Tackling the U.S. Opioid Crisis: A Data-Driven Solution and Policy Recommendations

BROOKINGS

Washington University in St.Louis
OLIN BUSINESS SCHOOL

The Olin Brookings Commission presents:

Tackling the US Opioid Crisis:

A Data-Driven Solution and Policy Recommendations

Tamara Ward

T. Ward & Associates

April 22, 2022

Table of Contents

Attachment

Olin Brookings Commission's Research and Policy Recommendations Summary Sheet

List of Figures

1   Abstract

In the United States, more than 100 billion hydrocodone and oxycodone pills were prescribed to patients between 2006 and 2014 (Olin Brookings Commission 2022). In 2017 alone, a staggering 191 million opioid prescriptions were filled (Centers for Disease Control and Prevention [CDC] 2018). A long-standing pattern of overprescribing and consumption of prescription opioids has led to drug misuse, dependency and countless deaths. In 2019, on average, 38 people died daily from overdoses involving prescription opioids (CDC 2021). Many of these prescription opioids were illegally diverted into communities through suspicious transactions within the supply chain (manufacturing through delivery), further fueling the opioid epidemic (Olin Brookings Commission 2022).

This paper will outline and examine the origins of prescription opioids, their use and misuse and their contribution to the long-established opioid epidemic; review the diversion of legally manufactured opioids for illegal use in communities; and provide an analysis of existing policy to combat drug diversion. The paper will offer a research-based proposal to leverage new data science tools to proactively detect suspicious opioid orders before they are released and distributed to communities. In conclusion, the paper will present policy recommendations that address opioid drug diversion issues better than the existing policy and will include a summary of implications of not implementing the policy recommendations.

2   Executive Summary

The use of prescription opioids for treating moderate to severe pain has been an established practice for decades. Indeed, in the 1990s the medical community began pushing to use more effective methods to manage pain, and opioids were thought to be the answer to the problem. Opioids are truly effective at treating acute pain, but when pain becomes chronic (often developing a psychological component), opioids are much less effective or require higher doses to achieve the same effect.

The 1990s brought an increase in over-prescription and mass consumption of opioids due to aggressive marketing practices by some pharmaceutical companies and assurances that the drugs would not lead to addiction. The changes in prescribing practices have influenced opioid misuse and dependence and spawned a public health crisis that would span more than 30 years and cost more than half a million lives.

The Olin Brookings Commission, a multiyear initiative underwritten by The Bellwether Foundation Inc., is a partnership between Olin Business School at Washington University in St. Louis and the Brookings Institution. In its first project, the commission aims to find solutions for stopping suspicious orders of prescription opioids before they are diverted to illegal channels and distributed in communities.

Olin's Center for Analytics and Business Insights (CABI) is tapping into advances in data collection, data mining, artificial intelligence and machine learning to tackle this problem by targeting the drug supply chain. The solution is to implement a suite of anomaly detection tools to identify diversion trends in registrant-submitted data in the Automation of Reports and Consolidated Orders System (ARCOS) maintained by the US Drug Enforcement Administration (DEA).

As part of its operation, ARCOS collects and maintains the current and historical records of selected controlled substance inventories and transactions from the point of manufacture to the point of sale, distribution or other disposition, and ultimately, to where the controlled substance is dispensed for consumption.

Using historical ARCOS data from 2006 to 2012, to include more than 400 million opioid transactions and 277,000 buyers, researchers developed a tool to flag and stop fraudulent opioid shipments before they are diverted. The result is the creation of a tool for flagging future diverters with 100% precision accuracy (i.e., if the tool flags a buyer as a diverter, it is almost guaranteed that the prediction is correct). In other words, the tool will not produce false positives.

We achieve this degree of precision accuracy because we are willing to live with a moderate degree (51%) of recall accuracy (i.e., the tool catches about one-in-two diverters). In other words, the tool will result in many false negatives.

In this policy report, the Commission will offer insights as to how these technologies can address this crisis, evaluate the existing policy obstacles, and recommend ways to empower industry and government to implement a real-time detection and alert system.

A series of forthcoming policy recommendations will focus on the DEA's collection and analysis of industry-reported data, as well as encourage collaboration with industry to identify and share supply chain stakeholders' issues.

2.1 A Message from Olin Brookings Commission Chair Anthony Sardella

Suppose you could make a difference in society and prevent something terrible from happening? What if, while making a difference, you could save lives?

More than 10 million people misused prescription opioids in 2020. There were 68,630 opioid-involved overdose deaths in the same year. Another 1.6 million people suffer from opioid use disorder, which means they are physically and psychologically reliant on the drug.

Undoubtedly, the opioid epidemic has been fueled by a dramatic increase in prescription opioid use to manage pain. This increase in consumption has led to an unprecedented amount of drug misuse and drug dependency.

In some cases, these legal drugs are diverted through unlawful channels, exacerbating the problem. But today, using new advanced data science capabilities, we have the opportunity to detect such diversion before it happens and protect lives.

Utilizing technology that learns from behaviors, in real time we can now identify anomalies and flag suspicious orders within data that tracks opioid shipments and other controlled substances from manufacturing to distribution—the supply chain.

The tools enable us to remove blind spots in the supply chain and prevent suspicious orders from reaching the wrong hands and causing harm in our society.

We offer you both new data science tools and policy solutions that have the potential to greatly bolster suspicious order monitoring using the DEA ARCOS database and encourage partnership with industry—all with the goal of helping improve the federal response to the opioid crisis.

Here is your opportunity to make a societal impact and save people's lives. Won't you join us?

3 Introduction and Background

How much is a human life worth?

Overdoses involving prescription opioids killed nearly 247,000 Americans from 1999 to 2019. During that period, prescription opioid-related deaths increased by more than fourfold (CDC Wide-Ranging Online Data for Epidemiologic Research [WONDER] 2020). In total during those two decades, nearly 500,000 people in the United States died from overdoses involving any opioid, including prescription and illicit opioids, according to the CDC (CDC 2021).

How much are half a million human lives worth?
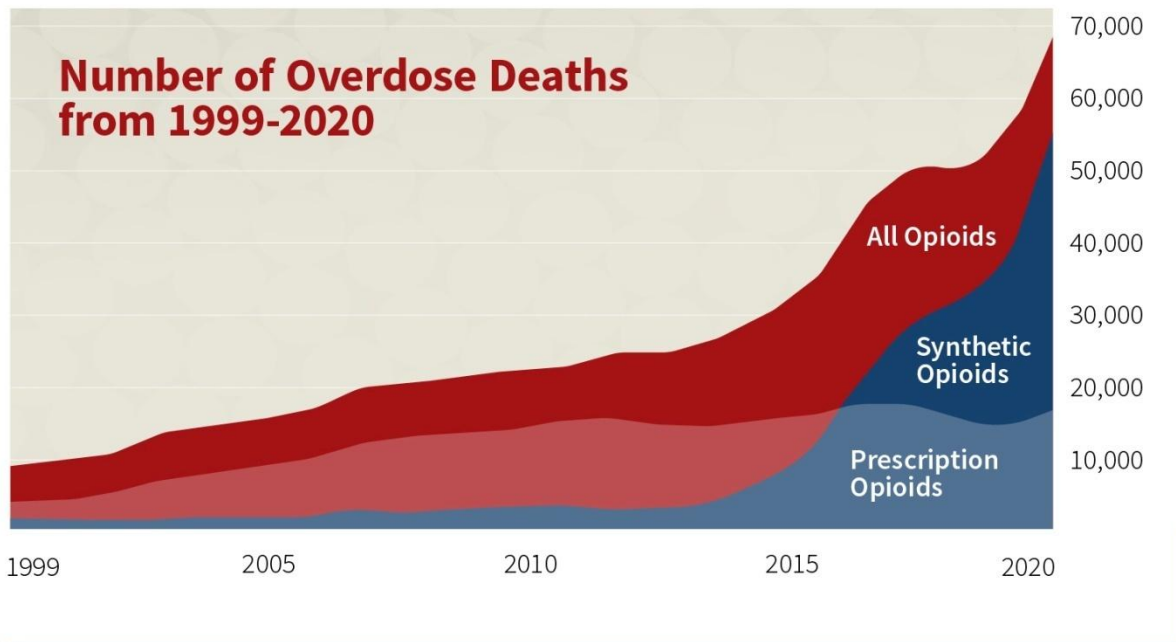
Figure 1: *Number of Opioid Overdose Deaths from 1999–2020*. National Institute on Drug Abuse (NIDA). January 20, 2022. "Overdose Death Rates." https://nida.nih.gov/drug-topics/trends-statistics/overdose-death-rates.

3.1   History

The use of opioids for pain management is not unique to the 20th and 21st centuries. Early introductions of this class of analgesics extracted from the opium poppy plant date back to the 1860s, when morphine was used to treat soldiers wounded during the Civil War in the United States. Many soldiers became drug dependent or addicted. In 1898, Bayer Co. introduced heroin, also an opioid, as a less addictive form of morphine. However, those with substance misuse disorders began abusing it as well. To combat the problem, the federal government placed restrictions on prescribing the class of drugs and outlawed heroin, unaware that more than a century later the nation would be fighting the same health crisis (Georgetown Behavioral Health Institute 2018).

3.2   Current Issue

Beginning in the 1990s, US consumption of prescription opioids for the treatment of pain increased exponentially, contributing to the current epidemic of opioid misuse and overdose deaths (Duff et al. 2021). In 2019, prescription opioids account for 28% of opioid overdose deaths (CDC March 24, 2021).

Exacerbating the problem, prescription opioids are funneled from legal channels to the illegal marketplace for profit most often in communities. Often the drugs wind up in the hands of drug abusers, social users and illicit drug users (Inciardi et al. 2007). The DEA estimated that sales of diverted prescription drugs topped $25 billion in 1993 alone (National Drug Strategy Network 1996).

The diversion of prescription opioids can occur anywhere in the supply chain, from manufacturing to the wholesale distributor, physician or medical practice, health system, pharmacy and even the patient.

3.3   The Good and Bad of Opioids

Traditionally, opioids were used to treat moderate and severe pain after injury or surgery, and for cancer pain management. More recently, opioids have been prescribed for chronic pain and non-cancer treatment (CDC August 2017). Opioid pain relievers act on the central nervous system by blocking pain signals to the brain. They also release endorphins, often yielding feelings of euphoria (Medical News Today 2018).

While effective in reducing pain and relieving stress, opioid use comes with serious risks. They can be highly addictive and ingesting copious amounts can stop breathing and lead to death (CDC August 2017). Those fortunate enough to survive an overdose may incur many health issues affecting the pulmonary, respiratory and central nervous systems as well as organ failure (CDC July 2017). The most common drugs involved in prescription opioid overdose deaths include methadone, oxycodone (commonly known as OxyContin®) and hydrocodone (commonly known as Vicodin®) (CDC August 2017).

3.4   Contributing Causes

3.4.1   Targeted Marketing

Aggressive marketing practices by some pharmaceutical companies have contributed to the overprescribing and mass consumption of opioids. Provider-directed marketing and ads misled physicians and consumers to believe prescription opioids were neither addictive nor dangerous (Georgetown Behavioral Health Institute 2018, Nguyen et al. 2019).

3.4.2   Overprescribing

Changes in prescribing practices have influenced opioid use, misuse and abuse. Opioid prescriptions increased by 169% from 1992 to 2010, according to NCDAS, with pharmacies filling 153 million opioid prescriptions annually (NCDAS 2022). In 2012, US healthcare

providers wrote nearly 260 million prescriptions for opioids, which equates to every US adult having their own prescription (CDC 2018). While in recent years opioid prescribing has decreased, the number of opioids prescribed in 2015 was still three times higher than in 1999 (Guy et al. 2017). A 2020 review of international opioid consumption revealed US healthcare providers prescribe opioids more often than their counterparts in other countries. They also prescribe in higher doses for various stages of care for acute and chronic pain conditions (Duff 2021).

<div align="center">3.5   Consequences</div>

3.5.1   Addiction

The 2019 National Survey on Drug Use and Health revealed 10.1 million people misused prescription opioids.

Opioids are the most abused class of drugs. As of 2021, more than 9 million people abuse prescription opioids (NCDAS 2022). One in six users of non-therapeutic opioids reported receiving the drugs through a doctor's prescription (Barker et al. 2011). More than 90% of opioid abusers use prescription opioids at least once in a year (NCDAS 2022). Often, prescription opioids become the gateway to illicit drug use to include heroin, fentanyl, methamphetamines and synthetic opioids.

10.1 million people
misused prescription opioids in 2020

1.6 million people
had an opioid use disorder in 2020

93,331 people
died from a drug overdose in 2020

1.6 million people
misused prescription pain relievers for the first time in 2020
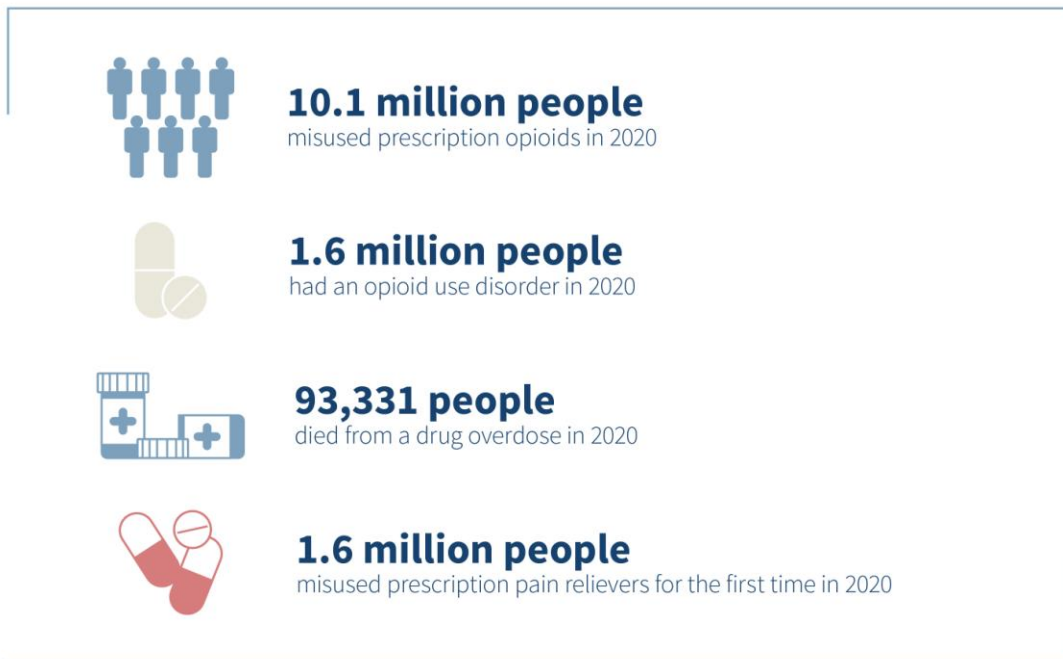
Figure 2: *Opioid Addiction by the Numbers.* NCDAS (2022).
https://drugabusestatistics.org/prescription-drug-abuse-statistics/.

3.5.2   Economic Impact

In addition to deaths and drug dependency, there is an economic burden associated with

prescription opioid misuse and abuse. The price tag is $78.5 billion annually, according to

NCDAS. In 2013, increased demand for healthcare and substance abuse treatment for opioids

accounted for $28.9 billion (NCDAS 2022). The public health crisis has led to lost productivity

in the workforce and placed added stress on the health insurance, emergency response and

criminal justice systems.
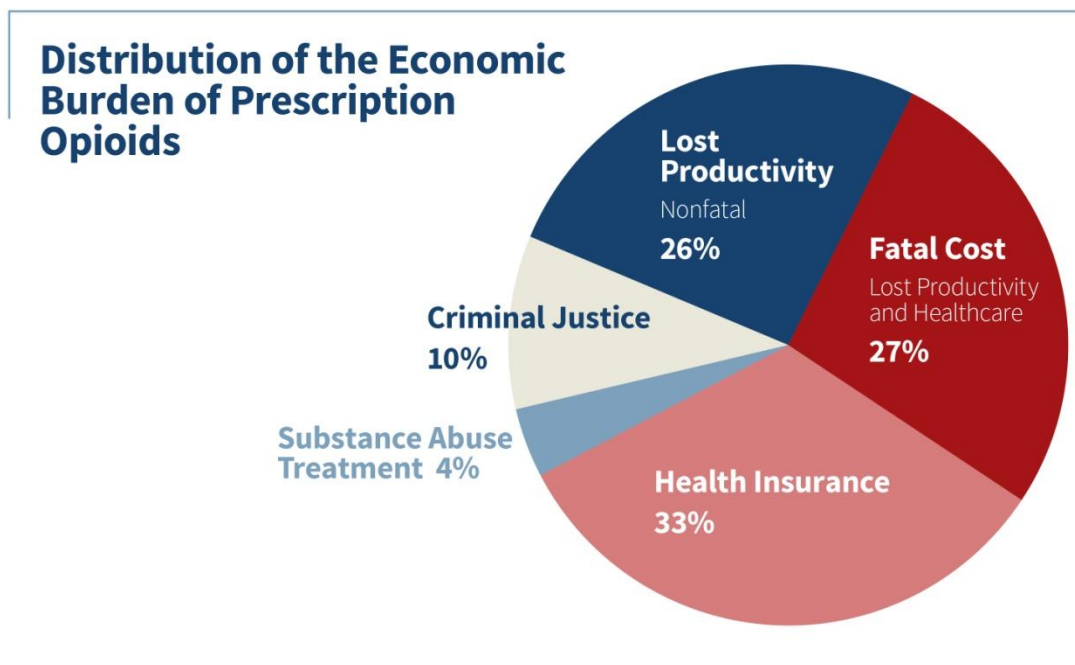
Figure 3: *Breaking Down the Economic Impact of Opioids*.
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5975355/figure/F1/.

4   Statement of the Problem

The real problem is the diversion of prescription opioids.

From the late 1990s to 2014, prescription opioids contributed either directly or indirectly to the deaths of more than 100,000 people in the United States (Franklin 2014). Prescription opioid-related overdose deaths increased from 3,442 in 1999 to 17,029 in 2017; the number of deaths declined from 2017 to 2019, then increased to 16,416 in 2020 (NIDA 2022). Combining overdose deaths related to illicit drugs and prescription opioids, nearly 92,000 Americans died of drug-related overdoses in 2020 (NIDA 2022).

The opioid epidemic, spanning more than two decades, is a multifaceted problem. The majority of addictions to opioids began with legal prescriptions issued for the treatment of pain (Georgetown Behavioral Health Institute 2018).

Practitioner prescribing practices and the pharmaceutical industry's aggressive and deceptive marketing contribute to the public health crisis. However, natural and synthetic legal and illicit opiates, which are also highly addictive, have all contributed, in waves, to the epidemic.

Although public policies, regulators and even lawsuits work to rein in industry and prescribers through accountability, the establishment of prescribing guidelines, and increased drug monitoring, the abuse of non-prescription and illicit opioids such as heroin and fentanyl continues to rise as prescription opioids become harder to get. In 2019, the American Psychiatric Association (APA) reported that 45% of people who use heroin started with an addiction to prescription opioids. However, the misuse and abuse of prescription opioids and the transfer of lawful prescription opioids to unlawful channels of distribution are the focus of this policy paper (APA 2018).

4.1   Misuse, Abuse and Addiction of Prescription Opioids

The risks of taking prescription opioids are numerous and serious. Overdose death notwithstanding, the most serious is opioid use disorder, the chronic addiction to opioids that impacts the brain and behavior and leads to the inability to control the use of the substance. An estimated 3 to 19% of people who take prescription pain medications develop an addiction to them (APA 2018). Longtime use of opioids often leads to physical dependence and addiction. Some users develop a tolerance to opioids. When the medicine no longer offers relief, they misuse or take greater amounts of opioids to achieve pain relief or a feeling of euphoria.

According to the American Medical Association, people misusing opioids may switch from prescription painkillers to illicit drugs like heroin, which is more readily available. More than half of people misusing opioid medications reported obtaining or stealing opioids from

family members or friends, going to multiple practitioners for additional prescriptions, a practice

known as doctor shopping, and filling prescriptions at different pharmacies to mask how many

pills they are actually taking (American Medical Association Alliance Inc. 2016).

<div align="center">4.2   Diversion of Prescription Opioids</div>

The majority of misused prescription opioids in the United States have been prescribed

for a legitimate use and then diverted for unlawful use (National Conference of Commissioners

on Uniform State Laws 1994). The US Department of Justice (DOJ) reports that "diverted

prescription drugs, often enter the community through the family medicine cabinet, theft and

robbery of local pharmacies, and through fraudulent prescriptions" (2022).
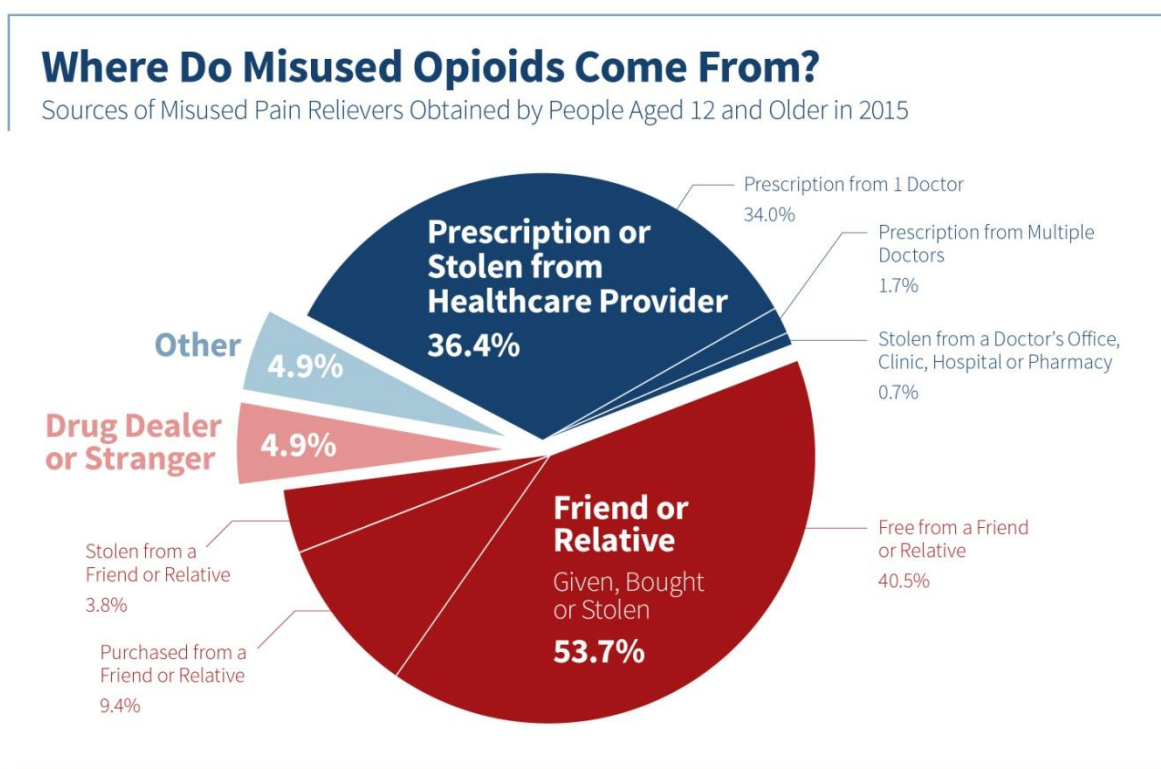
Figure 4: *Where Do Misused Opioids Come From?* Barker et al. September 2016. "Prescription
Drug Use and Misuse in the United States: Results from the 2015 National Survey on Drug Use
and Health."
https://www.samhsa.gov/data/sites/default/files/NSDUHNationalFindingsResults2010-
web/2k10ResultsRev/NSDUHresultsRev2010.pdf.

However, many opportunities exist to divert legal opioids for illicit use in the prescription drug supply chain, from manufacturing to point of sale.

Manufacturers or pharmaceutical companies produce prescription opioids.

Distributors purchase prescription opioids from manufacturers and deliver orders to pharmacies and healthcare facilities when ordered.

Pharmacies order opioids from distributors and then dispense opioids to patients with prescriptions.

Healthcare institutions such as hospitals, clinics and teaching schools dispense opioids to patients.

Physicians and other healthcare practitioners (dentists, nurse practitioners) write opioid prescriptions for patients with medical needs.

Manufacturers, distributors and pharmacies are often the targets of theft by criminal enterprise.

Figure 5: *Supply Chain of Prescription Opioids and Possible Avenues of Diversion*. GAO. January 2020. "Drug Control: Actions Needed to Ensure Usefulness of Data on Suspicious Opioid Orders. Report to Congressional Committees." https://www.gao.gov/assets/gao-20-118.pdf.

In her 2017 testimony before the Joint Economic Committee's hearing on "Economic Aspects of the Opioid Crisis," Lisa Sacco, an analyst in illicit drugs and crime policy, also pointed to bad-acting physicians, pill mills, the internet, pharmaceutical theft and prescription fraud as other sources of diversion during the late 1990s and early 2000s (Sacco 2017).

Manufacturers and distributors receive orders that are strange in amount or differ significantly from a normal pattern order (i.e., unusual in frequency). By law, distributors are

required to report these "suspicious orders" to the DEA. According to the Government

Accountability Office (GAO), the DEA received nearly 1.5 million suspicious order reports from

industry between 2014 and 2020. The GAO also reports healthcare providers may participate in

drug diversion schemes by writing illegal opioid prescriptions that are filled by a co-conspiring

pharmacist (2020, 37).

Unlike most retail pharmacy chains that rely on wholesalers to supply prescription

opioids, pharmaceutical chain Walgreens obtained the majority of its pain pills directly from

drug manufacturers and acted as its own distributor but neglected to report suspicious orders of

pain pills that it received from its retail pharmacies to the DEA, according to the law

enforcement agency in a June 2013 news release: " … the Registrants negligently allowed

controlled substances listed in Schedules II – V of the Act, such as oxycodone and other

prescription pain killers, to be diverted for abuse and illegal black market sales" (DEA 2013).

For its violation of the Controlled Substances Act, Walgreens agreed to pay $80 million in civil

penalties, according to the [settlement agreement](#).

This is only one example of bad practices fueling the opioid epidemic. State and local

governments have filed numerous lawsuits in federal court against the largest manufacturers and

distributors of opioids in an effort to recoup the costs in the fight against the drug epidemic. In

their suits, they allege that manufacturers and distributors created the crisis by engaging in

deceptive marketing practices and downplaying the drugs' addictiveness to promote the overuse

of prescription opioids. Well-known defendants include Purdue Pharma, Johnson & Johnson,

CVS, Walgreens and more. Also, billion-dollar settlements have been brokered between "big

pharma" and the DOJ, states and local municipalities (Llamas 2021).

In February 2022, it was announced that generic opioid manufacturer Johnson & Johnson and drug wholesalers McKesson, Cardinal Health and AmerisourceBergan will pay $26 billion for their role in perpetuating the opioid crisis (Mann 2022).

Continued diversion of prescription opioids anywhere along the supply chain will further exacerbate the problem and cost many more American lives and should be halted before even reaching the point of a government lawsuit.

5   Current Policies

The policies that largely govern how the US federal government tackles the opioid crisis today were put in place more than five decades ago and primarily focus on managing the drug's supply chain.

5.1   The Law

In 1970, Congress passed the [Controlled Substances Act](#), which classified drugs into five groups or schedules based on the likelihood of abuse, and imposed regulations and set quotas on the manufacturing and distribution of drugs. Opioids are Schedule II drugs because of their high potential for abuse and ability to lead to dependency (DEA 2022).

The Controlled Substances Act also requires any business that manufactures, imports, exports or distributes controlled substances to register with the federal government. Health practitioners licensed to dispense, administer or prescribe controlled substances and pharmacies authorized to fill prescriptions must also register (DEA 2022).

5.2   Enforcement

Three years after the Controlled Substances Act was signed into law, the DEA was established to enforce the controlled substances laws within the United States (DEA 2022). The DEA's Diversion Control Division is charged with preventing, detecting and investigating the

diversion of controlled pharmaceuticals from legitimate sources, without interrupting the supply of medicine for legitimate needs. According to the agency, their diversion investigations involve physicians who sell prescriptions to drug dealers or abusers; pharmacists who falsify records and subsequently sell the drugs; employees who steal from inventory and falsify orders to cover illicit sales; prescription forgers; and individuals who commit armed robbery of pharmacies and drug distributors (DEA 2022). Under the Controlled Substances Act, the cost to run the agency's Diversion Control Division is recouped from the registration and re-registration fees collected from controlled substance registrants. These fees are paid in three-year increments. According to the DEA, there are more than 1,500 DEA registered manufacturers and distributors.

Timeline of Events Impacting Industry-Reported Data on Prescription Opioids

1970
Controlled Substances Act

1971
Federal government requires manufacturers and distributors to report suspicious orders

1973
Drug Enforcement Administration (DEA) established and ARCOS created

2008
DEA develops the Suspicious Order Reporting System to store suspicious orders

DEA develops online access to ARCOS for DEA field investigators

1996-1997
DEA automates ARCOS

2009
DEA enhances ARCOS for efficiency and error reporting

2017
President declares the opioid crisis a national public health emergency

2018
DEA introduces new features to its ARCOS online system

DEA announces new ARCOS data-sharing agreement between agency and states' attorneys general

2019
DEA establishes the Suspicious Orders Report System Online centralized database to collect suspicious order reports

What is ARCOS?
Automation of Reports and Consolidated Orders System (ARCOS) is one of the DEA's diversion-related systems used to capture data and monitor the flow of controlled substances from manufacturing to distribution. Registrants must report the information monthly or quarterly.

Figure 6: *Timeline of Events Impacting Industry-Reported Data on Prescription Opioids*. GAO. January 2020. "Drug Control: Actions Needed to Ensure Usefulness of Data on Suspicious

Opioid Orders. Report to Congressional Committees." https://www.gao.gov/assets/gao-20-118.pdf.

5.3   Drug Monitoring Data

The DEA collects the data on the sale and purchase of controlled substances and prescription drugs, including opioids, from the pharmaceutical industry. The data is used to support ongoing drug diversion investigations and to identify diversion leads for DEA field offices (GAO 2020).

ARCOS is one of three diversion-related systems the DEA uses to capture data and monitor the flow of controlled substances "from their point of manufacture through commercial distribution channels to point of sale or distribution at the dispensing/retail level—hospitals, retail pharmacies, practitioners, mid-level practitioners, and teaching institutions" (DEA 2022). Registrants can transmit data via the internet through the ARCOS Electronic Data Interchange or via paper reporting using DEA Form 333 and must report the information monthly or quarterly.

Figure 7: *Overview of the Information Reported to the DEA to Monitor Controlled Substances*. GAO. January 2020. "Drug Control: Actions Needed to Ensure Usefulness of Data on Suspicious Opioid Orders. Report to Congressional Committees." https://www.gao.gov/assets/gao-20-118.pdf.

The ARCOS database captures the amount of prescription opioids that were distributed in the United States as well as detailed information on what type of and every pill that was legally sold in the United States as the crisis was growing.

5.4 State of Emergency

Nearly $900 million in opioid-specific federal funding was spent in 2017 for treatment and recovery services, training for first responders and increasing the availability of overdose-reversing drugs, such as Narcan, in the United States (US Department of Health and Human Services 2017).

On October 26, 2017, the federal government officially declared the nation in a state of public health crisis due to the opioid epidemic and launched a five-point strategy to fight the crisis:

1. Improve accessibility to treatment and rehabilitation services.

2. Promote the use of overdose-reversing drugs.

3. Strengthen public understanding of the epidemic through improved public health surveillance.

4. Support research on reducing pain and addiction.

5. Advance better practices in the first place for pain management and reduction.

A year later, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act of 2018, aka the SUPPORT Act, became law and amended the Controlled Substances Act to require all DEA registrants to report to the agency suspicious orders of controlled substances that are unusual in size, substantially different from a normal pattern or unusual in frequency. Amending its regulations to coincide with the SUPPORT Act, the DEA launched the Suspicious Orders Report System (SORS) online on October 23, 2019 (DEA 2022).

According to the DOJ, governments at all levels have partnered with educators, treatment professionals and nonprofit organizations to bring awareness and develop strategies and solutions to combat the opioid epidemic in communities across the nation. Strategies to tackle the crisis include targeted and proactive drug law enforcement activity to dismantle the trafficking organizations; prevention programs and drug awareness and education campaigns; and intervention and treatment options that address the short- and long-term health of opioid users and those recovering from addiction. Underway are customized efforts to address the

specific needs of local, tribal and regional areas impacted by the public health crisis. DOJ reports these efforts are supported by national and international efforts that "focus on various parts of this problem" (DOJ 2022).

<div align="center">5.5   Limitations with Current Policies and Programs</div>

5.5.1   DEA's Diversion Control Division

The DEA has been cited for failing to act on valuable information within its databases. In a House of Representatives Energy and Commerce Committee *Red Flags and Warning Signs Ignored: Opioid Distribution and Enforcement Concerns in West Virginia* 2018 report, lawmakers said the DEA did not utilize data "in a proactive manner to combat controlled substance diversion" in West Virginia. Review of historical ARCOS data revealed a significant increase in opioid shipments to West Virginia pharmacies that warranted closer inspection by the DEA (Energy and Commerce Committee 2018).

In a January 2020 GAO report to Congress titled *Drug Control: Actions Needed to Ensure Usefulness of Data on Suspicious Opioid Orders*, the GAO identified a handful of deficiencies associated with the DEA's drug diversion program (GAO 2020). The oversight entity said the DEA had "limited proactive and robust analysis of industry-reported data" and noted that while the DEA's current data systems are not designed to conduct real-time analysis, the agency could "conduct more analyses using automated computer algorithms to help identify questionable patterns in the data" to better support field offices. The GAO suggested the agency could analyze data to identify unusual volumes of deleted transactions or unusual volumes of drugs that were "disposed of rather than sold," as well as identify drug purchase or distribution trends in a given geographic area. Additionally, the DEA could compare unusual patterns in

neighboring areas, which could help the DEA proactively identify suspicious activities of registrants that may warrant investigation.

5.5.2 Antiquated ARCOS

ARCOS is not without its limitations. The DEA standardized ARCOS reporting in the late 1970s. It was not designed to conduct real-time analysis, which is needed today to flag, investigate and thwart suspicious orders. While registrants' reports for ARCOS were initially submitted on magnetic diskette, magnetic tape or cartridge, and on the DEA's paper Form 333, an electronic version of Form 333 is now available. However, the agency still allows registrants to submit hard copy reports, which requires manual entry by the DEA into ARCOS, increasing the possibility of errors and contributing to the delay in detecting fraudulent orders.

5.5.3 Insufficient Data Collection

The frequency and the method of collecting registrants' data in the ARCOS system present some barriers to identifying and halting suspicious orders. Registrants can choose either a monthly or a quarterly reporting frequency, leaving big gaps or opportunities for drug diversion. A DOJ's Office of the Inspector General September 2019 review of the DEA's regulatory and enforcement efforts to control the diversion of opioids revealed that "the dichotomy of reporting schedules forces DEA to wait a full year before ARCOS contains all of the ordering information needed to fully analyze the data and develop leads and trends" (Office of the Inspector General 2019).

5.5.4 Limited Data Access

There has been a desire for greater transparency of the ARCOS data to improve monitoring and coordination. However, access to the ARCOS data is limited. According to the Healthcare Distribution Alliance (HDA), which represents 36 distribution companies and more

than 130 manufacturer distributors, distributors have repeatedly asked the DEA for ARCOS data to aid anti-diversion efforts (HDA 2019).

5.5.5 *Industry*

"Big pharma" has long been blamed for initiating the opioid crisis. Today, many pharmaceutical companies employ anti-diversion specialists, some former law enforcement, to ensure compliance with drug laws. Opportunities for industry and government to partner in combating the crisis, especially in the supply chain, are few.

HDA reported that distributors are supportive of public policy that improves communication, coordination and monitoring across the opioid supply chain with DEA and other regulatory and law enforcement entities.

These limitations with the current policies and programs, if allowed to persist, provide continued avenues for diversion of prescription opioids in the supply chain, but opportunities to reduce diversion and, ultimately, deaths also exist.

6   Solution

6.1   Follow the Historical Data

Focused on the drug supply chain and stopping suspicious orders at the source, the Olin Brookings Commission and researchers from Washington University's CABI set out to determine whether new advanced data science tools could be leveraged to fight the opioid epidemic. The team of researchers—P.B. "Seethu" Seetharaman, Anthony Sardella, Michael Wall, Annie L. Shi and Chenthuran Abeyakaran—detailed the initiative in the research report "Nip it in the Bud! Managing the Opioid Crisis: Supply Chain Response to Anomalous Buyer Behavior," under review with the *Journal of Marketing*.

In order to establish a tool or process to flag and stop fraudulent opioid shipments before they are released into communities, the researchers must test it on historical data (Shi et al. 2021). The 2019 court-mandated release of limited ARCOS data provided the opportunity for CABI researchers to apply these new advances in data collection and data mining, as well as artificial intelligence and machine learning.

The now-public data tracked the course of every pain pill sold in the United States by manufacturers and distributors to pharmacies and practitioners nationwide from 2006 to 2012. The six-year dataset includes more than 400 million opioid transactions involving 277,000 buyers.

CABI mined the datasets and created a predictive capability, or anomaly detection tool, to decipher legitimate versus suspicious buyer activity. The tool is non-intrusive on patient privacy, as it does not rely on prescription-level data from drug retailers or physicians.

Identifying Legitimate vs. Suspicious Buyers

Identified **186** buyers who had their registrations revoked, labeling them as suspicious and pulling their **160,643** transactions.

Randomly selected **50,000** buyers from the remaining **276,814**, labeling them as legitimate and pulling their **65,708,911** transactions.

The ARCOS database contains **277,000** buyers who made over **400 million** transactions from 2006-2012.

Figure 8: *Identifying Legitimate vs. Suspicious Buyers*. Shi et al. December 21, 2021. "Nip it in the Bud! Managing the Opioid Crisis: Supply Chain Response to Anomalous Buyer Behavior."

Figure 9: *Research Process Overview*. WashU Olin Business School. Presented August 19, 2021, at WashU Brookings Commission Meeting. "Saving Lives by Detecting Suspicious Opioid Shipments."

6.2   Research Process

6.2.1   Make Data Actionable

ARCOS is a massive dataset, yet it does not contain all the information needed to make decisions, according to the CABI research team. The researchers were determined to make sure the data was presented in a way that provided future insights and led to improved decisions.

With a focus on opioid transactions, the researchers trained the anomaly detection tool on a random sample of 50,000 drug retailers. They also used a second set of data of known illicit transactions as identified by DOJ convictions. This data aided the tool in detecting suspicious retail buyers based on their historical opioid buying patterns.

6.2.2   Learn from Actionable Data

The researchers conducted an analysis with the new data structure to learn more about buyers and their behaviors. Additionally, they worked to understand key differences in the

characteristics and behaviors of convicted buyers they have identified in the second dataset and those of buyers without convictions to guide their model-building approach. For example, drug diversion activities were more likely to be committed at retail pharmacies than at chain pharmacies. Also, a disproportionate number of suspicious orders come from some distributors.

How Do Legitimate and Suspicious Buyers Differ?

Retail pharmacies appear to be more likely to be convicted than chain pharmacies.

Some distributors have disproportionately large contributions to the suspicious orders.

Legitimate Buyers

Buyer Type	Total Orders	Proportion of Orders	Cumulative Proportion		Distributor	Total Orders	Proportion of Orders	Cumulative Proportion
Chain Pharmacy	35,469,153	55.4%	55.4%		McKesson Corp.	13,841,072	23.5%	23.5%
Retail Pharmacy	20,125,346	31.5%	86.9%		Cardinal Health	11,265,678	19.1%	42.7%
Hospital/Clinic	4,570,555	7.1%	94.0%		AmerisourceBergen Drug Corp.	7,615,255	12.9%	55.6%
Analytical Lab	1,377,547	2.2%	96.2%		Walgreen Co.	7,579,511	7.4%	68.5%
Reverse Distributor	1,290,365	2.0%	98.2%		Wal-Mart Pharmacy Warehouse	4,340,918	3.6%	75.8%
Practitioner	708,515	1.1%	99.3%		CVS Pharmacy Inc.	2,103,122	1.8%	79.4%
M/O Pharmacy	169,557	0.3%	99.6%		Smith Drug Co.	1,077,288	1.8%	81.2%
Manufacturer	115,604	0.2%	99.7%		Kroger Limited Partnership	901,182	1.5%	82.8%
Maintenance & Detox	52,250	0.1%	99.8%		Morris & Dickson Co.	670,046	1.1%	83.9%
Pharmacy - Fed	32,519	0.1%	99.9%		Rite Aid Mid-Atlantic	636,884	1.1%	85.0%
Importer	16,928	0.0%	99.9%		Kinrary Inc.	593,296	1.0%	86.0%
Cenri Fill Pharmacy	16,828	0.0%	99.9%		N C Mutual Wholesale Drug Co.	456,764	0.8%	86.8%
MLP-Nurse Practitioner	8,281	0.0%	99.9%		Anda Pharmaceuticals Inc.	369,341	0.6%	87.4%
Researcher (II-V)	7,591	0.0%	100.0%		Smith's Food & Drug Centers Inc.	357,989	0.6%	88.0%
					Eckerd Corp.	345,915	0.6%	88.6%
					Thrifty Payless Inc.	302,498	0.5%	89.1%
					Advantage Logistics	298,035	0.5%	89.6%

Suspicious Buyers

Buyer Type	Total Orders	Proportion of Orders	Cumulative Proportion		Distributor	Total Orders	Proportion of Orders	Cumulative Proportion
Retail Pharmacy	122,588	76.3%	76.3%		AmerisourceBergen Drug Corp.	26,644	17.74	17.74%
Practitioner	18,585	11.6%	87.9%		Cardinal Health	24,306	16.18	33.92%
Chain Pharmacy	16,517	10.3%	98.2%		McKesson Corp.	21,559	14.35	48.27%
M/O Pharmacy	2,739	1.7%	99.9%		Smith Drug Co.	20,437	13.60	61.87%
Maintenance & Detox	170	0.1%	100.0%		HD Smith Wholesale Drug Co.	17,826	11.87	73.80%
Hospital/Clinic	33	0.0%	100.0%		Anda Pharmaceuticals Inc.	7,985	5.32	79.06%
MLP-Physician Assistant	10	0.0%	100.0%		CVS Orlando FL Distribution	5,570	3.71	82.76%
MLP-Nurse Practitioner	1	0.0%	100.0%		The Harvard Drug Group-MI	3,552	2.36	85.13%
					Masters Pharmaceutical Inc.	3,373	2.25	87.37%
					Rochester Drug Co-Operative Inc.	1,706	1.14	88.51%
					Miami-Luken	1,521	1.01	89.52%

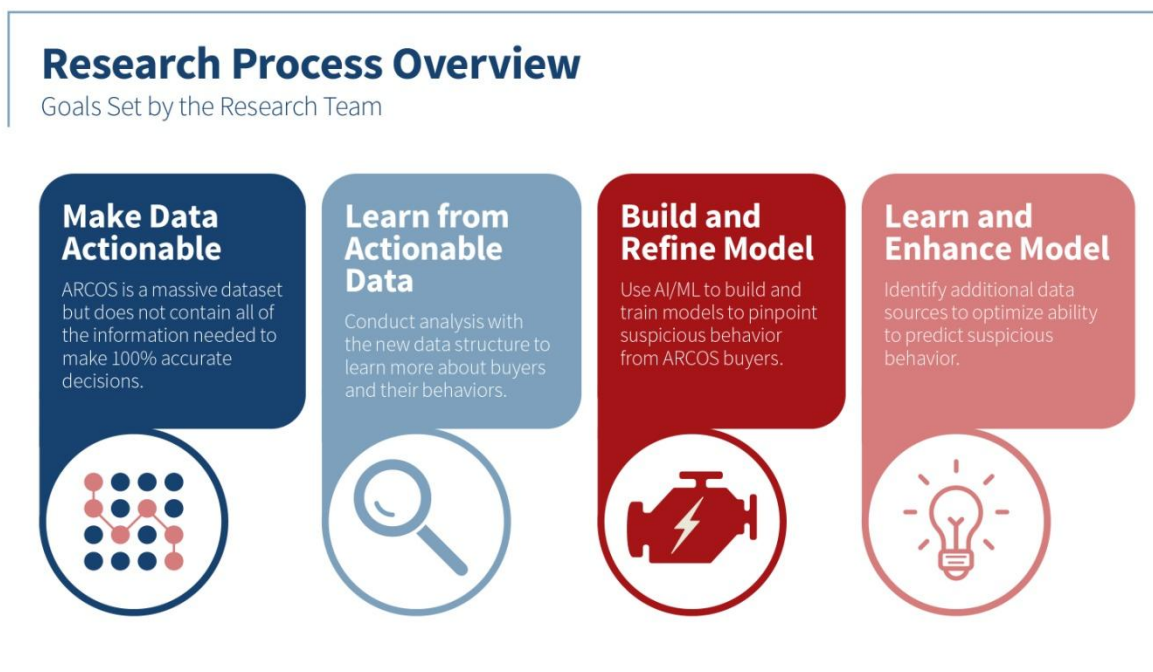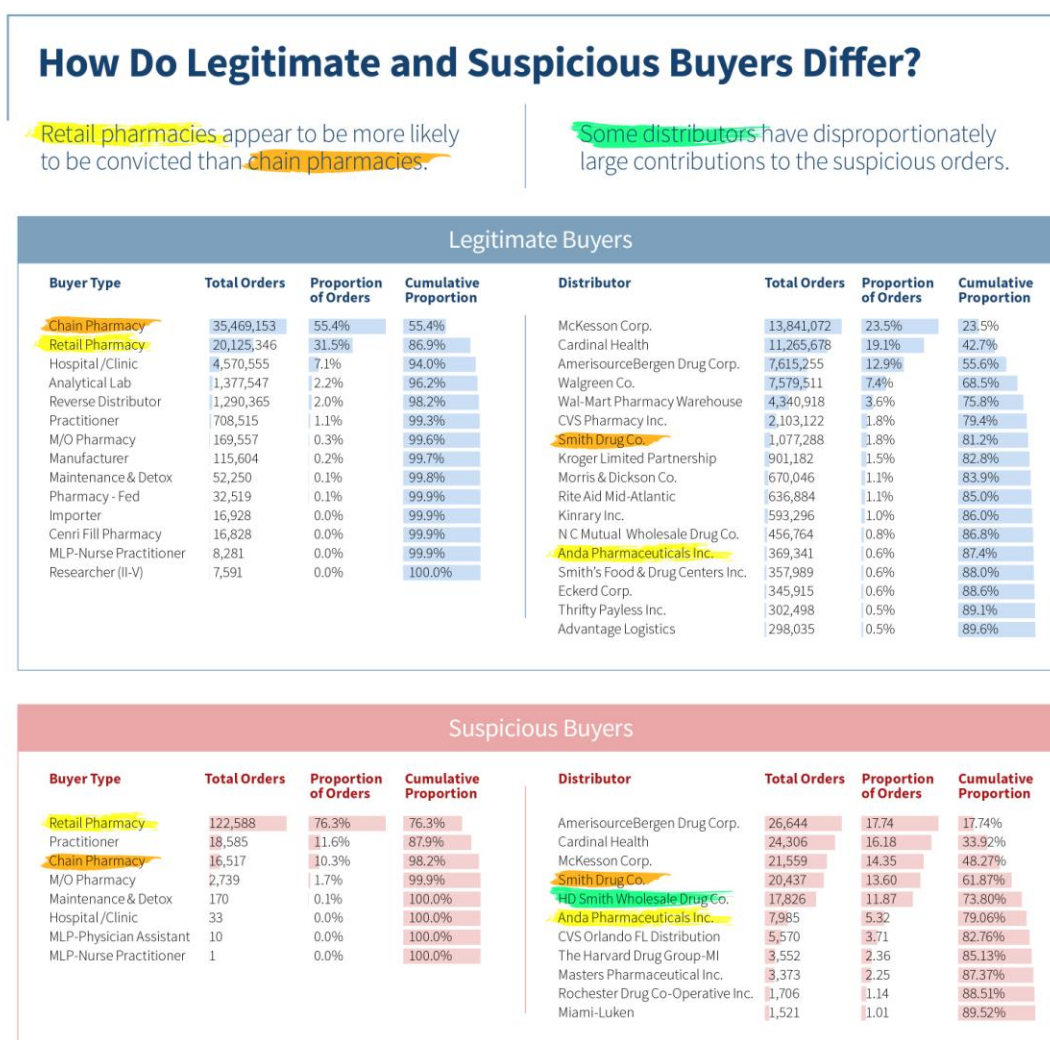Figure 10: *How Do Legitimate and Suspicious Buyers Differ?* WashU Olin Business School. Presented August 19, 2021, at WashU Brookings Commission Meeting. "Saving Lives by Detecting Suspicious Opioid Shipments."

6.2.3   Build and Refine Model

Using artificial intelligence and machine learning, the researchers employed 40 input variables to train the anomaly detection tool to pinpoint suspicious behavior from ARCOS

registrants. Ultimately, the researchers relied upon seven input variables to achieve predictive
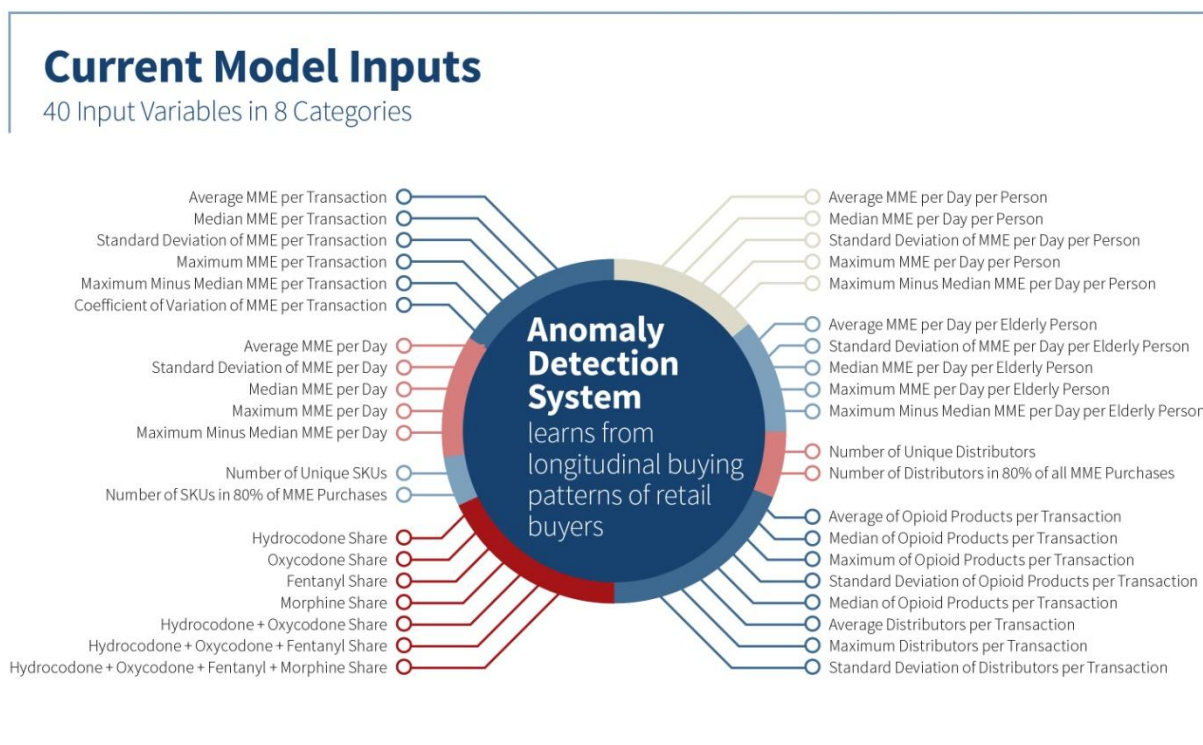
accuracy.

Figure 11: *Current Model Inputs*. WashU Olin Business School. Presented August 19, 2021, at WashU Brookings Commission Meeting. "Saving Lives by Detecting Suspicious Opioid Shipments."

6.2.4   Learn and Enhance Model

The team identified additional data sources to optimize the tool's ability to predict

suspicious behavior. The team used a standard for calculating the total daily dose of commonly

prescribed opioids to evaluate the data. Dubbed morphine milligram equivalents (MME), this

standard establishes reliable comparisons among various opioid transactions (CDC n.d.).

Upon examination, for example, the tool identified some buyers who purchased almost

10 times as much as legitimate buyers for average MME purchased per transaction and almost 20

times as much upon examination of median MME purchased per transaction. MME is an

industry standard for making comparisons.

6.3   Predictive Success

The result of the research is the development of an anomaly detection process for

flagging future suspicious transactions with 51% recall accuracy and 100% precision accuracy.
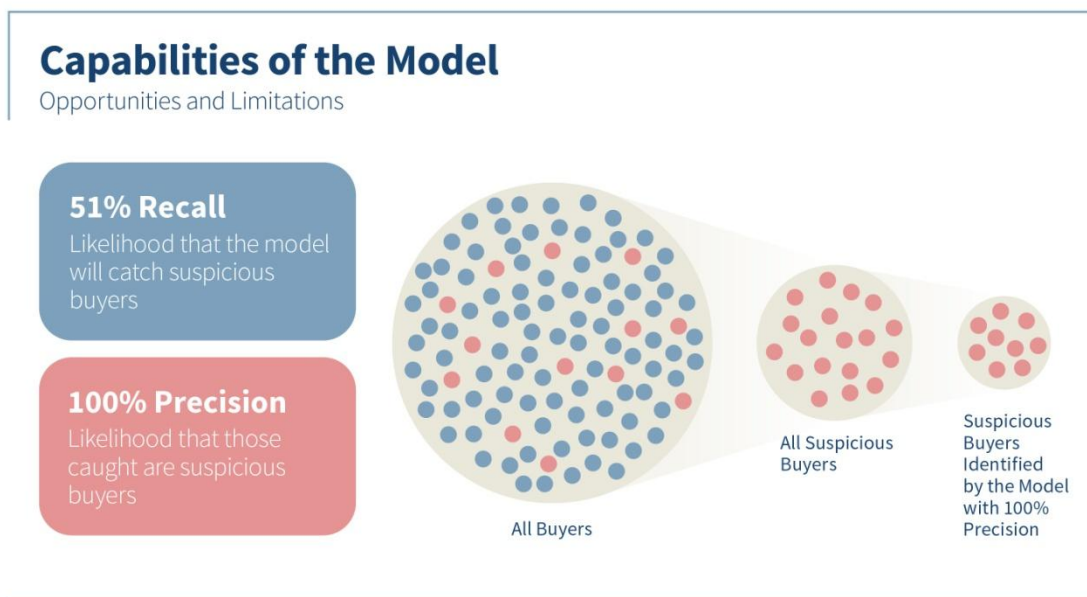

Figure 12: *Capabilities of the Model*. WashU Olin Business School. Presented January 18, 2022, at Olin Brookings Commission Meeting. "Opioid Research Study Policy Discussion."

Concerns for false positives are minimized as the anomaly detection avoids flagging

orders as suspicious with 100% precision. However, to prevent false positives, the tool may not

flag some suspected diverters, allowing their orders to sneak under the radar.

The algorithm can help law enforcement officials identify dubious opioid transactions in

the future. As a bonus, the same modeling approach could be leveraged across more than 100

other controlled substances tracked by ARCOS.

The use of this predictive algorithm will enable the DEA to predict a buyer's likelihood

of being a suspicious buyer, thus allowing the agency to allocate its human and capital resources

wisely among high-value leads.

Halting large shipments of opioids through early identification of suspicious orders placed by either (willfully or otherwise) negligent or outright criminal activities will prevent these dangerous drugs from reaching communities, thereby saving lives.

6.4   Supportive Public Policy

To support the successful implementation and use of the detection and alert tool, the Olin Brookings Commission investigated a host of public policy proposals regarding the diversion of prescription opioids. The policy areas include revision and modernization of data reporting; data sharing and cross-agency communication; response guidance for flagged transactions; and funding sources for system upgrade and maintenance and diversion program oversight.

With an eye on the federal agency that owns and has direct access to the ARCOS database and possesses the law enforcement capabilities to act on suspicious opioid orders, the Commission believes the DEA should be the primary user of the anomaly detection tool.

In order to help the DEA better identify possible diversion trends in registrant-submitted data in ARCOS, the Commission recognizes the need to strengthen the agency technology, strengthen its workforce's expertise in artificial intelligence and machine learning, and update the law that governs the agency, the ARCOS database and the registrants.

In summary, the forthcoming policy recommendations focus on the DEA's collection and analysis of industry-reported data, as well as collaboration with industry to identify and share supply chain stakeholders' issues relative to ARCOS data collection and reporting.

7   Policy Recommendations/Action Plan

The Olin Brookings Commission developed several recommendations that, in combination, can overcome existing policy obstacles and reveal opportunities for policy changes to empower industry and government to implement a real-time detection and alert system.

In developing the policy recommendations, the Commission hopes to accomplish the following objectives: help lawmakers enable better outcomes in the opioid public health crisis; help federal, state and local law enforcement be more effective; and help commercial entities (i.e., manufacturers, distributors and retailers) better collaborate and execute to secure the supply chain.

To support the use of artificial intelligence and machine learning to fight the opioid epidemic, the Commission suggests the following policy recommendations:

7.1   Technology

Obstacle: ARCOS technology was built several decades ago. The integration of the anomaly detection tool may require an upgrade to its technology infrastructure.

Recommendation:

1. By law, establish a daily or near real-time pilot for integration of anomaly detection tool to test the operational methods.

Obstacle: By law (§ 1304.33 Reports to Automation of Reports and Consolidated Orders System [ARCOS]), distributors must report sales of Schedule I, Schedule II and some Schedule III opioid-based medications in ARCOS quarterly or monthly. Reports are due by the 15th of the following month. The anomaly detection tool is configured to run against ARCOS data, flag suspicious orders and halt shipment for a 24-hour period to give authorities time to investigate. The current ARCOS reporting requirement does not support optimal use of the anomaly detection tool. The tool would most likely flag orders that have already been fulfilled.

Recommendation:

2. Modernize ARCOS technology infrastructure to support daily or near real-time data entry by registrants.

7.2   Data Access

Obstacle: By law, full access to data in ARCOS is limited to DEA. Distributors do not have access to ARCOS data to aid anti-diversion efforts.

Recommendation:

3. Update the law to require the annual release of ARCOS data to technology stakeholders for the purpose of testing and refining artificial intelligence and machine learning tools and revalidate initial findings with five years' worth of the most recently available data. Provide for daily or near real-time access in order to support the pilot (referenced earlier).

7.3   Data Sharing

Obstacle: Many federal agencies work in silos, often not consistently sharing pertinent information with other federal entities with similar missions or vested interests.

Recommendation:

4. Require the sharing of flagged data across federal agencies to include agencies with anti-diversion policy or law enforcement efforts, to include, but not limited to, the Office of National Drug Control Policy (ONDCP), United States attorneys' offices and High Intensity Drug Trafficking Areas (HIDTA).

7.4   Data Entry/Reporting

Obstacle: Current policy allows for registrants to submit hard copy reports monthly or quarterly to the DEA via mail for manual entry by the DEA into ARCOS, increasing the possibility of errors and contributing to a delay in detecting fraudulent orders by months.

Recommendation:

5. Update the law to require electronic reporting by all DEA registrants.

7.5   Workforce

Obstacle: Workforce challenges could be a barrier for the agency in the timely reviewing of ARCOS data. The additional requirement to integrate the anomaly detection tool into its process would require specialized skills in the field of artificial intelligence/machine learning. Expertise is needed to read and analyze spreadsheets, analyze statistics and develop statistical models of ARCOS data to aid in diversion detection.

Recommendations:

6. Ensure competency for DEA professionals in artificial intelligence/machine learning or data science through workforce development and/or recruiting to support investigations within the agency.

7. Encourage existing DEA investigators within the Diversion Control Division to receive training to effectively read and analyze spreadsheets, analyze statistics and develop statistical models of ARCOS data.

8. Enter into an interagency agreement with National Institute of Standards and Technology (NIST) to utilize its artificial intelligence/machine learning experts until the DEA acquires sufficient in-house expertise to drive the application of data science anomaly detection of illicit opioid trafficking.

7.6   Third Party

Obstacle: We have not identified an existing disinterested organization or institution that can overcome boundaries of protected and proprietary information sharing across pharmaceutical companies (manufacturers and distributors) to leverage the technology to capture data, compare key data against standard orders and trends, and perform cross-industry data sharing, specifically alerting all stakeholders (DEA and industry) of suspicious shipments.

Recommendation:

9. Identify an independent party—working in conjunction with the DEA—to leverage data captured from the tool for analysis and alerting industry of suspicious actors or transactions in the supply chain.

7.7   Funding

Obstacle: Real-time reporting capabilities, which are critical to the successful implementation of the anomaly detection tool, may require upgrades to the technology infrastructure that supports ARCOS, its Electronic Data Interchange (EDI) and the technology for DEA registrants. Funding will need to be allocated to overcome workforce barriers as well.

Recommendations:

10. Appropriate funding from the registration and re-registration fees to cover the cost of upgrading and maintaining the ARCOS infrastructure, including adequate data storage.

11. Appropriate such funding as needed for recruiting and talent development as proposed in recommendations 6 and 7.

7.8   Response Guidance

Obstacle: ARCOS tracks the flow of controlled substances from manufacturing to commercial distribution through to distribution at hospitals, pharmacies, practitioners and teaching institutions. These transactions are captured in summary reports provided to federal and state investigators to identify drug diversion. However, clear guidance is needed on how the DEA should respond when transactions are flagged with the implementation of the anomaly detection tool.

Recommendation:

12. Publish a notice in the Federal Register to solicit comments from the law enforcement community and industry's compliance component on response guidance for suspicious flags.

7.9   Industry Collaboration

Obstacle: Members of the pharmaceutical supply chain desire to and can contribute to the development of policy, business practices and industry guidelines as well as the development of innovative solutions. However, opportunities for industry and government to collaborate in combating the crisis, especially in the supply chain, are almost non-existent.

Recommendation:

13. Establish an industry advisory group made up of manufacturers, distributors, importers, exporters, hospitals and retailers to meet quarterly, and obtain industry perspective and collaboration.

7.10   Oversight

Obstacle: The SUPPORT Act of 2018 required the US Attorney General to submit to Congress a report detailing how it is using ARCOS data to identify and stop suspicious activity. The report was due no later than one year after the law was enacted. GAO delivered a comprehensive report in 2020. However, there is no recurring reporting mechanism or external oversight of ARCOS.

Recommendation:

14. Require DEA to report annually to Congress on the capturing, monitoring and action on ARCOS data, as well as technology challenges, with a focus on evaluating the efficacy of the artificial intelligence/machine learning-driven solution. Include

industry concerns and recommendations, as provided by the industry advisory group.

Share the annual report with other federal, local, state and industry stakeholders.

8   Summation and Conclusions

In the United States, unregulated prescription opioid distribution has sparked a public

health crisis spanning more than 30 years. For those who survive, the price of abusing opioids is

a physical and psychological dependence or health condition called opioid use disorder. When

prescription opioids are hard to obtain, those addicted to opioids often look to illegal channels to

get their fix, leading many down a path of abusing illicit opioids and other drugs.

8.1   Cause

Pharmaceutical companies marketed prescription opioids aggressively in the 1990s,

underplaying their addictive properties to health practitioners and the public. In response,

physicians prescribed opioids in excess, fueling the overconsumption of the analgesic by

patients.

In the supply chain, legal prescription opioids are often diverted into illegal channels and

fall into the hands of the general population.

8.2   Solution

With a focus on data collection and data mining, the Olin Brookings Commission and

CABI demonstrated in their report that new data science technology—machine learning and

artificial intelligence—can detect and flag prescription opioid orders before they are distributed.

When tested against historical ARCOS data, the tool examined the behaviors of known

good and bad registrants, recognized their differences and identified "suspicious buyers" with

51% recall accuracy and 100% precision accuracy—that is, the tool is built to avoid, with 100%

precision, falsely flagging legitimate buyers as diverters.

The anomaly detection tool can be used to detect future fraudulent orders and diversion trends based on real-time data.

To successfully deploy this anomaly detection system, gaps in current policies and programs must be addressed, through legislation or public policy, to:

- Strengthen the DEA by equipping its workforce with the skills needed to analyze and detect diversion trends, to include:

  - Expertise in artificial intelligence and machine learning

  - Expertise to analyze spreadsheets, analyze statistics and develop statistical models of ARCOS data

- Amend the Controlled Substances Act of 1970 to require:

  - Electronic filing into ARCOS by DEA registrants

  - Daily filing into ARCOS by DEA registrants

  - Mandating the sharing of ARCOS data with technology stakeholders to strengthen DEA and ARCOS anti-diversion capabilities

- Upgrade the ARCOS database, its storage and its related interface, if necessary, to allow for:

  - Integration with the anomaly detection tool

  - Near real-time data reporting

- Appropriate funding to support workforce development and technology advances

- Mandate the collaboration between DEA and industry stakeholders on anti-diversion initiatives through the establishment of an advisory group

- Mandate an annual report to Congress detailing efforts to capture, monitor and take action on ARCOS data. The report should denote technology challenges and evaluate the effectiveness of the artificial intelligence.

8.3 Why Adopt Policy Recommendations

Opioid overdoses claim thousands of lives every year. Millions more are addicted to opioids. Along with contributing to deaths and drug dependency, prescription opioid misuse and abuse have an economic impact. The cost of substance abuse treatment, lost productivity from both fatal and non-fatal overdoses, and stress on our criminal justice and healthcare systems is costing the nation tens of billions of dollars annually.

Managing the opioid epidemic at the source—the supply chain—is key to limiting the non-medical use of opioids, thus reducing misuse and abuse.

In addition to opioids, the proposed technology solution and accompanying policy recommendations can also be configured to detect fraudulent orders and diversion trends for many other controlled substances.

By implementing these policies effectively, we can curtail diversion in the supply chain and change the trajectory of overdose dependency and addiction due to prescription opioids.

9   Olin Brookings Commission

The Olin Brookings Commission is a three-year initiative that assembles industry leaders with scholars, policy experts and academics from the Brookings Institution and WashU in St. Louis's Olin Business School. Their goal is to examine ways to better address quality-of-life issues of universal importance.

The Commission's work is underwritten by The Bellwether Foundation Inc., a St. Louis-based charitable organization that supports innovative programs making a positive impact on lives. Each year the Commission will focus on a different matter.

In its first year, a six-member commission is tackling ways to curb the United States' opioid crisis. Focused on questionable opioid transactions within the drug supply chain, the Commission, through its WashU research partners, offers a data-driven solution to identify suspicious opioid orders and presents a series of policy recommendations to support the successful implementation of the solution. WashU Olin's CABI plays an integral role in this year's effort by researching, developing and testing the artificial intelligence and machine learning tool that can detect and flag suspicious opioid sales.

The 2021-22 Commission includes the following members:

- **Anthony Sardella** serves as Commission Chair and is an adjunct professor at WashU's Olin Business School. He is also a senior advisor to CABI. He founded evolve24, a company that focuses on predictive analytics and decision sciences to drive business solutions.

- **The Hon. Mary Bono** is the chairman of the board of directors for Community Anti-Drug Coalitions of America (CADCA). An eight-term congresswoman in the US

House of Representatives, she chaired the Energy and Commerce Committee's Subcommittee on Commerce, Manufacturing and Trade, as well as held other committee assignments. Bono is president and CEO of Integritas, a boutique consulting firm.

- **Dr. Ann Marie Dale** is a professor of medicine and occupational therapy at WashU's School of Medicine. She has more than 30 years of experience in clinical treatment and research in the area of occupational health and safety with a primary focus on injury prevention, epidemiology and health promotion.

- **Van Ingram** is executive director of the Kentucky Office of Drug Control, where he leads the coordination of substance abuse efforts in enforcement, treatment and prevention/education in the state. A former chief of police for the Maysville Kentucky Police Department, Ingram has more than two and a half decades in law enforcement in Kentucky and has been recognized for outstanding and distinguished service.

- **Gina Papush** is the former global chief data and analytics officer for Cigna's Evernorth. Previously, she served as the global chief data and analytics officer at QBE Insurance Group and held leadership positions in data and analytics within the financial services and consulting industries, including Citigroup, GE Capital and Fulcrum Analytics.

- **Darrell M. West**, vice president and director of Governance Studies, holds the Douglas Dillon Chair in Governmental Studies at Brookings Institution. He is also senior fellow for Brookings' Center for Technology Innovation. His current research focuses on American politics, technology policy and artificial intelligence, and he has

authored 25 books, including *Turning Point: Policymaking in the Era of Artificial Intelligence.*

Leading the research for CABI:

- **Seethu Seetharaman** is co-director of CABI. He is also the Patrick McGinnis Professor of Marketing, as well as the academic director of the Master of Science in Customer Analytics (MSCA) program, at the Olin Business School.

- **Michael Wall** is CABI's co-director and professor of practice for marketing and entrepreneurship at WashU. Prior to joining the university, Wall was vice president of digital strategy and solutions architecture for Rise Interactive, a digital marketing firm.

- **Luoyexin (Annie) Shi** is a marketing PhD student at WashU. She was bestowed with a doctoral fellowship at Olin Business School and is expected to matriculate in 2023. Shi's research focus is advertising effectiveness, e-commerce and machine learning in marketing.

- **Chenthuran Abeyakaran** received a Bachelor of Science in computer science in 2021 from WashU and is expected to receive a Master of Science in data analytics and statistics in 2022.

10 T. Ward & Associates

Contributors to this policy paper include:

- **Tamara Ward**, writer/policy analyst/project manager

- **Meghan Cady**, editor

- **Graham I. Haynes**, graphic designer

11 Bibliography

American Medical Association Alliance Inc. 2016. "Prescription Opioid Epidemic: Know the Facts." https://amaa.memberclicks.net/assets/docs/amaa%20opioid%20white%20paper_final_1.17.17.pdf.

American Psychiatric Association. November 2018. "Opioid Use Disorder." https://www.psychiatry.org/patients-families/addiction/opioid-use-disorder.

Barker, Peggy, Jonaki Bose, Joseph Gfroerer, Beth Han, Sarra L. Hedden, Arthur Hughes, Michael Jones, Joel Kennet, Pradip Muhuri, Dicy Painter, et al. September 2011. "Results from the 2010 National Survey on Drug Use and Health: Summary of National Findings." https://www.samhsa.gov/data/sites/default/files/NSDUHNationalFindingsResults2010-web/2k10ResultsRev/NSDUHresultsRev2010.pdf.

Centers for Disease Control and Prevention. August 31, 2018. "2018 Annual Surveillance Report of Drug-Related Risks and Outcomes – United States." Surveillance Special Report. https://www.cdc.gov/drugoverdose/pdf/pubs/2018-cdc-drug-surveillance-report.pdf.

Centers for Disease Control and Prevention. N.d. "Calculating Total Daily Dose of Opioids for Safer Dosage." https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf.

Centers for Disease Control and Prevention. March 24, 2021. "Drug Overdose: Prescription Opioid Overdose Death Maps." https://www.cdc.gov/drugoverdose/deaths/prescription/maps.html.

Centers for Disease Control and Prevention. Last reviewed March 17, 2021. "Drug Overdose: Understanding the Epidemic." https://www.cdc.gov/drugoverdose/epidemic/index.html.

Centers for Disease Control and Prevention. Last reviewed September 5, 2018. "Vital Signs: Opioid Painkiller Prescribing." https://www.cdc.gov/vitalsigns/opioid-prescribing/.

Centers for Disease Control and Prevention. Last reviewed July 6, 2017. "Vital Signs: Opioid Prescribing." https://www.cdc.gov/vitalsigns/opioids/index.html.

Centers for Disease Control and Prevention. Last reviewed August 29, 2017. "Opioids: Prescription Opioids." https://www.cdc.gov/opioids/basics/prescribed.html.

Centers for Disease Control and Prevention WONDER. 2020. National Center for Health Statistics. http://wonder.cdc.gov.

Drug Enforcement Administration. "Administrative Memorandum of Agreement (Appendix A)." Signed with Walgreens in 2011. https://www.dea.gov/sites/default/files/divisions/mia/2013/mia061113_appendixa.pdf.

Drug Enforcement Administration. "The Controlled Substances Act." Accessed March 25, 2022. https://www.dea.gov/drug-information/csa.

Drug Enforcement Administration. "Diversion Control Division." Accessed March 25, 2022. https://www.deadiversion.usdoj.gov/prog_dscrpt/index.html.

Drug Enforcement Administration. "Diversion Control Division: Automation of Reports and Consolidated Orders System (ARCOS)." Accessed March 25, 2022. https://www.deadiversion.usdoj.gov/arcos/index.html.

Drug Enforcement Administration. "Diversion Control Division: Suspicious Orders Report System (SORS)." Accessed March 25, 2022. https://www.deadiversion.usdoj.gov/sors/index.html.

Drug Enforcement Administration. "Our History." Accessed March 25, 2022. https://www.dea.gov/about/history.

Drug Enforcement Administration. "Walgreens Agrees to Pay a Record Settlement of $80 Million for Civil Penalties under the Controlled Substances Act." June 11, 2013. https://www.dea.gov/press-releases/2013/06/11/walgreens-agrees-pay-record-settlement-80-million-civil-penalties-under.

Duff, Johnathan H., Sara M. Tharakan, Carla Y. Davis-Castro, Ada S. Cornell, and Paul D. Romero. June 2, 2021. "Consumption of Prescription Opioids for Pain: A Comparison of Opioid Use in the United States and Other Countries." Congressional Research Service R46805. https://crsreports.congress.gov/product/pdf/R/R46805.

Energy and Commerce Committee. December 19, 2018. *Red Flags and Warning Signs Ignored: Opioid Distribution and Enforcement Concerns in West Virginia.* https://republicans-energycommerce.house.gov/wp-content/uploads/2018/12/Opioid-Distribution-Report-FinalREV.pdf.

Franklin, Gary M. September 29, 2014. "Opioids for Chronic Non-Cancer Pain: A Position Paper of the American Academy of Neurology." https://n.neurology.org/content/83/14/1277/tab-figures-data.

Georgetown Behavioral Health Institute. August 14, 2018. "The Origin and Causes of the Opioid Epidemic." https://www.georgetownbehavioral.com/blog/origin-and-causes-of-opioid-epidemic.

Greenbaum, Kurt. January 4, 2022. "Olin Scholars Create 'Very Valuable' System to Flag Illicit Opioid Transactions." https://olinblog.wustl.edu/2022/01/olin-scholars-create-very-valuable-system-to-flag-illicit-opioid-transactions/.

Guy, Gery P. Jr., Kun Zhang, Michele K. Bohm, Jan Losby, Brian Lewis, Randall Young, Louise B. Murphy, and Deborah Dowell. July 2017. "Vital Signs: Changes in Opioid Prescribing in the United States, 2006-2015." https://pubmed.ncbi.nlm.nih.gov/28683056/.

Healthcare Distribution Alliance. July 24, 2019. "What the ARCOS Data Won't Tell You." https://www.hda.org/news/2019-07-24-fact-check-arcos-data.

Inciardi, James A., Hilary L. Surratt, Steven P. Kurtz, and Theodore J. Cicero. 2007. "Mechanisms of Prescription Drug Diversion Among Drug-Involved Club- and Street-Based Populations." https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2879025/.

Llamas, Michelle. Updated September 24, 2021. "Opioid Lawsuits." https://www.drugwatch.com/opioids/lawsuits/.

Mann, Brian. February 25, 2022. "4 U.S. Companies Will Pay $26 Billion to Settle Claims They Fueled the Opioid Crisis." NPR. https://www.npr.org/2022/02/25/1082901958/opioid-settlement-johnson-26-billion.

Medical News Today. February 6, 2018. "Endorphins: Effects and How to Increase Levels." https://www.medicalnewstoday.com/articles/320839.

National Center for Drug Abuse Statistics. Last updated 2022. "Opioid Epidemic: Addiction Statistics." https://drugabusestatistics.org/opioid-epidemic/.

National Center for Drug Abuse Statistics. Last updated 2022. "Prescription Drug Abuse Statistics." https://drugabusestatistics.org/prescription-drug-abuse-statistics/.

National Conference of Commissioners on Uniform State Laws. 1994. "Diversion Prevention and Control Uniform Controlled Substances Act."

National Drug Strategy Network. October 1996. "Prescription Drug Abuse Rivals Illicit Drug Abuse, Some See Double Standard in Law Enforcement." https://www.ndsn.org/oct96/prescrip.html.

National Institute on Drug Abuse. June 2020. "Misuse of Prescription Drugs Research Report." https://nida.nih.gov/publications/research-reports/misuse-prescription-drugs/what-scope-prescription-drug-misuse.

National Institute on Drug Abuse. January 20, 2022. "Overdose Death Rates." https://nida.nih.gov/drug-topics/trends-statistics/overdose-death-rates.

Nguyen, Thuy, Barbara Andraka-Christou, Kosali Simon, and W. David Bradford. September 2019. "Provider-Directed Marketing May Increase Prescribing of Medications for Opioid Use Disorder." https://pubmed.ncbi.nlm.nih.gov/31370974/.

Office of the Inspector General. Updated in September 2019. *Review of the Drug Enforcement Administration's Regulatory and Enforcement Efforts to Control the Diversion of Opioids.* https://oig.justice.gov/reports/2019/e1905.pdf.

Olin Brookings Commission. Last updated 2022. "The Olin Brookings Commission – Driving Quality of Life." http://olin2013-preview.olin.wustl.edu/EN-US/Faculty-Research/research/olin-brookings-commission/Pages/default.aspx.

Olin Brookings Commission. N.d. "Project Brief: Saving Lives by Detecting Suspicious Opioid Shipments."

Sacco, Lisa N. June 8, 2017. "Economic Aspects of the Opioid Crisis." Statement before Joint Economic Committee, U.S. Joint Committee. Congressional Research Service T810017. https://crsreports.congress.gov/product/pdf/TE/TE10017.

Shi, Annie L., P.B. (Seethu) Seetharaman, Anthony Sardella, Michael Wall, and Chenthuran Abeyakaran. December 1, 2021. *"Nip it in the Bud!" Managing the Opioid Crisis: Supply Chain Response to Anomalous Buyer Behavior.*

Taylor, Dean Mark. April 7, 2021. "Bellwether Grant Sparks New Olin-Brookings Initiative Focused on Opioid Epidemic."

United States Department of Justice. Updated February 10, 2022. "Opioid Facts." https://www.justice.gov/opioidawareness/opioid-facts.

United States Department of Health and Human Services. October 26, 2017. "HHS Acting Secretary Declares Public Health Emergency to Address National Opioid Crisis." www.hhs.gov/about/news/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-address-national-opioid-crisis.html.

United States Government Accountability Office. January 2020. *Drug Control: Actions Needed to Ensure Usefulness of Data on Suspicious Opioid Orders.* Report to Congressional Committees. https://www.gao.gov/assets/gao-20-118.pdf.

WashU Olin Business School. Presented August 19, 2021, at WashU Brookings Commission Meeting. "Saving Lives by Detecting Suspicious Opioid Shipments."

WashU Olin Business School. Presented January 18, 2022, at Olin Brookings Commission Meeting. "Opioid Research Study Policy Discussion."

Appendix A.   Olin Brookings Commission Resource Links

- ["Nip it in the Bud!" Managing the Opioid Crisis: Supply Chain Response to Anomalous Buyer Behavior](#)

- [Olin Scholars Create 'Very Valuable' System to Flag Illicit Opioid Transactions](#)

- [Olin Researchers Using Machine Learning to Flag Suspicious Opioid Sales](#)

- [Bellwether Grant Sparks New Olin Brookings Initiative Focused on Opioid Epidemic](#)

- [Olin-Brookings Initiative to Address Opioid Epidemic](#) (*The Source*, Washington University in St. Louis)

Appendix B.   Acknowledgments

The 2021-22 Olin Brookings Commission would like to acknowledge the generosity of Ginger Smith and The Bellwether Foundation, as well as the contributions of Olin Dean Mark P. Taylor; the WashU Olin Marketing & Communications team; the Brookings Institution; Katie Cannady; Tamara Ward; Graham Haynes; and Meghan Cady.

In addition, the editorial team would like to acknowledge Scott Collier, director of controlled substances compliance at Mallinckrodt Pharmaceuticals and former DEA diversion control manager; Joel Dunn, lead controlled substances compliance consultant at Mallinckrodt Pharmaceuticals and former DEA diversion group supervisor and investigator; and Allison Ivie, vice president of Center Road Solutions and former director of strategic planning and research at Audrey Sheppard Women's Health Consulting.

Appendix C.   Glossary of Terms

Term	Definition
Algorithm	A process or set of rules to be followed in calculations or other problem-solving operations, especially by a computer
ARCOS	Automation of Reports and Consolidated Orders System
APA	American Psychiatric Association
Artificial intelligence	Development of computer systems able to perform tasks that normally require human intelligence, such as visual perception, speech recognition, decision-making and translation between languages
CABI	Center for Analytics and Business Insights
CADCA	Community Anti-Drug Coalitions of America
CDC	Centers for Disease Control and Prevention
Data mining	The practice of analyzing large databases in order to generate new information
Data science	The use of scientific methods to obtain useful information from computer data, especially large amounts of data
DEA	Drug Enforcement Administration
DOJ	Department of Justice
EDI	Electronic Data Interchange
GAO	Government Accountability Office
HDA	Healthcare Distribution Alliance
HIDTA	High Intensity Drug Trafficking Area
Machine learning	The use and development of computer systems that are able to learn and adapt without following explicit instructions by using algorithms and statistical models to analyze and draw inferences from patterns in data
MME	Morphine Milligram Equivalents
MSCA	Master of Science in Customer Analytics
NCDAS	National Center for Drug Abuse Statistics
NIDA	National Institute on Drug Abuse
NIST	National Institute of Standards and Technology
ONDCP	Office of National Drug Control Policy
SORS	Suspicious Orders Report System
SUPPORT Act	Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act
WashU	Washington University

OLIN BROOKINGS COMMISSION

Tackling the U.S. Opioid Crisis:
A Data-Driven Solution and Policy
Recommendations

The opioid epidemic has spanned more than 30 years and claimed more than half a million people in the United States. Prescription opioid overdose deaths more than quadrupled from 1999 to 2019 alone, with more than 247,000 people dying.

All Opioids
Synthetic Opioids
Prescription Opioids

70,000
60,000
50,000
40,000
30,000
20,000
10,000

1999   **NUMBER OF OVERDOSE DEATHS FROM 1999 TO 2020**   2020

What is the problem?

One contributor: the diversion of prescription opioids from legitimate use. The majority of misused prescription opioids in the United States have been prescribed for a legitimate use and then diverted for unlawful use in communities. Often, they are diverted into illegal channels through the legal supply chain.
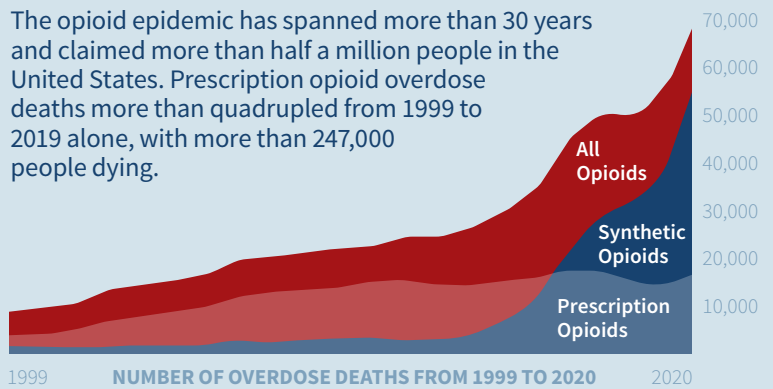
Limitations of Current Policies

- Five decades ago, the policies that largely govern how the government tackles the opioid crisis today were established.
- Drug Enforcement Administration (DEA) standardized Automation of Reports and Consolidated Orders System (ARCOS) reporting in the late 1970s.
- DEA has been accused of failing to act on valuable information within its database, but ARCOS was not designed to conduct real-time analysis.
- Registrants are allowed to file reports in paper form and can submit reports every three months.
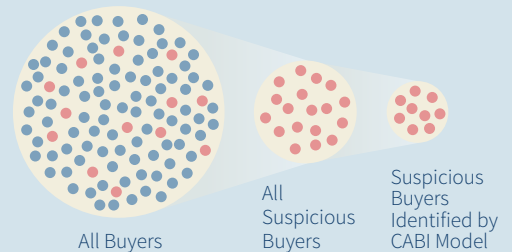- Access to ARCOS data is limited.

Opportunity to Improve on Current Policies

New advanced data science tools can be leveraged to stop suspicious opioid orders at the source. Olin's Center for Analytics and Business Insights (CABI) designed a tool to flag and stop suspicious opioid shipments. The researchers trained a detection tool using historical data from ARCOS.

CABI mined the datasets and created a predictive capability to differentiate legitimate versus suspicious buyer activity. The result is an anomaly detection tool capable of flagging future suspicious buyers with 51% recall accuracy and 100% precision accuracy. This yields high confidence that flagged buyers are suspicious without creating "false positives."

51% likelihood the model will catch suspicious buyers

100% likelihood that those caught are suspicious buyers

All Buyers

All Suspicious Buyers

Suspicious Buyers Identified by CABI Model

Olin Brookings Commission's Policy Recommendations

- Establish pilot for anomaly detection tool.
- Modernize ARCOS technology infrastructure for near-real-time data entry by registrants.
- Require annual release of ARCOS data to revalidate findings.
- Share data across federal agencies with anti-diversion policies or law enforcement efforts.
- Require electronic reporting by all DEA registrants.

- Ensure DEA has expertise in artificial intelligence, data science, statistical analysis and ARCOS data models.
- Fund registration, upgrades and maintenance of ARCOS infrastructure, recruiting and talent development.
- Solicit comments from the law enforcement and compliance component on response guidance for suspicious flags.
- Report to Congress on ARCOS data; evaluate the efficacy of the artificial intelligence/machine learning-driven solution.
- Build partnerships between government and industry.

Washington University in St. Louis
OLIN BUSINESS SCHOOL

BROOKINGS

Bellwether
FOUNDATION

Find the Olin Brookings Commission's full report online at **olin.wustl.edu/obcommission**