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Just a buzzword or the future of drug information: can blockchain help reduce the burden of unnecessary opioid prescriptions?

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Just a Buzzword or the Future of Drug Information: Can Blockchain Help Reduce the Burden of Unnecessary Opioid Prescriptions?

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For Mom

They say it takes a village to raise a child, and it very nearly took a village for this thesis to come to fruition. I would like to thank my family for their endless support - thanks to Mom, Dad, Kate, Zoe, and Ian for putting up with me all the time, especially throughout these past few months. Thanks to my housemates and all my friends here at Vassar for your reassurance and solidarity and for listening to me talk about this non-stop - you know who you are. And thanks to Vassar for taking a chance on me four years ago. Without that, I would not have stumbled my way into the STS program and would not have opened my eyes to the wonderful world of multidisciplinary studies. And last, but certainly not least, a special thanks to my two readers, Bob McAulay and Jason Waterman, for their willingness to learn alongside me and to take on a project that none of us really knew much about when we started.

Introduction

Today in the United States, an alarming number of young people are dying prematurely due to overdoses on prescription painkillers including oxycodone, hydrocodone, and methadone. A recent obituary of a 30-year-old mother that spread virally throughout online communities for its honesty, candor, and realistic portrayal of life and death with an opioid addiction mentions that "she tried OxyContin for the first time at a high school party, and so began a relationship with opiates that would dominate the rest of her life" (Obituary: Madelyn Linsenmeir, 1988-2018). It then mentions her struggles for sobriety and custody of her young son, both of which she lost. And although it is not often that news like this reaches hundreds of thousands of people around the country, this is far from unique.

There was a time when most of the discourse around death due to overdose ignored the realities of opioid dependence and would obscure the details of individual struggles (Garfield, 2017). That obituaries would go to great lengths to avoid discussing the circumstances around overdose deaths was commonplace and only served to increase public misunderstanding about opioid dependence. What leads a person to begin using drugs as well as what a person loses due to painkiller abuse is typically covered up, which is partly why the obituary that the excerpt above is taken from has resonated so strongly with others.

An additional factor contributing to this story's fast circulation is an increase in public discourse on the opioid crisis in the United States, and for good reason. People are talking because their family, friends, neighbors, classmates, and colleagues are dying from opioid misuse. In 2016 and 2017, approximately 130 people died every day from an opioid-related drug overdose. Nearly 11 and a half million people misused prescription opioids, 2 million of whom

did so for the very first time in 2016 and 2017 (Bose *et al.*, 2017). At one point, Linsenmeir's obituary refers to a system failing her, a system in which the doctors she befriended are complicit agents (Obituary: Madelyn Linsenmeir, 1988-2018). While her first exposure to an opiate was not through a prescription filled on her behalf, it was from an OxyContin pill which was likely prescribed to someone she knew. That there was enough of a surplus in this highly addictive substance for her to have access for recreational use is itself a failure of the medical system.

There are countless other stories of individuals who develop dependence from negligent, overly generous prescriptions after an injury or a surgery. Seeing as this issue stems from pills intended for medical use, recent attempts to curb opioid misuse have focused within the medical field. According to the National Institute on Drug Abuse, "physicians, their patients, and pharmacists all can play a role in identifying and preventing nonmedical use of prescription drugs" (Misuse of Prescription Drugs, 2018). Current efforts to address prescription opioid abuse within the medical field include evidence-based screening tools that are incorporated in routine visits, prescription drug monitoring programs (PDMPs), and the CDC's Guideline for Prescribing Opioids for Chronic Pain, meant to outline clinical standards for considering the benefits and drawbacks of opioid treatment (Misuse of Prescription Drugs, 2018). The recent establishment of the President's Commission on Combating Drug Addiction and the Opioid Crisis is aimed at improving our abilities to prevent and treat opioid addiction, and is indicative of the urgency of this issue.

These initiatives are addressing the right areas, but research on their effectiveness at reaching their goal shows mixed results, particularly when evaluating PDMPs. PDMPs are state-run electronic databases that aim to record the prescribing and distributing of controlled

prescription drugs and can also serve as effective tools for recognizing and preventing prescription drug misuse. They can help to identify some of the prime sources of detrimental prescription practices including fraud, forgeries, improper prescribing, improper dispensing, and doctor shopping, which is the practice of visiting multiple physicians to obtain multiple prescriptions (Brandeis University, 2014). Encouraging signs show that the implementation of PDMPs in some states has been associated with lower rates of opioid prescription and overdoses. In states such as Ohio, Indiana, Oklahoma, California, and others, the availability of PDMP data into medical practices has been associated with positive changes in provider behavior that reduced the frequency with which opioids were prescribed. Additionally, in Florida and Kentucky, for example, indications point to the increased incorporation of drug monitoring programs leading to declines in prescription drug overdose deaths (Brandeis University, 2014). The use of PDMPs, however, is not uniform across the various relevant actors in the opioid prescription network.

Despite the successes outlined above, problems of best practice, ease of integration into daily use, and interoperability between different relevant members of the network still pose issues for medical providers. When I began to research possible avenues for this thesis, I sought out novel, untested solutions that have the potential to build on the successes of PDMPs while mitigating the issues that currently restrict them from fully achieving their purpose. My intent with this was to find an emerging technology to evaluate whether it could work and to analyze it using a variety of STS theory. In my search, I stumbled upon a paper titled "Blockchain Technology Use Cases in Healthcare," which piqued my interest. Of the seven potential use cases outlined, there is a section called "Prescription tracking to detect opioid overdose and

overprescription" (Zhang *et al.*, 2018). In this section, the authors claim that "our current prescription tracking system still lacks the technology to do so effectively…Blockchain technology provides a promising approach to prescription monitoring that not only makes prescriptions safer, but also provides incentives for writing fewer prescriptions" (Zhang *et al*, 2018).

In this thesis, I would like to explore this assertion and examine the potential role that blockchain technology could have on reducing the burden of unnecessary nonmedical opioid use in the United States. Additionally, I aim to outline the specific niche that the introduction of blockchain technology would fill in the current landscape of prescription drug monitoring, to assess the feasibility of implementing this technology, and to consider its place using theoretical justifications. Exploring the role of an emerging technology is a complex endeavor, especially given the complicated nature of nonmedical opioid abuse today. In light of this, my main goal in this thesis is to determine whether the hypothetical new use for this relatively new technology is feasible and whether it would work as proposed, or if this is simply an instance of an over-hyped technological innovation representing a false dawn in the struggle to contain nonmedical prescription opioid use.

In chapter 1, I examine the root causes of today's opioid crisis by comparing it to prior waves that hit the United States during the late 19th and early 20th centuries, focusing on the role of physicians, drug suppliers, and public perception. After this, I emphasize the predominant role that the medical field has played in and continuing the issue today and why that might make blockchain technology a potential solution. In this section of my thesis, the distinction between a supply-side approach and a demand-side approach is a central argument. Whether the root cause

of this epidemic is due to overabundance or due to demand from individuals experiencing decreasing economic stability seeking drugs is important to discern because it allows us to determine the potential impact that blockchain could have on reducing drug use.

After this background information, I begin chapter 2 with an overview of what blockchain technology currently is as well as potential future innovations. While it is originally a technology meant to create a new financial system, its potential applications to healthcare are varied. One of these use cases is, of course, in monitoring opioid prescriptions. From this, I outline the benefits that the hypothetical implementation of this would have on increasing interoperability between all actors involved in prescribed opioid transactions. I then touch on current startup initiatives that are working on a way to incorporate blockchain into a novel opioid monitoring solution.

After outlining the potential benefits that blockchain could have on reducing the burden of nonmedical prescription opioid use, I then attempt to establish the feasibility of this proposed new application in chapter 3. I will begin by discussing historical patterns of technology adoption within the healthcare space and then will lead into how blockchain has been integrated into new fields beyond its original purpose. While I explore this, I will compare it with the barriers to implementation, particularly those that are somewhat ironically designed to protect us as patients. With this in mind, I address overall safety concerns and then outline whether a blockchain is currently both a necessary and a feasible technology to adopt into the prescription drug monitoring space.

After this, I examine this emerging technology through a variety of STS theoretical lenses and ask questions related to the social and political implications that blockchain use in policing

opioid prescriptions would have. These questions have to do with whether there is an inherent political neutrality to this, whether it is a disruptive technology, whether it is a technology that has a different meaning to different groups, and what the bioethical implications are to allowing health information to be accessed by multiple relevant parties. Additionally, in this chapter, I consider the meaning of the word decentralized, and reflect on whether applying blockchain to prescription drug monitoring would represent a shift away from this technology's decentralized origins.

After this, I will give my concluding remarks as well as make a final conclusion to the question that I pose in the beginning of the introduction. Would this actually be feasibly implemented, and if so, would it provide the anticipated benefit? I believe, while there will certainly be difficulties in adopting and integrating blockchain into drug monitoring efforts, that with enough time, it will immeasurably improve rates of exposure and addiction to opioids. Until that time comes, work done to implement blockchain into prescription monitoring systems would be complemented by additional harm-reduction initiatives to decrease the per capita social cost of drug use as well as the incidence of new opioid abusers.

How Did This Happen Again? What Can We Do to Prevent it From Continuing?

Although the phrase "opiate addiction" is not new to the United States, it has taken on an entirely new meaning between its emergence and the decades since the 1990s. Both the extent of opiate addiction as well as its typical case have changed drastically. Before discussing what a blockchain is as well as its potential relationship to the current prescription opioid issue, it would be a useful exercise to outline how opiate addiction has changed and what has allowed it to expand beyond its original scope. Additionally, the term "opiate" refers to any non-synthetic drug derived from opium, while an "opioid" refers to any of the natural or synthetic drugs derived from opium, such as those found in prescription pill bottles (Bloom, 2017). "Opiate" was the favored term for most of the 19th and 20th centuries, so therefore, while this thesis focuses on the current opioid epidemic, when discussing historical patterns of drug abuse, "opiate" will be used to refer to any natural prescription, such as morphine and "opioid" will be used to refer to more contemporary, synthetic prescription medicines derived from opium, including oxycodone, fentanyl, and tramadol.

In the early years of opiate use, from the late 19th through the early 20th centuries, when patterns of addiction were first seen, there were many potential sources by which individuals could be exposed to opium and morphine. At the forefront were the following: physician-administered opiates, exposure due to the Civil War, self-administration, and nontherapeutic, recreational use (Courtwright, 2001a). From the 1870s to the 1880s, America's per capita opiate consumption tripled, touching individuals from all walks of life, including veterans, immigrants, physicians, and housewives, all searching for substances to subdue symptoms of aches and pains (Courtwright, 2015). Opiate prescriptions continued to boom

throughout the 1880s until a paper published in the Boston Medical and Surgical Journal emphasized the negative effects of opiates, whose side effects and addictive tendencies outweighed the pain-killing benefits (Adams, 1889). Plainly and simply, Adams states the following:

> There are times when the dangers and disadvantages of this most brilliant of drugs seem wholly out of proportion to its benefits…The disadvantages of opium are these: (1) In an overdose it is an active poison. (2) In ordinary doses its benefits are largely offset by various functional derangements. (3) Its use involves the danger of the opium-habit (Adams, 1889).

Arguing that the use of opiates was outdated, author James Adams asserts that newer, non-opiate painkillers should be introduced to treat symptoms that led patients to seek physician care, and over the following two decades, pressure from within the medical community led to legislative measures that worked to turn the tide against the initial opiate wave (Courtwright, 2015).

The Adams paper's criticisms against opiate prescription were adopted by younger, more progressive physicians and pharmacists who campaigned for legislation at both the local and state levels to control transactions involving narcotics (Lyden and Binswanger, 2019). In the early years of the 20th century, a controlled approach to opiate use was adopted, and the general wave of anti-opiate views culminated in 1915's Harrison Anti-Narcotic Act, which regulated opiate prescribing and distributing (Terry, 1915). For the most part, these initiatives successfully

decreased opiate consumption to the point of essentially curtailing the first nationwide opiate epidemic. While there are certainly many surface-level differences between this narcotic crisis and the current wave of opioid abuse, a deeper look reveals surprising similarities between the past and the present.

At the onset of this first wave of opioid overuse and abuse, most of the addicts were women, while by 1923, some locations saw men become their addicted majority (Courtwright, 2001a). The foremost cause of addiction in the 19th century was the administration of opium and morphine by physicians. The percentage of morphine and opium addicts during this time that could trace their exposure to physician-administered substances ranges from 50% to 99%, indicating a majority of cases of opiate addiction, particularly as morphine injections became commonplace (Courtwright, 2001a). Well-off, predominantly white patients who could access medical care were given these injections for nearly everything, while due to socioeconomic factors, discrimination, and a lack of nonwhite physicians, minority patients were prevented from seeking medical care, which has perpetuated and still contributes to health disparities today (Anderson *et al*., 2009).

While this has undoubtedly contributed to higher relative rates of mortality and morbidity for minority populations relative to white populations, it certainly helps to explain the racial composition of the opiate-using population during the initial 19th and 20th century epidemic as well as today, where most of the individuals and communities suffering from opioid abuse disorder are working-class, non-college-educated white Americans, particularly males (Quinones, 2015).

Although the original wave of opiate abuse died down by the onset of World War II, developments have taken place in the past 30 or so years that have caused a new wave of opiate misuse, stemming from the emergence of synthetic painkillers derived from opium: prescription opioids. Both the original emergence of opiate abuse and its re-emergence in American society in the 1990s came from medicinal origins. As seen in the opiate epidemic near the turn of the 20th century, today's crisis stems from a variety of elements, foremost among them generous prescribing practices by physicians and the associated increases in opioid consumption by the public (Meldrum, 2016).

An assortment of disparate factors incorporated for the perfect storm in the current revival of nonmedical opioid use. These components contributed to the staggering increase in synthetic opioids that are prescribed, abused, and overdosed on that has been seen in the United States over the past generation. Generally speaking, in the 1960s and 1970s, health care providers eschewed prescriptions for pain management. During these years, no matter the patient or the case, physicians and other medical professionals were instilled with the fear of causing a patient to overdose from dangerous analgesics. "'Don't overdose, don't overdose,'" they were taught. "You give the smallest amount of medication over the longest period of time because you don't want to give a patient too much, for fear of addiction'" (Quinones, 2015). While wise, this sentiment did not remain widely-held for much longer after the beginning of the 1980s. As older approaches to patient care began to subside, pharmaceutical and technological developments offered hope of a different way to treat pain.

In 1986, the publication of a paper on the relationship between pain, opioid use, and addiction supported had far-reaching consequences beyond the author's original intentions.

From a sample of only thirty-eight patients managed by opioid analgesics, Russell Portenoy and Kathy Foley concluded that "opioid maintenance therapy can be a safe, salutary, and more humane alternative to the options of surgery or no treatment in those patients with intractable non-malignant pain and no history of drug abuse" (Portenoy and Foley, 1986). This single study was taken as a "declaration of independence for the vanguard of pain specialists interested in using opiates for chronic pain" (Quinones, 2015). Although many other researchers found little data to support this claim, these findings were largely taken as canon, and contradictory information suggesting the addictive nature of opioid analgesics was brushed aside (Lyden and Binswanger, 2019).

The idea that opioids themselves were non-addictive persisted, and changes in the practice of medicine complemented the idea that pain is best treated by opioid administration. Anesthesiologists, who previously worked with surgery patients exclusively before their procedures were suddenly accompanying patients through days and weeks of their post-operation recoveries. Physicians, too, were prescribing these substances more and more liberally, in an attempt to manage the purported under treatment of pain in the United States (Quinones, 2015). This culminated in a 1995 speech by the president of the American Pain Society, who said that "if pain were assessed with the same zeal as other vital signs are, it would have a much better chance of being treated properly. We need to train doctors and nurses to treat pain as a vital sign" (Campbell, 1995). His dream, of course, was to increase the use of opioids in pain management. It came true.

One of the earliest indications of today's opioid epidemic that was prominent during its emergence was the levels of addiction that were seen in Appalachia, Vermont, and Maine, among

other locations. We began to see this after the 1995 speech on pain treatment up through the turn of the century, and this starting year is no coincidence; it was in 1995 that OxyContin was released on the market (Keefe, 2017). At this moment, OxyContin was "hailed as a medical breakthrough, a long-lasting narcotic that could help patients suffering from moderate to severe pain" that subsequently "became a blockbuster, and has reportedly generated some thirty-five billion dollars in revenue for Purdue," the privately held pharmaceutical company that developed it (Keefe, 2017). Perhaps unsurprisingly, this staggering sum of money was appealing to the Sackler family, the owners of Purdue Pharma. For the previous century, opioids this strong were reserved for only the severest of pain, typically end-of-life pain. However, the company sought to make it acceptable to use OxyContin to treat moderate pain, and they succeeded in doing so (Davies, 2018). Because of OxyContin's novel time-release mechanism, which was purported to allow the pill to work over 12 hours, the FDA allowed Purdue Pharma to claim that their product would reduce abuse and addiction compared to other competing analgesics available for prescription. This was the green light that allowed Purdue to aggressively market its innovative product.

Purdue's marketing campaign aimed to change public opinion and to change physicians' prescribing practices. The company "funded research and paid doctors to make the case that concerns about opioid addiction were overblown" (Keefe, 2017). Sales representatives both branded OxyContin as a product that patients could "start with and to stay with," and targeted their marketing strategies at vulnerable communities (Keefe, 2017; Davies, 2018). Representatives purchased physician prescribing data, a fairly common practice, and entered communities where "competing opioids were already being prescribed in large quantities,"

where they falsely informed doctors that "addiction with this drug… 'happens in less than 1 percent of these cases'" (Davies, 2018). Roughly 5,000 medical professionals, including doctors, nurses, and pharmacists were then so enticed that they enrolled in seminars and became paid spokespeople on behalf of Purdue Pharma and OxyContin (Davies, 2018). At one point before the turn of the century, officials at Purdue found out that many doctors held the misconception that oxycodone, the active ingredient in OxyContin, was less powerful than morphine, which the company was quick to capitalize on (Keefe, 2017). Subsequently, the number of opioids prescribed rose, with OxyContin as the leading brand name, but Purdue Pharma's creation was not the only analgesic available on the market.

There are a variety of brand name opioids that patients can be prescribed. While OxyContin is the most notorious, different pharmaceutical companies have developed and sold opioids like Vicodin, Percocet, and Demerol, just to name a few. With such a variety on offer, it is almost as if patients developed the ability to pick and choose exactly which prescription they would like, and in many instances, that is exactly the case.

Pill mills, which are unsanctioned pain management clinics where physicians inappropriately prescribe and dispense prescription drugs, have been integral to the perpetuation of the opioid epidemic in the United States (Rutkow *et al.*, 2015). These establishments, which allowed for individuals to illicitly obtain prescriptions from unscrupulous physicians seeking financial gain, certainly exposed more individuals to opioids and have been chief targets for state-run prescription drug monitoring efforts to reduce the amount of opioids dispensed. While research on their impact is somewhat limited and has been mixed, signs show that prescription drug monitoring programs have been moderately effective, which is promising (Brandeis

University, 2014; Rutkow *et al.*, 2015). The above history has led us to where we find ourselves today. The opioid epidemic still remains an issue, and improving drug monitoring efforts to reduce prescription drug misuse remains a priority for those involved. And although the face, magnitude, and public opinion of opioid addiction has changed over the course of the last century-and-a-half, abuse of this class of drugs has always been a uniquely American problem.

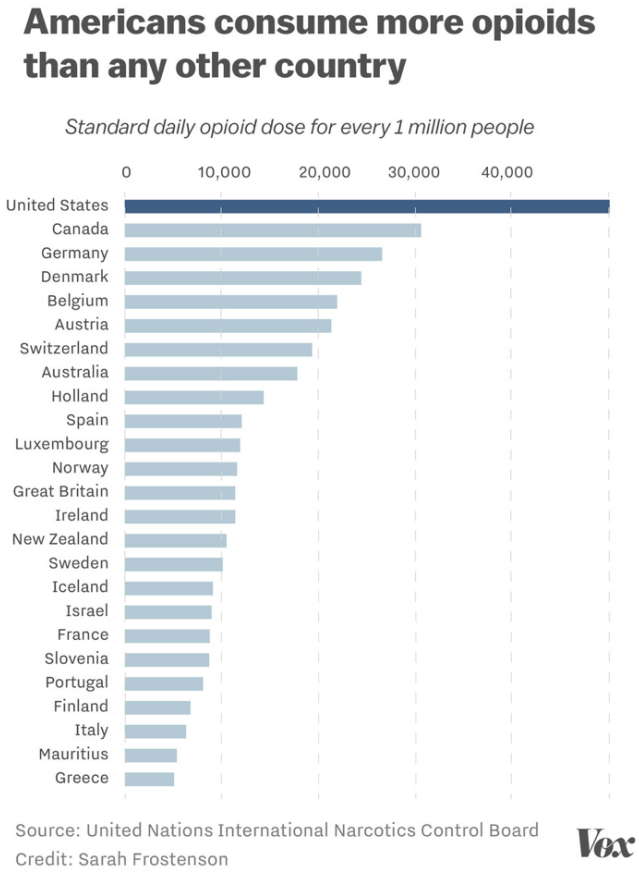

Figure 1: A chart of the standard daily opioid dose per every 1 million people in 25 countries worldwide.

As shown by Figure 1 above, it is clear to see that in the United States, significantly more prescription opioids are consumed per capita than in any other country around the world. Evidently, this is an issue that is centered around the United States.

The United States Department of Health and Human Services declared a public health emergency in the face of recent trends in opioid use within the country. In 2016 and 2017, an estimated 130 people died every day from an opioid-related drug overdose. Nearly 11 and a half million people misused prescription opioids. 2 million of these individuals did so for the very first time in these two years (Bose *et al.*, 2017). Roughly 17,000 deaths were attributed to an overdose on a commonly prescribed opioid, like oxycodone, and synthetic opioids other than methadone were responsible for nearly 20,000 overdose deaths. Overall, an estimated 40% of all opioid overdose deaths were due to a prescription opioid (U.S. Department of Health and Human Services, 2018). The burden of overdose deaths due to non-prescription opioids is high as well, but for the purposes of this thesis, the focus will be on the burden that prescription medications have placed on the opioid epidemic, for multiple reasons.

First, as outlined above, both the original opiate epidemic as well as the crisis our country is faced with today stemmed from medical misconceptions and wrongdoings. Second, because of the record-keeping associated with prescriptions, rather than transactions involving illicit drugs, I will focus on exploring the relationship between blockchain and prescription opioids because this is the domain where blockchain would have the highest anticipated effect. Furthermore, abusing prescription opioids is a risk factor for heroin use; of those who began to abuse opioids in the 2000s, roughly 75% reported that their first use was of a prescription drug (Cicero *et al*., 2014), while nearly 80% of heroin users reported abusing prescription opioids prior to heroin (Jones, 2013; Muhuri *et al*., 2013). Therefore, if prescription opioid abuse can be reduced, it is highly likely that there will be an associated decrease in nonmedical use of non-prescription opioids like heroin due to fewer individuals developing a dependence.

For as long as there have been groups abusing drugs, there has been a debate over the more likely cause of dependency. This disagreement comes down to whether a population's proximity to drug supply is a more likely indicator of drug abuse than a lack of opportunity leading to drug abuse; these two sides are known respectively as the supply-side and the demand-side. Historically, as well as currently, both the supply-side and demand-side factors have contributed to drug abuse, but determining which has a greater influence on the development of prescription opioid misuse will guide the best course of action for addressing the epidemic. Both sides of this chicken-and-egg issue are seemingly contradictory, yet each holds true (Courtwright, 2001b). Along with "most drug producers, distributors, and advertisers," David Courtwright asserts in his book, *Forces of Habit*, that "exposure is the critical precondition" (Courtwright, 2001b). Examples supporting this include,

> That Cubans once smoked 30 percent of all cigars made in Cuba, that Asian communities which grow and sell opium have consistently higher addiction rates than those which do not, that African transshipment points like Ghana or Nigeria have developed serious heroin and cocaine problems, that Kentuckians suffer exceptionally high rates of lung cancer - all of this strongly suggests that proximity, and hence familiarity and availability, matters. (Courtwright, 2001b)

Furthermore, the emphasis on the relative importance of supply-side interventions in lieu of demand-side solutions are supported by a global study involving over thirty different countries. In 1973, Philip Baridon collected official addiction rates for 33 countries and compared them to

twelve independent variables related to social, economic, and geographic factors, among others. Using a multiple-regression analysis to estimate relative causal weights, he found that proximity to drug supply alone explained for 45% of the variance in addiction rates, which is much more than any other variable can account for (Baridon, 1973). He concludes that "the most fundamental fact about drug abuse is frequently overlooked in the welter of complicated psycho-social explanations...if the drug is not available, there will be no abuse of it" (Baridon, 1973).

In support of these findings, it logically follows that it is easier to strategically intervene on the supply side than it would be on the demand side. A supply-side solution could involve initiatives like reducing the overall drug supply or increasing the regulations on prescriptions, whereas a successful demand-side resolution would necessitate solving structural societal issues of economic stability and job availability. At this moment, the latter presents a much tougher task than the former. However, the debate around the main cause of opioid abuse specifically is ongoing.

In light of the most recent resurgence in prescription opioid misuse, the distinction between a supply-side approach to approaching the epidemic and a demand-side approach have perpetuated the disagreement of where efforts should be focused to have the greatest benefit. Proponents of the supply-side approach cite the actions of Purdue Pharma in marketing OxyContin as the driving force behind the troublesome increase in opioid consumption, while those who support the demand-side theory refer to the rise in prescription opioid overdoses as "deaths of despair" that arise from at-risk individuals actively seeking drugs.

Recent data have shown an unmistakable reversal in deaths for middle-aged white Americans aged 45-54 without a college degree (Case and Deaton, 2015). While mortality for most demographic groups has been declining, as is expected with ever-improving medical technologies yearly overall increases in life expectancy, this has not been the case for this demographic group. This is a recent development, with it marking a reversal of decades of improvements in mortality. This reversal was found to be unique to the United States (Case and Deaton, 2015). In certain pockets of the country, this group has been impacted by economic insecurity and widening inequality, with many realizing during the middle of their lives that "they will not be better off than were their parents" (Case and Deaton, 2015). While this has surely contributed to the increase in drug-seeking and drug-using behaviors, it does not paint the entire picture. Increasing economic insecurity has been found commonly in many wealthy nations, none of whom have had the same mortality experience (Case and Deaton, 2015). Although Case and Deaton present a wide array of evidence that points to the supply-side argument for the start of today's opioid epidemic, they do not definitively choose a side. However, a similar recent paper titled "Deaths of Despair or Drug Problems," written by Christopher Ruhm, is prepared to support one approach.

Ruhm's recent research substantiates the primary role that Purdue Pharma played in setting the current opioid epidemic in motion. This paper examines the degree to which rises in county-level drug mortality rates from 1999-2015 result from "deaths of despair" which relate to economic conditions or if it is more likely that an increase in the "drug environment" would change drug-use habits in different population subgroups (Ruhm, 2018). This paper concludes that the risk of drug death over time across population subgroups is consistent with the

availability and cost of drugs, meaning that "the fatal overdose epidemic is likely to primarily reflect drug problems rather than deaths of despair" (Ruhm, 2018). Armed with this information, we can begin to consider locations of prescription drug availability where blockchain could be implemented to cut off the oversupply of opioids like OxyContin and, hopefully, reduce the burden of this crisis.

As mentioned earlier, current initiatives to reduce nonmedical prescription of opioids have come from a variety of governing bodies that have struggled to significantly reduce the burden associated with abusing this class of drugs (Brandeis University, 2014). Laws, regulations, and prescription drug monitoring efforts have not been as effective as policymakers would have expected because of unintended consequences and gaps in surveillance. The siloed nature of medical care in the United States can make the spread of information difficult and hinder law enforcement efforts related to current prescription monitoring programs (Zhang *et al*., 2018). Methods to improve the technical aspects of PDMPs have been proposed, and one of the most promising comes from an unlikely source: blockchain technology, a secure data-storage framework that emerged only a decade ago.

Blockchain's Relevance to Healthcare: Potential Applications to Opioids

Blockchain technology can be thought of as a new, more efficient way to store and manage information. At its essence, it is simply a sequence of numbers and letters that are coded into a computer software that allow for the secure recording and exchange of transactions between any two users connected to the same system (Campbell-Verduyn, 2018). Originally, its purpose was to serve as the underlying technology supporting transactions using Bitcoin, which can be best described today as an experiment in a decentralized, stateless, digital currency (Gupta, 2017). Bitcoin, and by association blockchain technology, emerged in 2008 when an anonymous individual or group of individuals published a whitepaper titled "Bitcoin: A Peer-to-Peer Electronic Cash System" (Nakamoto, 2008).

In this paper, pseudonymous author Satoshi Nakamoto outlines their vision for the future of monetary transactions, stressing the need for a "peer-to-peer version of electronic cash that would allow online payments to be sent directly from one party to another without going through a financial institution" (Nakamoto, 2008). As a non-proprietary, open-source software, the original Bitcoin blockchain has been replicated in developing similar blockchains for other online currencies as well as blockchains that manage and exchange a much wider collection of information (Campbell-Verduyn, 2018). In the decade since Bitcoin and blockchain were introduced, its relevance to uses other than financial transactions have been realized.

Before expanding on some of the technical aspects of blockchain, its various possible applications for good, and where it is applicable in healthcare, it would be useful to dispel the misconception that due to its origin, blockchain technology is simply a synonym for Bitcoin, and that through its association with Bitcoin it has contributed to an increase in illicit drug

distribution and use. Although blockchain's original purpose, where it was used to facilitate Bitcoin transactions, has likely contributed to black market transactions and to the flow of illicit opioids into the United States from abroad, its effect on increasing the population of drug users in the United States remains unclear (Aldridge, Stevens, and Barratt, 2017). While cryptocurrencies like Bitcoin have made it easier to access illicit substances through an online marketplace, a certain amount of technological competency and patience is required to acquire illegal drugs online, as these markets cannot be accessed by traditional Internet browsers and any shipment to a buyer will take multiple days. Perhaps because of this, the online drug market is not dominated by drugs like OxyContin whose users are highly dependent, but is rather oversaturated with substances like cannabis and ecstasy, whose users will not experience the withdrawals that individuals suffering from opioid use disorder do (Aldridge, Stevens, and Barratt, 2017). Bitcoin and illicit drug trades are a byproduct of blockchain's ability to manage and verify information, and optimistically, blockchain's innate capacity of authenticating transactions of goods and information can be applied for good in new contexts.

In its first context, a blockchain served as a distributed public ledger. In layman's terms, this is essentially an online accounting book whose transaction records are not held in a centralized database and are instead able to be accessed and verified by any member of the system (Casey and Vigna, 2018). Within Bitcoin, this manifested itself in verifying monetary transactions; a blockchain is time-stamped and unchangeable, so in often-anonymous transactions like those involving digital currencies, a record of the transaction exists and cannot be changed by either party involved without an addition to the record. In the case of financial transactions, the movement of money from the sending party to the receiving party is represented

in an online network as a "block" which is then broadcast to and approved by every other member of the network. At this point, the "block" is time-stamped and added to a sequence of all previous "blocks," forming a chain of "blocks," or a blockchain (Campbell-Verduyn, 2018). Vitally, the addition of a new data block onto the chain is unalterable; once new information is added, the change to the blockchain is permanent. This ensures that all possible information about each coin is encrypted in the value of the coin itself; blockchain ensures that owners can trace a coin's entire transaction history, down to the specifics of how long each previous owner held a coin for (Nakamoto, 2008). Despite its financial origins, the advantage of blockchain and the foundation for new ways it can be used stem from this irreversible digital time-stamped record.

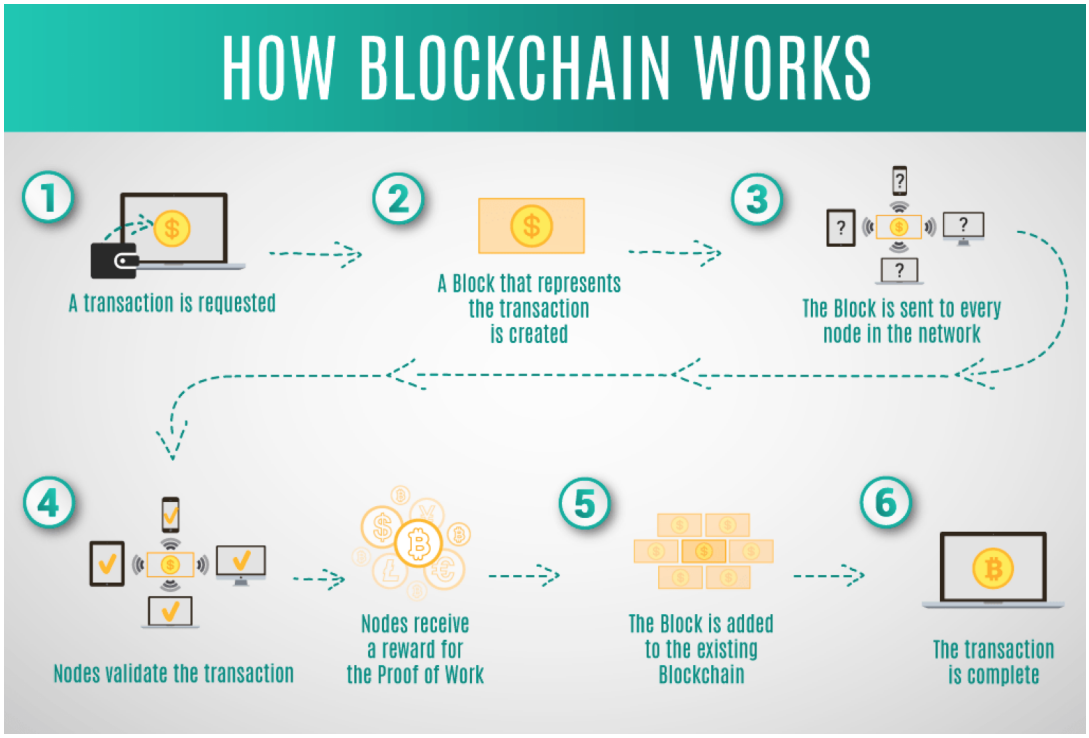

Figure 2: A detailed diagram of how a blockchain is formed. In the case of blockchain in healthcare, a transaction is not a financial transaction, but rather is a prescription of opioids from physician to patient. The nodes in the network include every other party that has access to prescription drug information, and the reward that the nodes receive as proof of work is the prescription transaction. Once this transaction is added as a block onto the existing blockchain, every other member of the network will have their blockchain updated at the same time. Because it is a generalized figure for blockchain, it fails to address privacy concerns of health information, which will be assessed more in chapter 3 with off-chain data storage sites.

Blockchain, like many other technologies, is evolving to fit needs beyond its original purpose of legitimizing transactions of stateless currencies. It no longer serves solely as the support system for online transactions. Rather, its possible applications for good have been picked up by corporations in finance, energy, deed protection, supply chains, and healthcare, among others. Companies including IBM, Microsoft, and Accenture have formed teams to develop blockchain-based technology to be integrated into their daily routines (Angraal, Krumholz, and Schulz, 2017). Other organizations have foreseen its relevance in validating artwork, verifying voting records, and helping disadvantaged populations prove ownership (Tapscott and Tapscott, 2016; Casey and Vigna, 2018). These issues all have to do with information access and validation, and are the types of problems that blockchain technology has the potential to solve. Researchers and practitioners in healthcare currently face struggles in their work due to difficulties with information verification and management stemming from inefficiencies in communication, siloed data storage, and more (Zhang *et al.*, 2018). When separated from its original cryptocurrency context, blockchain technology has the possibility to address these issues and improve the overall state of healthcare information and management.

To maximize efficiency and productivity in a healthcare system, interoperability between software systems is necessary. Across all levels within and between health organizations, this would facilitate effective communication and data exchange, two characteristics that are largely currently missing from the United States' healthcare system (Zhang *et al.*, 2018). A vital production inefficiency in healthcare systems today comes from the lack of secure links to connect independent systems together in an accessible network, while still ensuring the privacy of individuals in the system (Zhang *et al.*, 2017). While interoperability between healthcare

technologies currently exists, in its current form it is limited and often requires data transformation. Additionally, these systems are difficult to maintain because fundamental changes on one system will necessitate all other systems in the network to adapt as well (Zhang *et al*., 2018).

Blockchain has the capability to address these issues, beginning with the decentralization of data storage. Despite the significance of medical data sharing in promoting the delivery of adequate care to patients, healthcare systems often require patients to find and share their own medical records with other providers. This currently delays the dissemination of important medical information because data must be gathered, delivered, and picked up by patients. It is also unsafe, as at any point during the transmission of physical data copies, information can be lost moving from one place to another. Most importantly in the context of preventing opioid abuse, this information is often incomplete. Patients' health histories may be segmented due to the storage of data in disparate, siloed systems. In the United States, there is no universal source that stores the complete health records of an individual, which poses problems for both patients and service providers in keeping track of an individual's prior medical data (Zhang *et al.*, 2018). Some examples of blockchain implementation in healthcare are in patient identity verification, automated claim validation, supply chain management, medication manufacturing, medication distribution, and authenticating prescriptions (Angraal *et al.*, 2017). Blockchain presents an improved solution to these issues because of its ability to instantaneously authenticate and give proof to every member related to a transaction. In addition, because every new block is securely linked to the block preceding it, malicious changes to the blockchain cannot be made. Blockchain's goal as a digital ledger is to remove costly intermediaries, in terms of both time and

money, from the equation. Healthcare, which is filled with unnecessary transactionary and intermediary costs, would surely benefit from the integration of blockchain.

Some of these potential blockchain use cases have already seen demonstrated interest, particularly regarding compliance with the Drug Supply Chain Security Act (Zhang *et al.*, 2018). The federal government's attempt to increase safety in our current prescription medication system is a good start to promote the safety of drugs like legitimate opioids, but there is a lack of adequate technology to effectively shore up every hole in the prescription supply chain or to improve our current prescription tracking system (Zhang *et al.*, 2018). In the fight to reduce opioid abuse, the decentralized technological nature of blockchain has the potential to address opioid use through a prescription monitoring approach during the manufacturing and distribution process, which would make the prescriptions themselves safer by preventing counterfeit drugs from entering, incentivize physicians to write fewer opioid prescriptions, and provide both patients and healthcare providers with a more complete opioid prescription history (Zhang *et al*., 2018). Through these methods, blockchain has the potential to increase safety and reduce opioid abuse from both the supply side perspective of physicians and pharmaceutical companies as well as the demand side perspective by decreasing the ease by which individuals can "doctor-shop" to obtain an opioid prescription.

Again, the rising number of opioid users, opioid-related admissions to emergency departments, and overdose deaths is known to be an urgent public health issue, stemming in part from the inadequate patient information systems currently used by physicians. Although previous research has been unable to determine with confidence the prevalence of patients who search for these drugs for nonmedical purposes through "doctor shopping," prescription patterns

for patients with legitimate medical need is troublesome. Some patients were determined to have a sanctioned need for opioids and to still visit a large number of physicians for prescriptions, indicating that patient care is currently dangerously uncoordinated (McDonald and Carlson, 2013). If an individual were to seek out opioids for nonmedical use, this would demonstrate that given prescription trends, it would not be difficult to benefit from uncoordinated care to obtain multiple prescriptions from numerous physicians (McDonald and Carlson, 2013). Doctor shopping and uncoordinated care come from the information gap between patients' medical histories and what is available to attending physicians. This is where the implementation of blockchain technology into prescription monitoring has the potential to do good and reduce the number of opioids prescribed and, by extension, the number of opioids that are misused (Englehardt, 2017). By adopting a system where all relevant information is accessible to members of the patient care team, particularly physicians, it is less likely that patients will be able to visit multiple physicians in an uncoordinated manner to obtain opioid prescriptions.

In an attempt to control prescription practices, many states have established prescription drug monitoring programs that collect data on the quantity of scheduled drugs dispensed, the physicians prescribing these drugs, and the patients obtaining the drugs. Despite these attempts, many physicians do not access this information (Englehardt, 2017). Additionally, because these PDMPs have been implemented at the state level, a high amount of variation exists between state policies regarding vital program components such as data reporting, when transactions will be flagged for concern, and the scope of responsibilities held by physicians and law enforcement agencies in monitoring prescriptions (Finley *et al.*, 2017). Part of the problem with PDMPs is that they routinely require scheduled reporting from pharmacies about prescription-related data

for all medications of concern. These data often include information on medication data throughout the previous year, the dates when medications were dispensed, and information on the patient, physician, pharmacy, drug, and dose in each transaction (Islam and McRae, 2014). Of course, this information is vital in the struggle against opioid overprescription and misuse, and perhaps unsurprisingly, PDMPs have been shown to have an impact on provider prescription habits, patients' abilities to access and abuse narcotics, and overall health outcomes (Brandeis University, 2014). However, the implementation of blockchain technology into the overall prescription monitoring process would provide immense benefits to PDMPs' effectiveness.

Blockchain's usefulness in PDMPs would stem from its ability to automatically collect data during the prescription process, nullifying the need for individual pharmacies to retroactively input data. It would also assign patients a unique identifying code, which would reduce the possibility that the same individual would go undetected in the event that they seek out multiple prescriptions, either within or across state lines. Currently, there are pilot programs that are testing the efficiency and effectiveness of blockchain use cases in healthcare. One such program, designed in 2016, is called MedRec.

Developed out of MIT, MedRec's creators propose that it will serve as a decentralized universal health record management system that would handle electronic health records (EHRs) (Ekblaw *et al.*, 2016). Through blockchain protocols, the MedRec system is hypothesized to manage authentication, confidentiality, patient and provider accountability, and data-sharing, all of which are crucial aspects of the struggle to decrease opioid abuse. An intrinsic component of this system's potential success is its ability to integrate with healthcare providers' already-existing local data storage systems, increasing its potential interoperability as well as the

ease with which it can be integrated into the prescription tracking and monitoring system (Ekblaw *et al.*, 2016). In fact, this technology has already been piloted, with promising results.

John Halamka, who was responsible for health care data standards under the Bush and Obama administrations, has worked with the MedRec team to test their program at Beth Israel Deaconess Medical Center in Boston, Massachusetts. They tracked six months' worth of inpatient and outpatient medication data, looking at information such as vaccination history, blood work records, and prescriptions, simulating the exchange of these data between institutions by instead using two different databases within the Beth Israel system. The impact of blockchain-based technology on the state of information across data systems was so positive in this instance that the MedRec team is outlining its plan for more pilots throughout larger hospital networks (Molteni, 2017). If systems like this prove to be sustainable and implementable in the long run, it will likely entice providers to join the network to better access data that will increase their quality of care. It will likely also ensure that patients receive care that is better-suited to their medical condition and will be guided away from opioid use and will be guided toward more appropriate care (Zhang *et al.*, 2018). By addressing opioid access through both the physicians prescribing the medication as well as the patients attempting to access them, blockchain technology has demonstrated the potential to reduce the impacts of opioid overprescription by the suppliers as well as misuse in those demanding prescriptions. Not only does blockchain have the potential to address access to and abuse of opioid prescriptions, but it also has the fundamental technological basis to monitor the prescription supply chain, increasing pill regulation, making the opioids that people take safer than before.

The United States federal government realized that there was a problem with the prescription drug supply chain after 76 people died in the 2012 New England Compounding Center (NECC) meningitis outbreak, which took place when patients were given a contaminated steroid injection (Turner and Culp, 2013). Additionally, it was alleged that from 2006-2012, NECC knowingly shipped out pharmaceuticals that were either mislabeled, unsanitary, contaminated, or any combination thereof (Bidgood and Tavernise, 2014). Inconsistent tracking of transactional data at each step of the prescription medication supply chain, from the substances used to create the pill itself, to the manufacturing location, to every change of hands in the process of distribution to pharmacies does not have a universal tracking system. This inconsistency in prescription supply information is dangerous, and the auditing of pharmaceutical supply chains is something that blockchain has the true potential to impact (Engelhardt, 2017). Despite all of its promise, blockchain is not necessarily a panacea to the problems plaguing the opioid supply chain and prescription system. It is important to realize the limitations that blockchain technology has, as well as the potential difficulties that would inhibit its successful implementation into our healthcare system.

Ultimately, it is difficult to imagine that while there are different healthcare providers and differences in health insurance both within and across state lines in the United States that there will be one unifying blockchain. Instead, it is more realistic that there will be multiple blockchains and that ensuring interoperability between these blockchains will represent the best chance for the successful integration of this type of technology (Engelhardt, 2017). Additionally, a blockchain's quality is dependent solely on the training of those using it. If the information that is put on the chain is incorrect or low-quality, it will nevertheless be a permanent addition to

the unchangeable chain of information (Engelhardt, 2017). To ensure the maximum effectiveness of a blockchain in healthcare, care is needed to ensure that the entire implementation process includes connections between different blockchains as well as an all-inclusive education initiative so that everyone within a network will only include high-quality information. However, if the safety of information can be confirmed, the potential for blockchain to address issues such as those plaguing the safety of opioids within the supply chain or those afflicting opioid access and prescription practices, then blockchain has the potential to reduce the public health crisis of opioid overprescription and misuse.

How Feasible is Blockchain Integration into Prescription Monitoring Efforts?

While in theory, the integration of blockchain with the current prescription opioid monitoring network might seem to be straightforward, it would likely require a large-scale overhaul of current technical systems as well as the generation of support by a wide array of stakeholders. There are varying degrees to which new innovations can diffuse, and the extent to which a new technology is adopted largely depends on how easy it is to overcome obstacles related to the current accepted paradigm of technical systems. The characteristics of innovations, of which blockchain is undoubtedly one, primarily determine the how they are perceived by members of the system (Rogers, 2003). This, in turn, impacts the rate at which these members adopt and implement them, leading to their diffusion across a variety of sectors and use cases.

Perhaps unsurprisingly, the innovation-diffusion process and an innovation's rate of adoption are both dependent on time, and given that blockchain only came to be in 2008, we are still in the early stages for the technology itself, let alone its implementation across a variety of sectors. According to Everett Rogers in his seminal work, *Diffusion of Innovations*, the innovation decision process through which "a [decision-making unit] passes from first knowledge of an innovation…to a decision to adopt or reject, to implementation of the new idea" can be conceptualized by the following five steps: knowledge, persuasion, decision, implementation, and confirmation (Rogers, 2003). In the case of blockchain's diffusion into the prescription opioid monitoring space, there is an additional barrier: concerns over interoperability and integration into existing technical systems because, rather than the diffusion of an innovation like the radio or television, blockchain implementation is representative of a

change to the current infrastructure. And while there are some networks that are relatively quick to introduce and integrate new technologies, the healthcare sector is not one of them.

Of 27 sectors analyzed for a combination of their digital assets, usage, and labor dedicated to new technologies, healthcare ranked 24th, just ahead of hospitality, construction, and agriculture, but far behind the dynamic, rapidly-developing sectors of communications technology, media, finance, and insurance. In the instance of healthcare, many organizations "use incredibly sophisticated technology in diagnostics and treatment but substantial parts of their workforce use only rudimentary or no technology" (Gandhi *et al.*, 2016). It may not be surprising, then, that "fewer than 20% of payments to healthcare providers and their suppliers are done digitally" (Gandhi *et al.*, 2016). While there currently are drawbacks to the healthcare sector's general reluctance to adopt new technologies, there are very legitimate reasons to air on the side of caution when it comes to altering their systems, namely concerns over patient health that stem from potential issues of interoperability between new technologies and existing systems.

Historically, the field of healthcare has been agonizingly slow to adopt and implement new technological systems when compared to other, fast-moving spaces. This phenomenon is curious, especially when we consider that:

> Healthcare is constantly evolving. Wave after wave of new technologies, insurance models, information systems, regulatory changes, and institutional arrangements buffet the system and the people in it. But people and institutions, for the most part, do not like change. It is painful, difficult, and uncertain. Entire

> organizations in health care are devoted either to promoting innovations – selling the latest drug, imaging system, medical device, software package, or Internet site – or to preventing innovations from disrupting the status quo by counter-detailing, keeping drug reps away from doctors, requiring certificates of need, or disallowing reimbursement. Trying to change the pace at which new ideas about health care spread through the system is a priority of health care professionals; such changes easily have major impacts on cost, quality, and patient satisfaction. (Cain and Mittman, 2002)

From a public health standpoint, "technology drives healthcare more than any other force, and in the future it will continue to develop in dramatic ways…we need to actively work to ensure the best outcomes for society as a whole" (Thimbleby, 2013). While this statement rings true, it is infused with a touch of irony, especially when juxtaposed with one of the main factors why the healthcare sector is slow to adopt new technologies, especially health information technologies, which blockchain would fall under. People are more afraid of changing technical systems in healthcare systems rather than, say, financial systems, because the worst that could happen when altering monetary information systems is that people might not be able to transfer their wealth around; the worst that could happen in healthcare is the loss of patient health information and for patients to fall ill and die. In the words of the CEO of a medical software communications company, "healthcare is conservative, but it is conservative for a reason: lives literally depend on it. Every new piece of technology needs to be bulletproof" (Kandel, 2016). To ensure that the integration of blockchain in the prescription opioid monitoring space is

"bulletproof," it must be interoperable with the existing technology used across each state's PDMP system. Barriers to blockchain's potential future use in prescription opioid monitoring must be addressed and overcome before any steps toward its implementation are put into action.

There is currently an adapted form of blockchain that has been piloted by the United States Department of Health and Human Services that could potentially offer insight into how to integrate blockchain into a pre-existing technical system while ensuring that no functionality is lost during the implementation process. In December 2018, HHS was given the authority to operate the first blockchain-based tool in the federal government. This tool, called HHS Accelerate, integrates blockchain to "streamline the process the department uses to procure products and services from private vendors…aiming to speed up the procurement process and reduce its costs" (Livingston, 2019). In this situation, blockchain is added on as an infrastructure layer across older systems and removes intermediates from data sharing, allowing information to be shared from peer to peer in real-time, much like what would take place if blockchain were to be integrated into prescription drug monitoring systems (United States Department of Health and Human Services, 2018). This form of blockchain does not represent its original form. Rather, it has been adapted to fit pre-existing technical systems to ensure interoperability with the foundation that already exists. To successfully implement blockchain as the infrastructure to monitor prescription opioids, it will also have to take on an adapted form with variations from the first blockchain that appeared in 2008.

In blockchain's original form as well as some of its newer forms, it is considered to be a "disruptive" technology (Nofer *et al.*, 2017). Essentially, this means that it traditionally does not go after pre-existing business models and is not buoyed by lower-cost, higher-efficiency methods

that would entice new institutions to adopt it. Instead, in its original form, it is a technology on which new foundations can be built, with the capacity to construct new economic and social institutions, among others. While disruption may be useful in some sectors, throwing prescription opioid monitoring networks into disarray would likely lead to some disastrous results. Therefore, whatever form blockchain would take on to sufficiently monitor opioid prescriptions would have to be adapted so that it could be integrated into current drug monitoring efforts. This is one of the most important barriers to blockchain's implementation in this sense, but it is only one of many barriers to its general adoption.

Some of the obstacles to blockchain implementation include education, ethics, standards and certification, scalability, policy, regulation, legislation, trust between networks, cybersecurity, identity, compliance, capital formation, heuristics, external data, governance, financial forecasting, interoperability, and permission to access (Manion, 2019). Realistically speaking, there is no way that each of these challenges can be realistically resolved by a single entity; there is no one corporation, institution, or government that can make strides to address these issues without aid. However, there are organizations that are working to combine these categories into groups of activity areas to attack. Blockchain in Healthcare Global is one such group that has begun to work to resolve these issues. Their efforts are focused on developing policy and legislation stances, organizing industry self-regulation, delivering healthcare-focused professional education, and setting standards for blockchain's use in the healthcare space (Manion, 2019).

While this is a good place to start, this group's work currently focuses on industries that are entirely within the private sector. While relevant to using blockchain to monitor prescription

opioids, its work will not completely fix the issues that exist within prescription drug monitoring due to one systematic body: the government. The role of state and federal governments cannot be understated, and no matter how blockchain is implemented in opioid monitoring, its relationship to whatever entity governs it is of utmost importance to resolve.

The Health Insurance Portability and Accountability Act of 1996, better known as HIPAA, is a cornerstone piece of United States legislation that supplies data privacy and safety measures to protect patients' medical information. As a barrier to blockchain implementation, HIPAA would fall under the categories of policy, regulation, and legislation because, according to Brandi Reddick, a blockchain advisor who counsels on the processing of health insurance within pharmacies, "barriers don't exist in siloes, they're connected" (Reddick, 2019). Because HIPAA's regulations procedurally limit access to health information, only certain cleared individuals or entities can view a patient's health details.

As patients, everyone is granted the right to obtain a copy of their own health records, make corrections to it, receive notices on how your health information is used or shared, and more. Additionally, HIPAA has put safeguards into place that ensure that healthcare providers neither use nor disclose your information improperly. It also emphasizes the concept of "minimum information necessary." "Think of it as getting into a bar," according to Reddick. "The bouncer only needs to know that you're above 21; you shouldn't have to disclose your age. That's what it should be like as a pharmacist. A pharmacist should only see the minimum amount of information necessary to do their job" (Reddick, 2019). In the case of the Bitcoin blockchain, which is accessible by any member of the network, tweaks would have to be made to

translate over to the healthcare space to address concerns relevant to stakeholders within that network.

If no alterations were made, "every member in the distributed network of the healthcare blockchain would have a copy of every health record for every individual in the U.S.," which would pose issues of patient privacy, data safety, data storage, and data transfer (Linn & Koo, 2014). For there to be tangible benefits within healthcare from blockchain's adoption, it would likely need to serve as an gatekeeper for both access to and control over health records and data (Linn & Koo, 2014). How health information can be accessed, and by whom, is a question central to the decision of which form blockchain could take in prescription opioid monitoring. This issue of governance is a barrier, as is the issue of private-permission access to the blockchain. How do you keep private information off of the chain so that it can be accessed by relevant parties in the prescription drug monitoring network but so that it is inaccessible by outside members? And how can this be implemented while ensuring interoperability with existing technical systems to continue to monitor opioid prescriptions without a temporary loss of function?

Within the larger healthcare sector, one of the biggest barriers to implementation regarding interoperability with pre-existing, legacy technical systems is the speed with which the updated system can operate. Zachary Fitzner is the CEO of Fitzner Blockchain Consulting, a leading management consulting firm that provides advisory services to companies that are exploring the possibility of incorporating blockchain into their systems. To Fitzner, integration into existing technologies has a drawback, but one that may not be as relevant to prescription drug monitoring efforts as it would be to data transfers in a hospital system, for example. He

asserts that “legacy system integrations limit the capabilities of blockchain-based solutions...your new system is just as slow” (Fitzner, 2019). That’s not to say that there wouldn’t be benefits from this. Integration into legacy systems would still provide the advantage of a “distributed common ledger of this information and an immutable data set,” something that prescription drug monitoring programs would surely improve from, regardless of speed increases in data transfers. All that matters is that legacy system integrations would confer the expected service of standardizing the storage and location of prescription drug records.

Much of the general hype over blockchain stems, again, from its capacity to reduce intermediaries in transactions and to increase the speed with which transactions can be approved, verified, and recorded in whatever form the distributed ledger takes. While Fitzner does not foresee blockchain systems entering the healthcare space as readily as it has entered the financial sphere, largely because “to uncover the benefits in healthcare, one needs to have a trained eye to recognize the applications of this technology...and to have an intricate knowledge of how the multiple parties within the healthcare sector coordinate,” especially when compared to financial technologies, where the benefits of blockchain include quicker, cheaper transactions across the clock without intermediaries (Fitzner, 2019). However, just because the time for blockchain in healthcare might not be now, that doesn’t mean that we won’t see it in our lifetimes, or even in the near future. The consensus among blockchain consultants and those in the healthcare technology sphere is that although blockchain won’t be widespread in health systems as quickly as it has spread within financial institutions, it should come within the decade (Fitzner, 2019). This, of course, begs the question: is a decade too long to wait? And once we do see blockchain widely introduced into healthcare, what would be its best form?

There are countless options for the form that a blockchain for prescription opioid monitoring networks could take. The three most promising blockchains with potential to change the way the healthcare network operates are Corda, Hyperledger, and Ethereum, each of which have unique properties that would be advantageous to a number of potential drug monitoring systems. Developed in 2016, Corda would be readily able to enter health information systems because it only shares transaction data with participants that absolutely must see it, compared to a general blockchain where every participant can see and verify every transaction. In addition, it was designed to integrate easily with pre-existing infrastructure, giving it a high potential for success if combined with current PDMP technologies ("The Corda Platform," 2018). Because of its innate qualities, it would work well within the network of patients, physicians, providers, and pharmacies, but it might not be as compatible with any government oversight (Fitzner, 2019).

Hyperledger is a recently-developed blockchain that possesses the technical specifications to be used in government-run prescription drug monitoring programs. The hyperledger project is still in its developing stages in the Linux Foundation, but would offer permissioned parties, like prescription monitoring bodies, to access the platform with unique identifiers (Fitzner, 2019). Because it is under development and can be moulded to fit a variety of needs, it is likely that a custom solution for control over transactions and to synchronize all nodes on the blockchain would be developed.

The MedRec blockchain, which is discussed in the previous chapter, is run on an Ethereum base (Molteni, 2017). Ethereum is one of the most widely-used blockchains and currently offers one of the best systems the best decentralized mechanism for storing personal prescription data, with smaller, private networks a possibility for "pseudo-anonymous

interactions between all of one patient's health providers" (Fitzner, 2019). MedRec's promising results in Beth Israel Deaconess Medical Center are indicative of future successful applications to larger-scale prescription drug data storage (Molteni, 2017).

Because of the various beneficial qualities of these three types of blockchains, not to mention lessons that can be learned from any of the other hundreds currently growing, I believe that it is plausible that an as-of-yet undeveloped blockchain will be created to address prescription monitoring. It is likely that this blockchain will primarily blend the advantageous characteristics of the three mentioned above, considering that it will need to be tailored to the unique requirements and challenges of entering the healthcare sphere and the vital prescription monitoring network.

My goal when I began to write this thesis was to evaluate the potential of whether blockchain could be feasibly implemented and used to monitor opioid prescription practices as was hypothesized in Zhang *et al*.'s paper "Blockchain Technology Use Cases in Healthcare" (2018). Given the obstacles that lie in the way of its implementation, it begs the question: do we even need a blockchain to accomplish this? Is there no existing technological system that can reduce nonmedical opioid prescriptions?

My answer is the following: blockchain currently presents the best possible system for multiple parties to share immutable, accessible records of transactions involving opioids. If we are to reverse the trend where increasing amounts of analgesics are prescribed when they are not medically necessary, I believe that it is worth the time, energy, and resources to build upon smaller-scale blockchains in healthcare and drug monitoring to implement blockchain on a larger scale. Large-scale institutional technologies do not exist on their own, however. They shape and

are shaped by their social, economic, and political contexts, among others. It is possible that in choosing to use blockchain, we may also irreversibly shape the relationship between the prescription drug sector, physicians, and patients for the future. In the following chapter, I attempt to address this concern by applying a variety of theories of science and technology to blockchain in prescription opioid monitoring.

Unpacking Decentralization

The current state of prescription opioid abuse is incredibly complex, and its relationship to technology is simply a portion of its story, but it is one worth examining when considering the implications that the introduction of blockchain may have on the state of patient and provider health information. While the opioid epidemic we see today did not originate because of inadequate drug monitoring programs, it may certainly be perpetuated by inadequacies in state-run PDMPs. The establishment of a newer, blockchain-based monitoring system is one that is promising for its technical capacity to effectively account for every opioid-related transaction. But because this emerging technology has only been in existence for the last decade and is only now emerging from relative obscurity, its social, political, and economic implications have not been extensively considered, particularly as it relates to the healthcare industry.

Whether a technology is intrinsically political often depends on the context in which it is created as well as the settings in which it is used. According to STS theorist Langdon Winner, "the theory of technological politics suggests that we pay attention to the characteristics of technical objects and the meaning of those characteristics…this approach identifies certain technologies as political phenomena in their own right" (Winner, 22). When considering blockchain itself as potential political artifact, there are two schools of thought. The first is when the design, invention, or arrangement of a new technology "becomes a way of settling an issue in the affairs of a particular community," while the second is considering "inherently political technologies," which are "man-made systems that appear to require or to be strongly compatible with particular kinds of political relationships" (Winner, 22). Do blockchain's properties mimic societal needs? If so, which needs are filled?

Examining blockchain implementation in opioid monitoring through Winner's two methods is a necessary exercise to determine its political characteristics. When considering blockchain through the first lens of technical arrangements and social order, decision-makers must remain aware of the restraints that are currently inherent in healthcare networks, chiefly among them being the siloed nature of patient information. If we do not include attention to the way this technology is designed and arranged, "we will be blinded to much that is intellectually and practically crucial…many of the most important examples of technology that have political consequences are those that transcend the simple categories 'intended' and 'unintended' altogether" (Winner, 25). Additionally, once the hypothetical decision to use blockchain in this new role is made, there is a second set of choices that determine the politics intertwined in the very way it is used.

Equally critical as the first set of choices, the second phase is concerned with the "specific features in the design or arrangement of a technical system after the decision to go ahead with it has already been made" (Winner, 28). For the integration of blockchain into prescription opioid monitoring efforts, these decisions would relate to the locations of blocks on the chain, which actors within the network can access certain classifications of patient health data, and whether the blockchain itself will follow a centralized, semi-centralized, or completely decentralized arrangement. Even after organizations concerned with prescription drug monitoring decide to institute this system, the issues of programs, components, and modes of access will determine the direction blockchain goes within this space.

The second belief system that is used to consider the political order of a technology is that some technical systems, by their very nature, are political in an intentional way. Followers

of this set of beliefs advocate that "the adoption of a given technical system unavoidably brings with it conditions for human relationships that have a distinctive political cast – for example, centralized or decentralized, egalitarian or inegalitarian, repressive or liberating" (Winner, 29). The characteristics of certain technologies, especially those such as blockchain which are meant to radically alter established arrangements, are inextricably linked to the distribution of power and can therefore not be distanced from the political order that their introduction means to develop.

Blockchain itself was created as a technology meant to wrestle financial power away from its centralized locations within banking and investment institutions (Nakamoto, 2008). Because of this initial motivation, blockchain is an inherently political technology, and questions of the distribution of authority in its administration and management are vital to consider. To confidently determine its political role, an understanding of its surrounding conditions, which can be made analogous to more common scenarios and then applied back to the technology itself. For example, within his essay "On Authority," Friedrich Engels remarks on the distribution of authority of technical systems and their impact on social hierarchies. "Everywhere," he writes, "combined action, like the complication of processes dependent on each other, displaces independent action by individuals. But whoever mentions combined action speaks of organization; now, is it possible to have organization without authority?" (Engels, 731). By integrating blockchain technology into pre-established prescription drug monitoring efforts, we would expect there to be a more developed organizational system to govern the system's new functions.

The role of authoritarian systems and a centralized administrative hierarchy is a fascinating topic, particularly as it is seemingly at odds with the original intended purpose behind blockchain over a decade ago. If it is indeed true that newer, developed technologies require more developed, centralized rule, we would expect that "as society adopted increasingly complicated technical systems as its material basis, the prospects for authoritarian ways of life would be greatly enhanced" (Winner, 31). This opinion is one that supports the hypothesis that the adoption of blockchain in prescription drug monitoring must also require the development and upkeep of a set of social conditions that serve as the functional environment for monitoring efforts.

A second view of the potential relationship between blockchain's use in opioid monitoring is that blockchain might be strongly compatible with certain social and political relationships but that it does not necessarily require arrangements of a certain type. For example, "advocates of solar energy have argued that technologies of that variety are more compatible with a democratic, egalitarian society than energy systems based on coal, oil, and nuclear power" (Winner, 32). In the case of blockchain's role in monitoring opioids, the technology would be analogous to the example of solar energy that Winner provides. "Solar energy is decentralizing in both a technical and political sense: technically speaking, it is vastly more reasonable to build solar systems in a disaggregated, widely distributed manner than in large-scale centralized plants" (Winner, 33).

From a political standpoint, a distributed technical system like solar energy or blockchain prescription monitoring networks allows individuals and small communities to "manage their affairs effectively because they are dealing with systems that are more accessible,

comprehensible, and controllable than huge centralized sources" (Winner, 33). The contrast between supposedly egalitarian systems like blockchain and inegalitarian, centralized systems becomes increasingly marked when supporters of a technology incorporate these terms into their descriptions of it. Within discourse around blockchain, the term decentralization has taken on relevance, but within the context of implementing it in prescription drug monitoring systems, it remains to be seen what form it would take on and whether it would truly be decentralized or whether it would take on a semi-centralized or centralized form, or some hybrid form in between these three.

In line with blockchain's inherent political nature, its creator and its supporters frequently praise it when referring to its potential to lead to a decentralized administration and egalitarian distribution of power in whichever field it is implemented. This term, decentralization, did not emerge alongside the rise of blockchain. As mentioned earlier, it is a term that has influenced the work of Langdon Winner and it can be applied to technologies across nearly all disciplines. However, it is vital, and is worth examining in-depth, particularly as it relates to prescription drug monitoring and to the context of unifying patient and prescription information in the healthcare sector. Because current available evidence "tends to show that many large, sophisticated technological systems are in fact highly compatible with centralized, hierarchical managerial control," it will be fascinating to explore how blockchain, itself an intricate technology, could be compatible with decentralized, egalitarian control (Winner, 35).

Taken literally, a decentralization means "the undoing of the process of becoming central" (Winner, 86). It is a vague term, and potentially leaves its reader with more questions than answers. Among these questions are the following: What is the center? Can there be more

than one center? What is causing the process of becoming central? What is undoing the process?

In this case of prescription drug monitoring, there is surely not one center; if there were, all relevant medical data would be stored in one place, and there would be no potential for a unifying technology like blockchain to improve the state of information. Currently, the disparate and fragmented state of information implies that there are multiple centers, and that the promise of decentralization that is assumed to come with blockchain refers to the breaking down of healthcare silos that currently act as barriers for information flow, making the spread of information easier between patient, physician, pharmacist, and drug manufacturer. Each of these groups relies on the other, but the current state of information and financial resources mean that some have a more widespread influence than others, and may stand to interpret any attempt at decentralization as harmful to their current interests.

"Disputes about centralization and decentralization frequently hinge on the issue of who has how much social, economic, or political power and whether or not the exercise of such power is legitimate." (Winner, 87). It appears that perhaps in the current set-up, most of the power is held at the tail ends of the pharmaceutical supply chain. That is, the drug manufacturers, combined with patients, have the most control. Currently, despite the improving efforts of PDMPs in detecting suspicious activity, patients still dictate the demand for prescriptions, while many patients can maneuver around drug monitoring efforts. On the opposite end of the spectrum, the drug companies who promote the sale of their products and incentivize physicians to fill scripts yield unbelievable power in the opioid market. A decentralized way to ensure that prescription opioid information is accessible to all relevant

parties, including those mentioned above as well as pharmacies and hospitals, would spread power more evenly, away from these concentrated spheres of influence.

Because of this, the political aim that underlies the original purpose of the blockchain could still be met if power were spread equally among all actors. However, this use would betray the beliefs of the original supporters of decentralizing technologies, who believed that decentralization, and therefore increasing the numbers of centers of decision-making, is achievable because "ordinary people are perfectly capable of making decisions and acting for themselves" (Winner, 88). While this generally holds true, the purpose of blockchain in prescription opioid monitoring would do precisely the opposite for the ordinary person; it would inhibit them from accessing non-medical prescriptions, and therefore protect them from their own destructive tendencies.

Generally, when analyzing a technology's place within an existing social, economic, and political fabric, it can be useful to look at the way in which its structure represents answers to questions about the location, number, and output of centers, but most importantly the power that is contained within each center (Winner, 91). In the opioid monitoring network, it is unquestionable that certain centers exhibit more leverage than others. As discussed earlier, the majority of the power appears to be held at each end of the supply chain; the patients and the drug companies arguably influence the nonmedical use of prescription opioids more than physicians or pharmacies might. Without demand from patients, or the supply from companies like Purdue Pharmaceuticals, there would be no need for pharmacies and physicians to essentially serve as middle men, facilitating drug transactions. While certain providers may be more likely to promote these transactions than others, they would be unable to do so without

connections to patients and incentives trickling down from drug manufacturers. From this, I determine that it is possible for a blockchain in opioid monitoring to reflect a centralization of health information, rather than the decentralization that was intended with the first ever form of blockchain. Although this form of blockchain would represent a centralization, it is still as progressive and liberating as the original, decentralized blockchain.

Conclusion

If successful, blockchain in healthcare, and specifically blockchain used to reduce nonmedical use of prescription opioids, would have many consequences, both intended and unintended. Misusing prescription opioids is a risk factor for heroin use; of those who began to abuse opioids in the 2000s, 3 out of every 4 reported that their first use was of a prescription drug (Cicero *et al*., 2014), while nearly 80% of heroin users reported first abusing prescription opioids (Jones, 2013; Muhuri *et al*., 2013). Therefore, a beneficial consequence of this could be that over time, fewer individuals will develop opioid abuse disorder because they will not have the opportunity to become dependent, and that fewer individuals will transition to using heroin because they may not be over-prescribed in the first place.

By the same token, it could increase the prevalence of heroin use within the greater population of opioid abusers, and could therefore increase overdose rates or rates at which tainted drugs are used for certain populations who would have abused opioids without being introduced to prescription drugs. Despite this, given that the vast majority of individuals with opioid use disorder were first exposed through prescription drugs, it is to be expected that by reducing the amount of opioids that are prescribed, especially to individuals without any prior use history, fewer individuals will be exposed, thereby reducing the number of addicted individuals over time.

The current prescription drug monitoring efforts in the United States, in the form of state-run PDMPs, have shown encouraging signs in reducing the amount of opioids prescribed in multiple states (Brandeis University, 2014). However, there are often problems of interoperability with the technical infrastructure used by physicians, pharmacies, and drug

providers. Moreover, issues of delays of data entry and the entry of incorrect information, as well as the need for physicians to set aside time to manually search these databases can hinder the effectiveness of these programs and prevent them from reaching their full potential. It is in this shortfall of our current monitoring efforts that Zhang *et al.* (2018) saw the capacity for blockchain to be integrated into our prescription drug surveillance schemes, and it was from their hypothesized use case for blockchain that this thesis came to be.

In determining whether the implementation of blockchain into prescription drug monitoring efforts would be relevant, feasible, and beneficial, I first set out to better understand the overarching root causes of today's opioid epidemic. I determined that, although both sides of the supply and demand argument are valid and have contributed to where we are today, the abundance of opioid supply is what is most responsible, as well as the most realistic point to focus initiatives to reduce prescription drug misuse. Reducing the number of individuals who obtain prescriptions that are not absolutely medically necessary would be the best place to start, and using blockchain to augment current prescription monitoring systems is certainly a relevant possible solution.

Blockchain's adaptability to fit a variety of information storage needs as well as its properties of keeping accurate, immutable, accessible data mean that it presents an optimal solution to fix the shortfalls associated with current PDMPs. If it is able to be integrated properly with existing systems, it would greatly improve prescription monitoring programs by upgrading patient verification systems, increasing provider accountability, and augmenting surveillance methods for potentially dubious prescriptions. Although blockchain presents the

best system for improving PDMPs, issues with its feasibility of large-scale implementation remain and must be addressed before moving forward.

As discussed, the healthcare sector is notoriously slow to adopt new technologies, particularly when compared to the financial and banking institutions, for example, with whom blockchain was originally built to compete. There are also many barriers to general blockchain implementation that remain relevant when considering its place in the prescription opioid monitoring network. Chiefly among these issues is that of patient health information and concerns over its accessibility and privacy to members of the drug monitoring network. Because of the sensitive nature of health information storage, and maintaining the integrity of patient privacy, modifications to the archetypal blockchain are necessary for it to be applied to healthcare institutions, particularly those that rely on patient health information to monitor prescription drugs. Currently, there are blockchain systems that present promising options for opioid monitoring that could be vital to the future success of blockchain integration, but timescale to implementation remains an issue. Individuals who are professionally involved with blockchain in a variety of capacities foresee that it will take a substantial amount of time, at least a decade, for blockchain to successfully integrate into the healthcare space in general, and could take even longer to contribute to drug monitoring efforts.

On top of considering its technical specifications and how realistic its implementation would be, it is important to analyze blockchain through relevant STS theory, as holds true for most, if not all technologies. Blockchain's origin as a decentralizing financial technology gives it intrinsic social and political properties, but in the case of using blockchain to standardize prescription drug monitoring programs to make prescription information more accessible to

relevant governing bodies, it would serve as a centralizing technology, but in a dispersed network. In addition, its disruptive nature, in that it is a foundational technology that would eventually necessitate the development of a new technological infrastructure, may pose difficulties for its integration into drug monitoring efforts in the short term, but could reasonably be expected to be resolved in the longer term.

Looking forward, in the short term, it appears likely that solely focusing efforts to reduce nonmedical opioid prescriptions on the integration of blockchain into drug monitoring may not be as effective on its own as we need. Because of its position as a largely foundational technology, combined with the likely length of time until full-scale implementation and adoption by relevant parties in the healthcare, monitoring, and regulatory spaces, there should be distinct additional efforts made. Proposed initiatives with highly-anticipated benefits for reducing the burden of the opioid crisis include pharmacotherapies such as maintenance with methadone, buprenorphine, or naltrexone, which would control cravings and could reduce the likelihood of currently-addicted individuals from continuing to seek out opioids, both prescription and non-prescription (Kolodny *et al.*, 2015). Additionally, because prescription drugs are currently responsible for only a portion of the overall burden due to opioids, more novel approaches to curbing opioid use may be required. If heroin use, for example, were decriminalized in a harm-reduction approach and viewed as a medical problem rather than a criminal problem, we would be able to more easily monitor its spread, and may be surprised by the results.

In 2001, Portugal was in the midst of a terrible heroin epidemic; nearly 1% of the population, across all class and geographic divides, was suffering from heroin use disorder (Bajekal, 2018). Lawmakers decided to decriminalize the possession and use of drugs, as long as

the user had less than a 10 day supply of the substance. They began to focus on treatment and harm reduction practices from which they have benefitted immensely. Since decriminalization, the per capita social cost of drug use in Portugal has decreased by 18% (Goncalves *et al.*, 2015). And most importantly, in the aim of reducing the number of individuals who try opioids for the first time and subsequently develop a dependence, drug use has declined among the 15- to 24-year-old population, which is the group at the highest risk of initiating harmful drug use (Bajekal, 2018). While Portugal and the United States are undoubtedly very different environments, emulating their social approach while also using blockchain technology to improve the technical infrastructure supporting our current prescription drug monitoring efforts could very well be the best way to end the current prescription opioid epidemic, and to ensure that, unlike in the past, we never experience it again.

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