Curbing the Tide: An Innovative Technology Solution to the Opioid Epidemic

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Objectives

- Understand the opioid epidemic in the United States
- Review pros and cons of current solutions
- Introduce PillSafe as the new delivery standard for schedule II prescriptions

Our Addiction Problem

The opioid epidemic has been spinning out of control for more than twenty years. The crisis began in the late 1990s when physicians across the country started prescribing painkillers at an increasingly higher rate. Pharmaceutical companies reassured these well-meaning doctors that the drugs posed little risk of addiction.

While pain relief drugs, such as oxycodone and hydrocodone, helped patients manage their acute or chronic pain, the powerful medications sent many into the depths of dependence. When addiction outpaced patients' prescriptions, many turned to street drugs like heroin or synthetic fentanyl, and the crisis deepened.

As addictions continued to soar, cities and towns began to see the divergence of these dangerous drugs take hold. As a result, opioid use further escalated, leading to a four-fold[1] increase in overdose deaths since 1999. The staggering loss of life has had devastating consequences on many aspects of American life.

The Science Behind Addiction

People who repeatedly use both prescription and illicit painkillers experience chemical changes in their brain's reward center, flooding the brain with the "feel-good hormone," dopamine. When dopamine overwhelms the brain, it prompts people to repeat the behavior that is causing the surge. Unfortunately, the brain doesn't differentiate between healthy activities like exercise and harmful behaviors like heroin use. These changes affect everything from self-control to cravings, making it extremely difficult to quit. Long-term drug use further solidifies these chemical changes, causing irreparable damage that impairs brain functions such as memory, judgment, and learning[2].

The Opioid Epidemic

OxyContin was the brainchild of Purdue Pharma, the company that is now inextricably linked to the opioid epidemic. On the heels of their success with MS Contin, the first time-release morphine pill, Purdue created OxyContin, the brand-name version of oxycodone. Despite their knowledge that the drug was significantly more potent and addictive than morphine, the company aggressively marketed the pain killer to American doctors, overstating its benefits and downplaying its risks. Purdue succeeded in normalizing a therapy mainly reserved for end-of-life cancer patients for people with everyday pain.

By the time physicians understood the highly addictive properties of OxyContin, it was too late for many patients. While doctors have become more discerning with their prescriptions and the government has updated its guideline[3] to suggest caution, the epidemic has continued to grow each year. In 2017, the U.S. Department of Health and Human Services (HHS) deemed opioid use a public health emergency. Despite this declaration and an industry commitment to bring about change, prescription opioid overdoses still took nearly 27,000 American lives in 2018. That year, U.S. medical professionals wrote more than 4.2 billion prescriptions, 424 million for addictive medications.

No city or town is immune to the destruction of opioid addiction. Regardless of geography, race, gender or socioeconomic status, countless American families have felt the ripple effect of misuse and abuse, and it's tearing communities apart. The epidemic does not spare anyone, not even our infants. Opioid use among pregnant women has led to an increase in the birth of addicted babies, who enter this world experiencing devastating withdrawal symptoms.

The current opioid epidemic also comes with a high price tag. According to the Centers for Disease Control and Prevention (CDC), fatal prescription opioid overdoses and opioid use disorder cost our country $1.02 trillion[4] in 2017b alone. Other economic costs include:

- $480.7 billion in lost value of life
- $35 billion in healthcare and opioid use disorder treatment
- $14.8 billion in criminal justice spending

State and local governments are attempting to recoup some of these costs from various companies. Currently, all fifty states are pursuing litigation against manufacturers and distributors. The courts have already awarded more than $57 billion in settlements stemming from the opioid crisis. That sum represents only four settlements, a small fraction of the pending cases. These governments are not only charging pharmaceutical companies like Perdue Pharma, but they are also pointing fingers at such household names as Walmart, Costco and CVS for their failure to monitor and report suspicious activities[5]. In the end, these lawsuits will cost American companies more than $100 billion.

In light of these endless lawsuits, liability protection is top of mind in the healthcare and pharmaceutical industries. Pill manufacturers are paying billions of dollars, negatively affecting its distributors, pharmacies, doctors, and ultimately, patients. As a result of trying to manage the crisis, pill manufacturers decreased the dosage per pill, further complicating pain management for doctors and patients.

From physicians and surgeons to pharmacists and drug manufacturers, the opioid epidemic is one of the most significant challenges of their careers. Managing acute and chronic pain with highly addictive substances is tricky. Every day, healthcare professionals weigh their patients' needs for pain relief with their own liability for prescribing opioids and other painkillers. When taken as prescribed, painkillers can bring much-needed relief to patients who have exhausted other therapies. Unfortunately, these powerful drugs are often abused or fall into the wrong hands.

Divergence: A Multi-Billion-Dollar Problem

Ninety-five percent of divergence happens at the patient level. People diverge their drugs for various reasons, giving, trading, stockpiling or selling them to others. For many, divergence is a tempting source of revenue. At the height of the epidemic, when doctors were still prescribing 80-milligram pills for everyday problems such as shoulder pain, a standard prescription could yield significant income for a patient. A 30-day supply of 80-milligram pills, for example, had a street value of approximately $19,000. While manufacturers have stopped making such large-dose pills and doctors are prescribing the addictive drug with more caution, this type of divergence is still problematic. Even at lower doses, a 30-day supply of 40-milligram oxycodone pills still brings in a significant payday of $9,000.

Currently, even the most secure pill bottles on the market do little to prevent patient access, the underlying problem with divergence. With the unhindered ability to open pill bottles, patients can diverge some or all of their pills for profit or misuse. According to a Substance Abuse and Mental Health Services Administration's survey, 50.8 percent of people said they obtained opioids by buying, taking or being given them by a friend or relative[5]. Even when people do not intentionally sell their medication, drugs go missing. Since pain medications can impair memory, some patients assume responsibility for missing pills, believing they mistakenly took an extra or misplaced it. Often, friends or family members have diverted the medication for personal gain.

This type of divergence occurs both in the home and on the job. Some medical professionals with frequent access to opioids use them to self-medicate for their stress or pain. Pharmacy technicians, nurses, emergency medical personnel, and even doctors, skim patients' pills to feed their addictions. According to a 2014 study, when access is easy, "physicians are…five times as likely to misuse prescription drugs." [6] These incidents are often underreported or unreported altogether, so when pills disappear, fellow medical professionals don't know how it's happening.

The Rise of Home Delivery

For more than fifty years, mail and specialty pharmacy orders of prescription drugs have grown steadily. From 1998 to 2017, the number of mail-order prescriptions more than doubled in the United States. Currently, fifty-five percent of the nation's medications are delivered through the US Postal Service and 80 percent of all Veterans fill their prescriptions (over 125 million annually) by mail.

With companies like Amazon, Berkshire Hathaway and Walmart Health entering the market, mail order is the future of prescription drug delivery. Like digital point-of-purchase payments and online grocery orders, the adoption of mail-order medications accelerated during the recent pandemic. With stress and anxiety on the rise and much of the country on lockdown, COVID-19 created additional emergency needs for drugs such as benzodiazepines and serotonin selective reuptake inhibitors (SSRIs), pushing mail-order numbers even higher.

In 2019, the Centers for Medicaid and Medicare spent $329 billion[7] on prescription medications. With more lawsuit payout on the horizon, these costs are only rising. In response, big box stores and mom-and-pop pharmacies are up-charging customers by 18-25 percent for medications across the board. To save on drug costs, many insurance companies now require their members to order prescriptions by mail.

While home deliveries are convenient and cost-effective, the mail-order of opioids and other controlled dangerous substances (CDS) is largely unstable. Without a mechanism to prevent illegitimate access, the delivery of addictive medication poses both a significant risk and a daunting challenge. If the United States is going to stop this crisis, our country needs to address patient access to prevent theft and divergence.

Current Solutions Make Access Easy

When it comes to prescription drugs, safety is essentially an illusion. The industry needs to change its current drug packaging and distribution methods to stop the epidemic in its tracks. As soon as patients receive their medication, whether they purchase from a pharmacy or by mail, they have immediate and unlimited access. With ninety-five percent of divergence resulting from patient access, restricting it solves a large part of the problem.

History demonstrates that restricting access decreases risk and saves lives. In the late 1950s, another epidemic sparked lasting changes to pill containers. An American pediatrician from Duke University noticed a disturbing trend of accidental child overdoses from aspirin. Recognizing the culprit as accessible drugs from household medicine cabinets, the doctor set out to make changes. By inventing the child-resistant lid, he saved countless young lives.

While these child-proof bottles have remained the standard of care for decades, they are no longer enough. We are now contending with a more nuanced type of accidental overdose. Instead of a naive child mistakenly consuming a drug, we see teens and adults overdose, not realizing the inherent dangers of their increased dose. As their tolerance to opioids builds, patients often surpass their prescribed dosage, increasing the risks of an unintentional overdose.

The Fox Escorting the Chicken to the Henhouse

In the past decade, several companies have tried to stem the tide of abuse, addiction and accidental overdose. From password-protected and patient-monitoring bottles to automatic dispensers and smart caps, each product has a common flaw. Not only do they fail to tackle the underlying issue of access, but they also assume patients will buy their product and transfer the medication into it.

It is unrealistic to give a potential abuser complete access to a highly addictive drug and expect them to lock it away. This type of wishful thinking is what has brought us to this point. The opioid epidemic will slow to a crawl once patients no longer have access to more than their prescribed and scheduled dose.

While companies intended these inventions to act as a deterrent, they do not keep patients from willingly diverting their medication. None of the current solutions has put a dent in the misuse and abuse problem. The key to solving this epidemic is forced compliance.

Pillsafe: Disruptive Innovation That's Changing the Game

PillSafe is a pioneering **smart technology** that is disrupting the pharmaceutical industry and shifting the standard of care. A game-changing response to the opioid epidemic, PillSafe forces compliance by completely restricting access to medication. Once a prescription is placed in a PillSafe bottle, it cannot be opened by anyone, at any time**.** Since patients can't abuse what they can't access, PillSafe keeps medication safe from divergence and abuse.

PillSafe's intelligent design includes several innovative features that give people safe and controlled access to medication according to the prescription schedule. The patented, licensed technology includes the following features (we can add customized technologies):

Built-In Pill Counter and Prescription-Based, Timed-Release Features

Once filled, PillSafe bottles cannot be opened. Unlike other locking bottles, PillSafe forces patient compliance with its programmable prescription parameters. When filling prescriptions, pharmacists place the correct number of pills in the bottle and input the amount, along with the dosage schedule, into the accompanying software. Since the container is locked, patients can only access the dispensed pill at the prescribed time. Also, by ensuring compliance, fewer doses are missed, and tolerance is kept in check.

Most patients base their need for their next dose of medication on their pain level. In a hospital setting, medical staff has complete control over when they provide pain medication. However, patients can determine their next dose upon leaving the hospital or pharmacy with an unlocked prescription bottle. Staying dedicated to a prescription schedule is essential to preventing addiction. Without compliance, tolerance can quickly build and cause an unintentional overdose.

PillSafe's intuitive timer provides a countdown between doses. When the device dispenses a pill, it automatically locks, displays an updated number of tablets, and restarts the countdown. While locked, the lid will turn but not engage the dispensing mechanism even if the access code is entered correctly. Once the display reads "ready," the patient can access their medication according to their prescribed schedule by pressing down and rotating the lid to dispense another pill.

Unique Access Code

Each PillSafe **smart device** is set with a unique three-digit passcode, which pharmacy staff can provide to the patients at pick-up. If mail-ordered, patients can acquire their access code by email or text when their package has arrived. Once entered, the patient can access the medication only at the prescribed time. Should others learn their passcode, the patient can change their combination to prevent access. For added security, pharmacies can choose to send access codes only after the patient answers security questions. For example, pharmacists could ask for the patient's social security number, an identifying feature on the bottle or a number listed on the label.

Theft-deterrent pill destruction mechanism

PillSafe disruptive technology takes theft deterrence to a new level. If someone attempts to

tamper with or forcibly open PillSafe, the bottle will destroy the medication. Each PillSafe device contains an electronic net that can detect a breach attempt of any kind. If a breach occurs, the bottle will release a customized spray, rendering the remaining pills unusable.

Cost Savings

In the past few decades, drug misuse and abuse have financially hurt those involved in manufacturing, prescribing and selling medications. To decrease liability, the industry must take steps to reduce patient access. By restricting access, PillSafe can control patient behavior, force compliance and protect professionals from costly lawsuits.

Despite the cost-saving benefits, liability also prevents some insurers from allowing patients to order controlled substances through the mail. When implemented, PillSafe could save companies between 18-25 percent with required member mail-order prescriptions. The device's guaranteed safety and security features can reassure these slow-to-adopt companies and pave the way for future savings.

PillSafe also benefits the bottom line for both patients and pharmacists. With the 90-day supply option offered at most mail-order pharmacies, patients can save on shipping and cost-per-pill. When people order a three-month medication supply, pharmacies save employee time and secure the sale of more medication.

The cost of drug abuse extends far beyond liability. Addicts who overdose not only end up with costly hospital stays and emergency room bills but they can develop side effects that require expensive treatments. Denying access saves both the patient and the insurer.

What Makes PillSafe Smart?

Unlike past solutions, PillSafe rises to the challenges of addictive drug delivery. Providing professionals with a complete solution that saves lives from overdoses, PillSafe's intelligent design will save the industry billions of dollars and protect itself from liability. The creators of this revolutionary delivery system designed it with each segment in the supply chain in mind.

Pill Manufacturers: Manufacturers have spent billions of dollars reformulating time-release pills to deliver drugs slowly, even when crushed. Despite these valiant efforts to increase safety, the underlying issue remains. With the current packaging solutions, patients still have immediate and full access to the drugs. Without restricted access, manufacturers will always be vulnerable to litigation.

Physicians: Throughout the opioid epidemic, many physicians have lost their license to practice medicine because of their patients' behavior. As people diverge their medications, physicians have become collateral damage. Without a centralized CDS database, physicians miss such behaviors as pharmacy-and-doctor-shopping and struggle to keep pace with the burdensome governmental reporting requirements.

While a nationwide reporting system is built, PillSafe can help doctors protect themselves from liability by ensuring medication adherence and preventing patient overdoses. When patients have access to more than the prescribed dose, they can medicate based on their perceived pain

level rather than the scheduled dosage. This behavior can build drug tolerance, create dependence and lead to an overdose.

The device's pill timer can also decrease a patient's overall usage by up to 25 percent. Doctor offices requiring monthly pill counts for addictive medication prescriptions can trust PillSafe to precisely track missed pills. Knowing with certainty that the device prevents patients from diverting their medication, doctors can better manage prescriptions to ensure the lowest possible dose of potentially addictive substances. Currently, doctor office pill counts provide an opportunity for staff to skim pills from patients' prescriptions for divergence. By limiting access, PillSafe puts an end to staff theft of medication.

Governments: One of the biggest challenges in this epidemic is getting accurate information in real-time. We are one step closer with PillSafe. Cities, counties and states can verify that medications have arrived safely to the intended recipient. With endless possibilities, PillSafe is futureproof. Our creators can include additional features that aid governmental reporting.

Patients: According to a Mayo Clinic study[8], approximately half of all patients never realize the full benefits of their medication because they don't adhere to their prescriptions. With reminders and theft deterrence built-in, PillSafe can increase medication adherence and enable people to live healthier, happier lives.

Insurance Companies:
Every day, approximately one thousand Americans receive treatment in the emergency room for misuse or abuse of prescription opioids. In addition to those ER visits, insurers pay billions of dollars for hospitalizations due to overdoses or harmful side effects. Even with non-addictive medications, lack of compliance can have devastating impacts. For example, a patient with high blood pressure who is not compliant with their prescription dosage or timing may experience a heart attack or stroke as a result. By ensuring compliance, PillSafe can prevent these events and significantly reduce insurer costs.

Payers can also contain costs by requiring members to purchase their prescription drugs through the mail. Mail order, or home delivery, can save up to 25 percent compared to big-box, brick-and-mortar pharmacies with higher overhead costs. However, even in states that permit mail-order opioids, most patients don't access the medication this way because they can't refill until they have finished their current prescription. With PillSafe, pharmacies can send drugs like opioids and benzodiazepines a few days early, knowing that the device will keep the medication safe and secure while in transit. Also, insurers that have shied away from mail-order for fear of liability can start saving.

Pharmacies: Both mail-order and brick-and-mortar pharmacies have had to defend themselves against claims of negligence. Many of the pending lawsuits have cited pharmacies for failing to recognize, investigate and report suspicious behavior. PillSafe can help pharmacies keep track of customer medications, helping them identify misuse and abuse. By doing so, they can refuse to fill questionable prescriptions, report them and avoid liability.

The Great Vault System

Much like PillSafe, the Great Vault keeps addictive medications safe and secure from divergence. The patented device can hold and protect the large numbers of pills that frequently travel from manufacturer to pharmacy. Since only an authorized pharmacist can open the Great Vault, pharmacy staff cannot skim pills. The Great Vault also protects drug shipments from interception by nefarious actors who trade medication for counterfeit pills. If tampered with or taken outside of the Vault's geofence, the device releases a liquid to destroy the controlled substances it contains.

The Markets for PillSafe

In 2019, American physicians wrote 424 million addictive prescriptions[9]. With this large number of drugs in circulation, the current annual market for PillSafe is extensive. Starting with addictive drugs, which are only ten percent of the pharmaceutical market, our device will create a positive change in the epidemic where other products have failed.

All medication requires adherence to a prescribed schedule. That's why the future market for PillSafe is vast. In 2019, doctors in the United States wrote 4.22 billion prescriptions[9]. When taken as directed, most medications enhance quality of life. But, when compliance fails, problems, even death, can occur.

For more information about PillSafe licensing opportunities, email Sanford Green @ tmgint6@gmail.com

INFOGRAPHICS

#1 2017 STIMULANT PRESCRIPTIONS
Amphetamines Overdose Deaths: 12,676 (2018)

- Number of prescriptions annually in the US: 52.4 million
- Types of Stimulants:
  - Amphetamines: 56%
  - Methylphenidate: 17%
  - Weight Loss Stimulants: 11%
  - Provigil: 3%
  - Other: 13%
- Total Prescriptions
  - Dextroamphetamine; Dextroamphetamine Saccharate; Amphetamine; Amphetamine Aspartate: 24,155,783
  - Methylphenidate: 16,450,268
  - Lisdexamphetamine Dimesylate: 8,884,102
  - Dexmethylphenidate Hydrochloride:3,102,542
  - Phentermine: 2,428,841

2017 SEDATIVE PRESCRIPTIONS

Barbiturates/Tylenol: 3.1 million

- Zolpidem (Ambien): 15,564
- Eszopiclone (Lunesta): 11,501,000

- Zaleplon (Sonata): 1,271,000
- Barbiturates used as sedatives: 452,000
- Barbiturates total annual: 19 million
    - Phenobarbital: 13.3 million

#2 LITIGATION AND SETTLEMENTS

US vs. Johnson & Johnson, McKesson, Cardinal Health, and Amerisource Bergen: $26 Billion
US vs. Teva: $23 Billion
US vs. Perdue Pharma: $8.3 Billion
DOJ vs. Walmart (FierceHealthPayor): ?
Ohio DOJ vs. CVS, Rite Aid, Walgreens, Giant Eagle, and Walmart: $? Billions
Major Drug Store Chains Sue 500 doctors across
NE Ohio vs. Physicians

#3 PRESCRIPTIONS BY NUMBER

25,699 OVERDOSE DEATHS
14,975 Deaths from Prescription Opiates[4]
10,724 Deaths from Prescription Benzodiazepines[5]
424 MILLION ADDICTIVE PRESCRIPTION
168 Million Opiate Prescriptions[6]
61 Million Benzodiazepine Prescriptions[7]
58 Million Psychostimulant Prescriptions[8]
57 Million Neuralgia Prescriptions (Gabapentin and Pregabalin)[9]
30 Million Insomnia Prescriptions[10]
25 Million Tramadol Prescriptions[11]
19 Million Barbiturate Prescriptions[12]
6 Million Carisoprodol Prescriptions[13]

SOURCES

1 https://www.cdc.gov/drugoverdose/epidemic/index.html
2 https://www.drugabuse.gov/publications/drugfacts/understanding-drug-use-addiction
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PILLSAFE DELIVERY SYSTEM