

A good example of the NCVIA in operation is in the case of \textit{Bruesewitz v. Wyeth LLC}. In \textit{Bruesewitz}, a newborn received a vaccine from her doctor, which covered a few different communicable diseases.\textsuperscript{120} The federal government approved the vaccines more than 20 years before they were administered to this newborn.\textsuperscript{121} The newborn began experiencing seizures and developmental delays all the way into her teens.\textsuperscript{122} The family sued under the vaccine framework and lost because the side effects the child was experiencing were not listed on the table.\textsuperscript{123} The family then tried the case as a regular torts claim for design defect.\textsuperscript{124} They lost that as well because, under the NCVIA, the court found that claims for design defect are barred, so long as the manufacturer provided a proper warning, and in this case they did.\textsuperscript{125} The Supreme Court of the United States affirmed that decision.\textsuperscript{126} However, it is important to recognize the fact that a two-justice minority disagreed and argued that the majority’s opinion removed a duty owed by the manufacturers to continue to improve their vaccines, to continue to study them, and to utilize better, feasible alternatives when possible.\textsuperscript{127} The

\begin{thebibliography}{99}
\bibitem{117} Id.
\bibitem{119} Id.
\bibitem{120} \textit{Bruesewitz}, 562 U.S. at 230.
\bibitem{121} Id.
\bibitem{122} Id.
\bibitem{123} Id.
\bibitem{124} Id at 231.
\bibitem{125} Id at 243.
\bibitem{126} Id.
\bibitem{127} Id at 250.
\end{thebibliography}
result is that cases against vaccine manufacturers are now extremely difficult to win and they no longer have to update and improve their vaccines.\textsuperscript{128} Instead, updates and improvements are a judgment call that they can make on their own time, as they see fit.\textsuperscript{129}

This is the exact framework, with potentially only a minor adjustment, that should be applied to Naloxone, and any side effects that may come about from its administration. If new side effects of Naloxone begin to surface in the future, the first step would be for the manufacturers to add them to their warning labels. The next thing is they should be thoroughly documented, studied, and listed in a table similar to the one used for vaccines. If different brands of Naloxone are causing different side effects, then they should be listed by brand name on the table. Obviously, a side effect and harm table will take time to develop because side effects would have to become causally linked to Naloxone via research, and that could require substantial study. Granted, this is all currently over hypothetical future side effects. However, if side effects do come about, which happens more often than not, Congress will have the same problem they had with vaccines. Under those circumstances, an act would have to be passed to set up the framework in the first place, just like it was for vaccines. If the situation reaches that point and it becomes necessary, then Congress should go ahead and add that to its agenda.

Just like with vaccines, if new side effects begin to surface, there are will be a lot of people trying to sue the manufacturers, especially since everyone else involved in the process is already immune to suit. This would place a massive burden on the manufacturers and their efforts to keep up with the increasing demand for Naloxone resulting from the access expansion legislation. If things boil over to this point, and an entire act is passed, then parties who suffer need to be paid out of a fund created through taxes on purchases of the antidote to cap damages at a reasonable limit, protect the manufacturers to a decent extent, and to keep the court system’s Naloxone case load

\textsuperscript{128} Blake, \textit{supra} note 108.
\textsuperscript{129} \textit{Id.}
at a manageable limit. This is the preferred framework, that way all interests are protected. Without it, damages would be far too excessive. Further, the damages would have to be paid out by the manufacturers themselves, who would likely go out of business as a result. Without the manufacturers, there would be no more Naloxone to prevent overdoses, and a lot of people would likely lose their lives. It is a slippery slope, but that is likely what would happen, and it is the exact same concern that Congress had with vaccines.130

The only alteration that should be made to the vaccine framework comes from the dissent in Bruesewitz. There is an obvious interest in protecting the manufacturers however. As Justices Ginsberg and Sotomayor stated in their dissents, the manufacturers need to be proactive in keeping up with research and modifications to their Naloxone products as necessary.131 As new information becomes discoverable and known, with technological advances, and with time, the products and warning labels need to be altered as well, in order to make them as safe and effective as possible.132 As mentioned before, vaccine manufacturers exercise a lot of autonomy and can make their own judgments on when to update their products, but that should not be the case for Naloxone.133 It is counterintuitive not to require the manufacturers of Naloxone, a substance administered to tens of thousands to fight an epidemic, to keep up with the times and technology. Imposing that duty on manufacturers is not asking all that much of them and maintains a vital avenue of relief for people harmed by their Naloxone products. Just like in the Bruesewitz dissent, if the manufacturers cannot do that, then plain and simply, they should be exposed to liability in the case that their product causes harm.134

130. Blake, supra note 108.
131. Bruesewitz, 562 U.S. at 250.
132. Id.
133. Blake, supra note 108.
134. Bruesewitz, 562 U.S. at 250.
CONCLUSION

To sum it up, any new, surfacing side effect(s) that may come to light need to be placed on the warning labels. If the situation significantly worsens, an act similar to the NCVIA should be passed by Congress to set up this manageable framework for Naloxone, the side effect(s) should be documented into an organized table, and finally, the manufacturers should be protected for the betterment of society, so long as they meet their responsibilities of keeping up with innovation and research for their Naloxone products. The situation is not to that point yet, so the fact that it has gone relatively unaddressed is acceptable for the time being. The fact of the matter is, the situation might never reach that point. However, when it does, the NCVIA is the model that Congress and the courts should apply. “Failing to prepare is preparing to fail.”

135 This is the preparation because failure on this scale is not an option.

135. John Wooden.