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A Prescription for Crisis: Opioids, Patients, and the Controlled Substances Act

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A PRESCRIPTION FOR CRISIS: OPIOIDS, PATIENTS, AND THE CONTROLLED SUBSTANCES ACT

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I. INTRODUCTION

The opioid crisis is one that continues to astonish the public.[1] From the lack of accountability, poor government oversight, inconsistent enforcement, and an all-out failure to bring it to a head, the crisis is a never-ending disaster seemingly playing on loop.[2] The question that experts ask and fail to answer is what remedies courts should consider in future settlements beyond monetary damages and whether the suggested remedies

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[1] *See generally* Cobin D. Soelberg, Raeford E. Brown, Derick Du Vivier, John E. Meyer & Banu K. Ramachandran, *The US Opioid Crisis: Current Federal and State Legal Issues*, 125 ANESTHESIA & ANALGESIA 1675 (2017).

[2] *See id.*; *see also* ENERGY & COMMERCE COMM. MAJORITY STAFF REP., 115TH CONG., RED FLAGS AND WARNING SIGNS IGNORED: OPIOID DISTRIBUTION AND ENFORCEMENT CONCERNS IN WEST VIRGINIA 6 (2018) [hereinafter W. VA. RED FLAGS REPORT].

would help in preventing a recurrence of another opioid-type public health crisis. While this question is important and deserves an answer, it is not the correct question that needs to be asked presently.

As the adage goes, "a bad tree does not yield good apples." As such, experts should first ask why the opioid crisis has been able to grow at an alarming rate since the introduction of Purdue's OxyContin in 1995 and continues to grow twenty-seven years later.[3] Only after answering this initial question can the question of what can be done to prevent another opioid-type public health crisis be answered permanently. While it is hard to grasp such a large-scale failure with multiple facets needing to be looked at and evaluated, the opioid crisis is the epitome of the "Pareto Principle,"[4] and the resolution of one cog, which in this case is the Controlled Substances Act itself and its enforcement, will create a resolution to the opioid epidemic itself.[5]

II. A BRIEF OVERVIEW OF THE OPIOID EPIDEMIC

Since the Drug Enforcement Administration's ("DEA") founding in 1973, its sole purpose is to enforce controlled substances laws.[6] As of 2019, the DEA had a workforce of 4,924 special agents and 5,245 support staff for a total of 10,169 employees with a budget of $3.17 billion dollars.[7] While the employee breakdown distinguishes special agents and support staff, it does not break it down further by job function.[8] As such, some may be janitors, secretaries, assistants, analysts, supervisors, etc. who are required to do many other jobs than just ensuring compliance by opioid manufacturers.[9] As of 2019, there were 1,840,501 registrants[10] that the DEA oversees, and this number continues to grow at an estimated three percent annually.[11] To

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[3] *See infra* Part II.

[4] The "Pareto Principle," also known as the 80/20 Rule, assumes that eighty percent of all effects are caused by twenty percent of the causes. *What Is the Pareto Principle? Definition and Meaning*, MKT. BUS. NEWS, https://marketbusinessnews.com/financial-glossary/pareto-principle/ [https://perma.cc/854H-Q4NR].

[5] *See infra* Part III.

[6] *Mission*, U.S. DRUG ENF'T ADMIN., https://www.dea.gov/about/mission [https://perma.cc/YD38-SAWF].

[7] *Staffing and Budget*, U.S. DRUG ENF'T ADMIN., https://www.dea.gov/data-and-statistics/staffing-and-budget [https://perma.cc/KN53-4JMK] [hereinafter *Staffing and Budget*]. Between the introduction of OxyContin in 1995 and 2019, the DEA budget has more than tripled from $1.001 billion to $3.17 billion. *Id.*

[8] *See id.*

[9] *See id.*

[10] DEA "registrants" refers to those involved with manufacturing, distributing, dispensing, importing, exporting, or handling controlled substances, and requires registration and approval from the DEA. *See* DRUG ENF'T ADMIN, U.S. DEP'T OF JUST., DRUGS OF ABUSE: A DEA RESOURCE GUIDE 11 (2020).

[11] *See* Registration & Reregistration Fees for Controlled Substance and List I Chemical Registrants, 85 Fed. Reg. 14810, 14815 (Mar. 16, 2020) (to be codified at 21 C.F.R. pt. 1301) ("Currently, the [DEA's Diversion Control Program] regulates over 1.8 million registrants.

put these numbers into perspective, for every single DEA employee, there are 181.31 registrants.[12] If each employee were to do nothing but oversee the registrants, that would allow for 13.2 minutes per week on each registrant.[13] The numbers clearly show that the disparity between the number of DEA employees and registrants is negligent at best.[14] More realistically, it is a wanton disregard for the safety and health of those they claim to protect.[15]

While the DEA is tasked with enforcement of the controlled substance laws and regulations,[16] the Food and Drug Administration ("FDA") is tasked with ensuring that only drugs and devices proven to be safe and effective are approved for sale and marketing to specific target groups.[17] However, looking at the FDA's "Timeline of Selected FDA Activities and Significant Events Addressing Opioid Misuse and Abuse," it is apparent that while the FDA was aware of the ongoing public health crisis, it chose to aid and abet the DEA's wanton disregard by failing to address the opioid crisis through action. Rather than halting the approval process for new opioids until the epidemic could come under control, the FDA chose to continue approving while holding public meetings to discuss the public health crisis posed by opioids.[18] The following briefly outlines selected FDA activities and significant events addressing opioids.

From 1911 to the 1990s, the primary use of opioid medications was for the treatment of acute pain in cancer patients.[19] In 1987, MS Contin was approved and became the first opioid pain medication formulation that allowed dosing every twelve hours instead of every four to six hours.[20] Duragesic, the first opioid pain medication in the form of a patch, which allowed it to be changed every three days, was approved in 1990.[21] OxyContin was approved in December 1995, which was marketed as a less addictive opioid due to its believed "controlled-release" formula.[22] In 1998, Actiq (fentanyl) was approved as the first pain medication to treat cancer

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DEA's regulated industry increases approximately 3 percent per year annually. It is estimated that there will be over 2 million registrants by 2023.") [hereinafter Registration & Registration Fees].

[12] *See id.*; *Staffing and Budget*, *supra* note 7.

[13] *See* Registration & Registration Fees, *supra* note 11; *Staffing and Budget*, *supra* note 7.

[14] *See* Registration & Registration Fees, *supra* note 11; *Staffing and Budget*, *supra* note 7.

[15] *See* Registration & Registration Fees, *supra* note 11; *Staffing and Budget*, *supra* note 7.

[16] *Mission*, *supra* note 6.

[17] *What We Do*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/about-fda/what-we-do [https://perma.cc/5W8S-FAXG].

[18] *Timeline of Selected FDA Activities and Significant Events Addressing Opioid Misuse and Abuse*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/media/126835/download [https://perma.cc/2C6X-AJG2] (Mar. 30, 2021) [hereinafter *Timeline of Selected FDA Activities*].

[19] *Id.*

[20] *Id.*

[21] *Id.*

[22] *Id.*; *OxyContin: Balancing Risks and Benefits: Hearing of the Committee on Health, Educ., Lab., and Pensions*, 107th Cong. 77–770 (2002) (statement of Sen. Jack Reed).

breakthrough pain.[23] In the early 2000s, reported opioid overdose deaths rose significantly and the number of people admitting using OxyContin recreationally increased from 400,000 in 1999 to a staggering 2.8 million people in 2003.[24]

In 2001, additional warnings were added to the label of OxyContin, pointing out the potential for misuse and abuse.[25] By January 2003, the FDA issued a warning letter to Purdue Pharma for misleading advertisements.[26] In 2006, Fentora (fentanyl buccal) was approved.[27] Purdue Pharma and three of its executives pled guilty and paid a fine of $634 million for lying about the addictiveness of OxyContin in 2007.[28] Then in 2009, Onsolis (fentanyl) and Embeda (morphine sulfate and naltrexone) were approved.[29] Additionally, in 2009, the FDA held a stakeholder meeting to ask for help developing an effective opioid Risk Evaluation Mitigation Strategies ("REMS") program with the Industry Working Group ("IWG"), which consisted of pharmaceutical representatives from twenty-two companies.[30]

> A significant percentage of deaths and overdose from opioids, especially from ER/LA opioids, results from theft of pain medicine from medicine cabinets and accidental exposure to the drugs. Since 2009, FDA has worked with DEA and other organizations to help educate the public on safe disposal of

[23] *Timeline of Selected FDA Activities*, *supra* note 18; *Highlights of Prescribing Information*, U.S. FOOD & DRUG ADMIN. (Dec. 2016), https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020747s043s044lbl.pdf [https://perma.cc/8E8G-Z3QS] (Actiq).

[24] *Timeline of Selected FDA Activities*, *supra* note 18.

[25] *Id.*

[26] *Id.*

[27] *Id.*

[28] This was the first settlement regarding Purdue Pharma's deceitful and illegal marketing of its drug OxyContin. Barry Meier, *In Guilty Plea, OxyContin Maker to Pay $600 Million*, N.Y. TIMES (May 10, 2007), https://www.nytimes.com/2007/05/10/business/11drug-web.html [https://perma.cc/Q4YX-GXUY]. Another was in 2020 for $8.3 billion and included pleading guilty to three felony criminal charges, including conspiracy to defraud the United States and violate anti-kickback laws. Brian Mann, *Federal Judge Approves Landmark $8.3 Billion Purdue Pharma Opioid Settlement*, NPR NEWS (Nov. 17, 2020), https://www.npr.org/2020/11/17/936022386/federal-judge-approves-landmark-8-3-billion-purdue-pharma-opioid-settlement [https://perma.cc/AG6L-VSQA]. The most recent settlement was approved in 2022 for $6 billion. Lauren del Valle, *A US Bankruptcy Judge Approved Purdue Pharma and Sacklers' $6 Billion Settlement Agreement with States, Connecticut AG Says*, CNN (Mar. 10, 2022), https://www.cnn.com/2022/03/09/us/us-bankruptcy-judge-approves-purdue-pharma-sacklers-settlement/index.html [https://perma.cc/9N6J-PMBL].

[29] *Timeline of Selected FDA Activities*, *supra* note 18; *Highlights of Prescribing Information*, U.S. FOOD & DRUG ADMIN. (Dec. 2016) https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/022266s017s018lbl.pdf [https://perma.cc/A8C7-2LXK] (Onsolis); *Medication Guide*, U.S. FOOD & DRUG ADMIN. (Apr. 2014), https://www.fda.gov/media/77512/download [https://perma.cc/4KYD-6ALA] (Embeda).

[30] *Timeline of Selected FDA Activities*, *supra* note 18

opioids when they are no longer needed for pain.[31]

In 2010, the FDA approved a new formulation of Purdue's OxyContin, which caused the medication to change into a gummy consistency if an abuser attempted to crush it.[32] Three additional medications were approved in 2011 by the FDA, including Abstral (fentanyl), Oxecta (oxycodone hydrochloride), and Lazanda (fentanyl).[33] The FDA approved Subsys (fentanyl sublingual spray) in 2012.[34] During the 2013 calendar year, drugs containing hydrocodone were rescheduled from a Schedule III to a Schedule II controlled substance.[35] Throughout 2014, the FDA approved Evzio (naloxone), Targiniq ER (oxycodone hydrochloride and naloxone hydrochloride), and Hysingla ER (hydrocodone bitartrate).[36]

The FDA approved OxyContin (oxycodone) for use on certain pediatric patients in 2015.[37] During November 2015, the FDA approved MorphaBond (morphine sulfate) and Narcan nasal spray (naloxone).[38] In 2016, Xtampza ER (oxycodone), Probuphine (buprenorphine), and Troxyca ER (oxycodone hydrochloride and naltrexone hydrochloride) were approved.[39] In 2017, Arymo ER (morphine sulfate), Vantrela ER (hydrocodone bitartrate), and RoxyBond (oxycodone hydrochloride) were approved.[40] The FDA approved the first generic version of Suboxone (buprenorphine and naloxone) and the first oral Sufentanil pain medication in 2018.[41] On September 20, 2019, the FDA issued a statement on the agency's continued efforts to increase the availability of all forms of naloxone in the attempt to reduce overdose deaths.[42] Olinvyk (oliceridine)

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[31] *Id.*
[32] *Id.*
[33] *Id.*
[34] *Id.*; *Onsolis*, DRUGS.COM (Jan. 17, 2022), https://www.drugs.com/onsolis.html#:~:text=Onsolis%20was%20discontinued%20in%20July%202011.&text=The%20Onsolis%20brand%20name%20has,may%20be%20generic%20equivalents%20available [https://perma.cc/WW84-5YNZ].
[35] *Timeline of Selected FDA Activities*, *supra* note 18.
[36] *Id.*
[37] *Id.*
[38] *Id.*
[39] *Id.*
[40] *Id.*
[41] *FDA Approves First Generic Versions of Suboxone Sublingual Film, Which May Increase Access to Treatment for Opioid Dependence*, U.S. FOOD & DRUG ADMIN. (June 14, 2018), https://www.fda.gov/news-events/press-announcements/fda-approves-first-generic-versions-suboxone-sublingual-film-which-may-increase-access-treatment [https://perma.cc/NNG5-H4HS].
[42] Norman E. Sharpless, *Statement on Continued Efforts to Increase Availability of All Forms of Naloxone to Help Reduce Opioid Overdose Deaths*, U.S. FOOD & DRUG ADMIN. (Sept. 20, 2019), https://www.fda.gov/news-events/press-announcements/statement-continued-efforts-increase-availability-all-forms-naloxone-help-reduce-opioid-overdose [https://perma.cc/9VYT-8WWG].

was approved in 2020.[43] Then, by March 2021, the FDA approved Hydrocodone bitartrate.[44]

Combining an overwhelmed DEA tasked to enforce the fundamentally flawed Controlled Substances Act of 1970 ("CSA") with the FDA's continuous approval of highly addictive opioids since 1987, paints a horrific picture: 10.1 million people admitting to misusing prescription opioids in 2019.[45] Of the 10.1 million people, 1.6 million misused prescription pain relievers for the first time.[46] Additionally, 1.6 million people admitted to having an opioid disorder between 2019 and 2020.[47] Since it has become more difficult for patients, both legitimate users and abusers to obtain opioids, the number of illicit drug users has risen.[48] As such, 2 million people admitted to using methamphetamine in 2019, while 745,000 people admitted to using heroin.[49] Of those 745,000 heroin users, 50,000 admitted it was their first time.[50] With all of these opioid users, it comes as a sad but not surprising realization that of the 70,630 people who died in 2019 from a drug overdose,[51] 48,006 were attributed to overdosing on synthetic opioids other than methadone and 14,480 deaths were attributed to overdosing on heroin.[52]

With such disturbing numbers all around, it is disheartening that legislators, regulators, and experts failed to address the root cause of the epidemic and continue to wonder how they can resolve the crisis through the judicial system with only the patient, public, and private businesses on trial. This Paper will evaluate the foundation on which the crisis is built and

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[43] *Timeline of Selected FDA Activities*, *supra* note 18.

[44] *Id.*; *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations*, U.S. FOOD & DRUG ADMIN., https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=A&Appl_No=208269#348 [https://perma.cc/5QB9-WXZ2].

[45] *See* SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., KEY SUBSTANCE USE AND MENTAL HEALTH INDICATORS IN THE UNITED STATES: RESULTS FROM THE 2019 NATIONAL SURVEY ON DRUG USE AND HEALTH (2020), https://www.samhsa.gov/data/sites/default/files/reports/rpt29393/2019NSDUHFFRPDFWHTML/2019NSDUHFFR090120.htm [https://perma.cc/9H5W-6ZYW].

[46] *Id.* at 60.

[47] *Id.* at 40.

[48] *Id.*

[49] *See* SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., *supra* note 45.

[50] *Id.*

[51] "In 2019, 70,630 drug overdose deaths occurred in the United States for an age-adjusted rate of 21.6 per 100,000 standard population." Holly Hedegaard, Arialdi M. Miniño & Margaret Warner, *Drug Overdose Deaths in the United States*, 1999–2019, CTRS. FOR DISEASE CONTROL & PREVENTION (Dec. 2020), https://www.cdc.gov/nchs/products/databriefs/db394.htm [https://perma.cc/SG3A-F3R6].

[52] *See The Opioid Epidemic by the Numbers*, U.S. HEALTH & HUM. SERVS. (Feb. 2021), https://www.hhs.gov/opioids/sites/default/files/2021-02/opioids-infographic.pdf [https://perma.cc/A4XM-UZYH] (providing statistics from the 2019 National Survey on Drug Use and Health, 2020 and the National Center for Health Statistics' National Vital Statistics System, Provisional Drug Overdose Death Counts).

work to resolve the single cog in this "Pareto Principle"[53] issue known as the Controlled Substances Act.

A. Current Foundation of Opioid Oversight

During the 1960s, fear of illicit drug use, both domestically and by soldiers serving overseas in the Vietnam War, heavily increased.[54] Along with the fear of drug use, civil disobedience was a hot topic, as many opposed the United States' involvement in the Vietnam War, which created the perfect platform for President Nixon to run on.[55] "Law and Order" and the "War on Drugs" were ideas that most of society could get behind and in turn, assisted with getting Nixon elected to the office of the president.[56] To make good on promises of tackling the surge in drug use, the 91st United States Congress enacted the Comprehensive Drug Abuse Prevention and Control Act of 1970 ("CDAPCA").[57] Title II of the CDAPCA established what is known as the Controlled Substances Act ("CSA").[58]

1. The Controlled Substances Act

In June 1971, President Nixon stated that drug abuse was "public enemy number one" and officially declared a "war on drugs."[59] To ensure that the CSA was enforced, Nixon went on to create the DEA on July 1, 1973.[60] While it is reasonable to believe the government has the best interest of the public in mind when passing laws, the real purpose may be more despicable.[61] No government official has been more truthful than Ronald

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[53] *See* MKT. BUS. NEWS, *supra* note 4 and accompanying text.

[54] Adam Janos, *G.I.'s Drug Use in Vietnam Soared—with Their Commanders' Help*, HISTORY (Aug. 29, 2018), https://www.history.com/news/drug-use-in-vietnam [https://perma.cc/YB26-ADS4].

[55] *See* Emily Dufton, *The War on Drugs: How President Nixon Tied Addiction to Crime*, ATLANTIC (Mar. 26, 2012), https://www.theatlantic.com/health/archive/2012/03/the-war-on-drugs-how-president-nixon-tied-addiction-to-crime/254319/ [https://perma.cc/4NL9-CD8V].

[56] *See id.*

[57] *See* Comprehensive Drug Abuse Prevention & Control Act of 1970, Pub. L. 91-513, 84 Stat. 1236 (1970).

[58] *See id; See also* 21 U.S.C. § 801.

[59] Chris Barber, *Public Enemy Number One: A Pragmatic Approach to America's Drug Problem*, RICHARD NIXON FOUND. (June 29, 2016), https://www.nixonfoundation.org/2016/06/26404/ [https://perma.cc/ET9V-7YCN].

[60] *See* Exec. Order No. 11,727, 38 Fed. Reg. 18,357 (July 6, 1973).

[61] Tom LoBianco, *Report: Aide Says Nixon's War on Drugs Targeted Blacks, Hippies*, CNN (Mar. 24, 2016), https://www.cnn.com/2016/03/23/politics/john-ehrlichman-richard-nixon-drug-war-blacks-hippie/index.html [https://perma.cc/6DT5-GPUG].

> You want to know what this was really all about? The Nixon campaign in 1968, and the Nixon White House after that, had two enemies: the antiwar left and black people. You understand what I'm saying? We knew we couldn't make it

Reagan in his August 12, 1986 speech when he stated, "The nine most terrifying words in the English language are: I'm from the government, and I'm here to help."[62]

Although amended numerous times, the CSA established the classification system for controlled substances and the general controls that pertain to each schedule.[63] Currently, five schedules of controlled substances have been established known as Schedules I, II, III, IV, and V.[64] These controlled substances are scheduled based upon three factors: their abuse potential, accepted medical applications in the United States, and their safety and potential for addiction.[65] Regardless of their classification, scheduled drugs need additional controls regarding the manufacture, dispensing, distribution, and prescribing to protect the public.[66]

Schedule I products are defined as a drug or other substances with a high potential for abuse, that currently have no accepted medical use in treatment in the United States, and that lack an accepted safety for use of the drug or other substance under medical supervision.[67] Examples of a Schedule I substance are heroin, LSD, marijuana, MDMA, and ecstasy.[68]

Schedule II products are defined as a drug or other substance with a high potential for abuse, which does have an accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions, with abuse potentially leading to severe psychological or

> illegal to be either against the war or black, but by getting the public to associate the hippies with marijuana and blacks with heroin, and then criminalizing both heavily, we could disrupt those communities. We could arrest their leaders, raid their homes, break up their meetings, and vilify them night after night on the evening news. Did we know we were lying about the drugs? Of course, we did.

Dan Baum, *Legalize It All*, HARPER'S MAG. (Apr. 2016), https://harpers.org/archive/2016/04/legalize-it-all/ [https://perma.cc/P6JW-RFZY].

[62] *See Reagan Quotes & Speeches*, RONALD REAGAN PRESIDENTIAL FOUND. & INST., https://www.reaganfoundation.org/ronald-reagan/reagan-quotes-speeches/news-conference-1/ [https://perma.cc/3VWV-38M3].

[63] *See* 21 U.S.C. § 812(b), (c). The Controlled Substances Act defines an opioid as "any drug or other substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability." 21 U.S.C. § 802(18).

[64] *See* 21 U.S.C. § 812(a) ("Such schedules shall initially consist of the substances listed in this section. The schedules established by this section shall be updated and republished on a semiannual basis during the two-year period beginning one year after October 27, 1970 and shall be updated and republished on an annual basis thereafter.").

[65] *See* 21 U.S.C. § 812(b)(1)–(5) ("Except where control is required by United States obligations under an international treaty, convention, or protocol, in effect on October 27, 1970, and except in the case of an immediate precursor, a drug or other substance may not be placed in any schedule unless the findings required for such schedule are made with respect to such drug or other substance.").

[66] *See, e.g.*, U.S. DEP'T OF JUST., DIVERSION INVESTIGATOR'S MANUAL § 5126 (1996).

[67] *See* 21 U.S.C. § 812(b)(1).

[68] *Controlled Substance Schedules*, U.S. DRUG ENF'T ADMIN., https://www.deadiversion.usdoj.gov/schedules/ [https://perma.cc/77CV-EM6B].

physical dependence.[69] Examples of Schedule II substances are Oxycodone, Fentanyl, Morphine, and Hydrocodone.[70]

Schedule III products are defined as a drug or other substances with a potential for abuse less than drugs in Schedule I and II, and that have an accepted medical use in treatment in the United States, with abuse potentially leading to moderate psychological or physical dependence.[71] Although Schedule III drugs and products are considered less dangerous than Schedule II, it is important to keep in mind that they are potent substances, which require additional controls mandated by the CSA to prevent diversion and misuse.[72] Examples of Schedule III substances are ketamine, Tylenol with codeine, Suboxone, and Tridal.[73]

Schedule IV products are defined as a drug or other substance with a low potential for abuse relative to Schedule III drugs, and that have an accepted medical use in treatment in the United States, with abuse potentially leading to limited psychological or physical dependence relative to Schedule III drugs.[74] Examples of Schedule IV substances are Xanax, Soma, and Ambien.[75]

Schedule V substances are: drugs with a low potential for abuse relative to Schedule IV; have an accepted medical use in treatment in the United States; and whose abuse can potentially lead to limited psychological or physical dependence relative to Schedule IV drugs.[76] Examples of Schedule V substances are Lomotil and Lyrica.[77]

Additionally, the CSA requires that all major participants in the controlled substance supply chain (manufacturers, distributors, dispensers, and prescribers) be registered, thus creating the so-called "closed system."[78] It further defines the basic controls expected of both manufacturers and distributors.[79] A critical condition for granting and maintaining a manufacturer or distributor's registration is the "maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels."[80] The failure of any registrant "to refuse or negligently fail to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or

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[69] *See* 21 U.S.C. § 812(b)(2).

[70] *Drug Scheduling*, U.S. DRUG ENF'T ADMIN., https://www.dea.gov/drug-information/drug-scheduling [https://perma.cc/HB8L-V55E].

[71] *See* 21 U.S.C. § 812(b)(3).

[72] *Drug Scheduling*, U.S. DRUG ENF'T ADMIN., *supra* note 70.

[73] *Id.*; *Controlled Substances*, DEA DIVERSION (Nov. 18, 2021), https://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf [https://perma.cc/2K84-WVJQ].

[74] *See* 21 U.S.C. § 812(b)(4).

[75] *See Drug Scheduling*, *supra* note 70.

[76] *See* 21 U.S.C. § 812(b)(5).

[77] *See Drug Scheduling*, *supra* note 70.

[78] 21 C.F.R. § 1306 (2010).

[79] *Id.*

[80] 21 U.S.C. § 823(e)(1); *see also* 21 U.S.C. § 823(a)(1), (b)(1) (governing manufacturers and distributors respectively).

information required" by the CSA is a criminal offense.[81]

The Code of Federal Regulations establishes a series of steps that manufacturers and distributors are required to institute, including the following:

> Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry either with the Administration or with the appropriate State controlled substances registration agency, if any, to determine that the person is registered to possess the controlled substance.[82]

Next, "design and operate a Suspicious Order Monitoring ("SOM") system to disclose to the registrant suspicious orders of controlled substances, and "inform the Field Division Office of the Administration of suspicious orders when discovered."[83] Then, "[n]otify the Field Division Office of the Administration . . . in writing, of any theft or significant loss of any controlled substances within one business day of discovery of the theft or loss."[84] Finally, ensure any common carriers used in the supply chain have sufficient security measures in place to prevent losses during transit.[85]

2. Amendments & Safeguards to the Controlled Substances Act

a. The Chemical Diversion & Trafficking Act

In 1988, the CSA was amended to include the Chemical Diversion and Trafficking Act ("CDTA").[86] The CDTA helps to provide a system of controls and criminal penalties with regard to domestic and international diversion.[87] This is done without the interruption of access to the chemicals required for legitimate commerce.[88] Additionally, the CDTA defines precursor chemicals, which include N-Acetylanthranilic acid, Anthranilic acid, Ergotamine tartrate, Ergonovine maleate, Phenylacetic acid, Ephedrine, Pseudoephedrine, Benzyl cyanide, Benzyl chloride, and Piperidine.[89] Alternatively, essential chemicals include Potassium permanganate, Acetic anhydride, Acetone, and Ethyl ether.[90]

Further, the Act established a mechanism and criteria for adding or

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[81] *See* 21 U.S.C. § 842(a)(5).
[82] *See* 21 C.F.R. § 1301.74(a).
[83] *See id.*; *see also* Masters Pharm., Inc. v. DEA, 861 F.3d 206 (D.C. Cir. 2017); 21 C.F.R. § 1301.74(b) ("Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.").
[84] 21 C.F.R. § 1301.74(c).
[85] *See id.* at § 1301.74(e).
[86] 21 U.S.C. 801.
[87] *See id.*
[88] *See id.*
[89] *Id.*
[90] *Id.*

deleting chemicals from such lists.[91] In turn, criminal penalties result from the following unlawful conduct: (1) possession, manufacture, distribution, sale, importation, or exportation of a precursor or essential chemical, and (2) possession, manufacture, distribution, or importation of drug manufacturing equipment, tableting or encapsulating machines, and gelatin capsules.[92]

b. The Chemical Handler's Manual

To provide guidance regarding the amended CSA and the passage of additional chemical control laws, the DEA created the Chemical Handler's Manual ("CHM").[93] The 2004 edition of the CHM stated,

> when a regulated person suspects that an order may be intended for illicit purposes, good practice requires that every reasonable effort be made to resolve those suspicious. In addition to making the required reports, the transaction should not be completed until the customer is able to eliminate the suspicions. The distributor may have to forego some transactions.[94]

Appendix E-3 of the CHM described a "voluntary formula" to be used by distributors to wholesale and retail levels.[95] The formula calculated the quantity which, if exceeded in one month, constitutes an order which may be considered excessive or suspicious and therefore requires reporting to DEA.[96]

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[91] *Id.*

[92] *Id.*

[93] *See* Karen P. Tandy, Laura M. Nagel & Patricia M. Good, *Chemical Handler's Manual*, U.S. DEP'T JUST. (Jan. 2004), https://www.justice.gov/sites/default/files/open/legacy/2014/05/09/2004-chemical-handlers-manual.pdf [https://perma.cc/2Q3Y-5RNQ]; *see also* Expert Report of Dr. Seth B. Whitelaw ¶ 5.3, In re National Prescription Opiate Litigation, No. 18-OP-451321 (N.D. Ohio Apr. 15, 2019).

[94] *See* Tandy et al., *supra* note 93, at 19.

[95] *See id.* at 41.

[96] *Id.*

> 1. Add purchase quantities for the last 12 months for all customers within same Distribution Center and for customer type (Hospital, Pharmacy or Other) for any List I chemical containing item stocked by the Distribution Center.
>
> 2. Add Customer months for every record used in above total. (Months within the last 12 that customer purchases of the item were not zero.)
>
> 3. Divide total quantity purchases by the total customer months.
>
> 4. Then multiply by the factor below to give the maximum amount that the customer can order per month before showing up on the suspicious order report. Note: Factor equals 3 for C-II and C-III Controlled Substances Containing List I Chemicals and 8 for C-III-IV-V Controlled Substances and non-Controlled OTC products containing List I chemical items.
>
> 5. At the end of each month, a report will be transmitted to DEA (separate

c. Suspicious Order Monitoring

i. National Wholesale Druggist Association's Suspicious Order Monitoring Program

In 1987, the National Wholesale Druggists' Association ("NWDA") developed a suspicious order monitoring program based on the DEA's Automated Reports and Consolidated Order System ("ARCOS") dictionary.[97] The DEA requires that drug manufacturers and distributors actively monitor orders of all controlled substances and report excessive orders, as part of their drug diversion surveillance.[98] The agency allows companies to set up systems of their choosing, not necessarily based on the ARCOS dictionary.[99] Furthermore, the DEA also has not strictly defined what constitutes an excessive order.[100]

ii. Healthcare Distribution Management Association's Guidelines

In 2008, the Healthcare Distribution Management Association created

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> reports for List I Chemicals and Schedule II-V Controlled Substances) of all purchases of List I Chemicals and/or CII-V Controlled Substances and List I containing OTC items by any customer whose purchase quantities exceed the parameters (above) any (2) consecutive months or in three (3) of any moving six (6) month period. Using a computer to manage and report on high volume transaction business activities with extremely short order cycle times (receipt to delivery) is the only viable, cost effective methodology for the reporting of orders which may be considered excessive or suspicious.

Id.

[97] *See NWDA "Suspicious Drug Order" Monitoring Program*, PINK SHEET (May 11, 1987), https://pink.pharmaintelligence.informa.com/PS011879/NWDA-SUSPICIOUS-DRUG-ORDER-MONITORING-PROGRAM [https://perma.cc/683T-46U5]. In 2000, the National Wholesale Druggists' Association became the Healthcare Distribution Management Association ("HDMA"), reflecting the "Association's vision of a progressively more efficient and effective distribution system" and in 2016 HDMA became the Healthcare Distribution Alliance ("HDA"), to reflect the organization's growing role as a convener of the supply chain both domestically and globally. *See History*, HEALTHCARE DISTRIB. ALL., https://www.hda.org/about/hda-history [https://perma.cc/J3TJ-EBYD].

[98] *Id.*

[99] *See id.*

[100] *See id.*; *see also* Letter from J. Rannazzisi, Deputy Assistant Adm'r, Off. Of Diversion Control, to All Registrants (Sept. 27, 2006) [hereinafter DEA Letter, Sept. 27, 2006]; Letter from J. Rannazzisi, Deputy Assistant Adm'r, Off. Of Diversion Control, to All Registrants (Feb. 7, 2007) [hereinafter DEA Letter, Feb. 7, 2007]; Letter from J. Rannazzisi, Deputy Assistant Adm'r, Off. Of Diversion Control, to All Registrants (Dec. 27, 2007) [hereinafter DEA Letter, Dec. 27, 2007]; Letter from J. Rannazzisi, Deputy Assistant Adm'r, Off. Of Diversion Control, to All Registrants (June 12, 2012) (informing registrants that the DEA does not endorse a particular system or sets of controls) [hereinafter DEA Letter, June 12, 2012].

voluntary anti-diversion guidelines based upon the DEA's guidance.[101] While each entity will need to make them fit their individual organization, general guidelines were created which include the following: knowing your customer due diligence; monitoring for suspicious orders; suspending or stopping an order of interest shipment; investigating orders of interest; filing suspicious order reports with DEA; and implementing employee training and standard operating procedures, among additional recommendations.[102]

iii. The Diversion Control Division

The Diversion Control Division ("DCD") is a division of the DEA with a mission to "prevent, detect, and investigate the diversion of controlled pharmaceuticals and listed chemicals from legitimate sources while ensuring an adequate and uninterrupted supply for legitimate medical, commercial, and scientific needs."[103] The DCD primarily completes its mission by requiring all non-practitioners to implement physical security and other controls established by 21 C.F.R. §§ 1301.72–.76(a).[104] These controls include: making a good faith inquiry to determine if the person or entity receiving controlled substances is authorized to receive them;[105] maintaining a system to detect and disclose suspicious orders;[106] notifying the DEA of thefts or significant losses;[107] and ensuring any common carriers used in the supply chain have adequate security measures to prevent losses.[108]

As laid out by the DEA regulations, a manufacturer's and distributor's suspicious order monitoring ("SOM") program must meet a relatively short list of requirements.[109] First, the registrant must design and operate a system to disclose suspicious orders of controlled substances.[110] Accordingly, the distributor must inform the local DEA field office when the distributor discovers a suspicious order.[111] At a minimum, orders are deemed

[101] *See generally* HEALTHCARE DISTRIB. MGMT. ASS'N, INDUS. COMPLIANCE GUIDELINES: REPORTING SUSPICIOUS ORDERS AND PREVENTING DIVERSION OF CONTROLLED SUBSTANCES 13 (2008).
[102] *See* W. VA. RED FLAGS REPORT, *supra* note 2; *see also* Expert Report of Dr. Seth B. Whitelaw, ¶ 5.3.1 (Apr. 15, 2019).
[103] *Diversion Control Division*, U.S. DRUG ENF'T ADMIN., https://www.dea.gov/operational-division/diversion [https://perma.cc/GJ7A-WNS6].
[104] *See* 21 C.F.R. § 1301.71(a) (2022) ("All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the Administrator shall use the security requirements set forth in §§ 1301.72–1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion.").
[105] *Id.* § 1301.74(a).
[106] *Id.* § 1301.74(b); *see also* DEA Letter, Sept. 27, 2006, *supra* note 100.
[107] 21 C.F.R. § 1301.74(c).
[108] *Id.* § 1301.74(e).
[109] *See id.* § 1301.74(b).
[110] *Id.*
[111] *Id.*

suspicious if they are (a) of unusual size; (b) deviate substantially from a normal pattern; or (c) of unusual frequency.[112]

iv. The Rannazzisi Letters (2006–2012)

The Rannazzisi letters are a series of letters written in 2006, 2007, and 2012 by the Deputy Assistant Administrator of the Office of Diversion Control, Joseph Rannazzisi.[113] These letters were sent to every entity in the United States that was registered with the DEA as a manufacturer or distributor of controlled substances to provide guidance on suspicious orders and the prevention of diversion.[114]

The initial letter, dated September 27, 2006, and the subsequent letter, dated February 7, 2007, were sent out to remind all registrants of their basic obligations to design and operate a system to flag suspicious orders of controlled substances and disclose this information to the DEA.[115] Additionally, the September 27, 2006, and February 7, 2007 letters also specifically note that this requirement is in addition to, and not in lieu of, the general requirement under 21 U.S.C. § 823(e) that a distributor maintain effective controls against diversion.[116]

These letters further outline "circumstances that might be indicative of diversion."[117] These circumstances are outlined as follows. The first indicator included orders with excessive quantities of a limited variety of controlled substances with few, if any, other drugs.[118] The second indicator included orders with a limited variety of controlled substances in quantities disproportionate to the quantity of non-controlled medication ordered.[119] The third indicator included orders with excessive quantities of a limited variety of controlled substances with excessive quantities of lifestyle drugs.[120] The final indicator included orders with the same controlled substance from multiple distributors.[121]

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[112] *See id.*; *see also* Masters Pharm., Inc. v. Drug Enf't Admin., 861 F.3d 206, 6 (D.C. Cir. 2017) (upholding DEA's interpretations of its regulations relative to defining a suspicious order and the timing of reporting); 21 C.F.R. § 1301.74(b).

[113] *See supra* note 100.

[114] *Id.*

[115] *Id.*

[116] *See* DEA Letter, Sept. 27, 2006, *supra* note 100, at 2; *see also* DEA Letter Feb. 7, 2007, *supra* note 100, at 2.

[117] *See* DEA Letter, Sept. 27, 2006, *supra* note 100, at 3; *see also* DEA Letter, Feb. 7, 2007, *supra* note 100, at 3 (listing circumstances that might be indicative of diversion).

[118] *See* DEA Letter, Sept. 27, 2006, *supra* note 100, at 3; *see also* DEA Letter, Feb. 7, 2007, *supra* note 100, at 3.

[119] *See* DEA Letter, Sept. 27, 2006, *supra* note 100, at 3; *see also* DEA Letter, Feb. 7, 2007, *supra* note 100, at 3.

[120] *See* DEA Letter, Sept. 27, 2006, *supra* note 100, at 3; *see also* DEA Letter, Feb. 7, 2007, *supra* note 100, at 3.

[121] *See* DEA Letter, Sept. 27, 2006, *supra* note 100, at 3; *see also* DEA Letter, Feb. 7, 2007, *supra* note 100, at 3.

The third letter in the series, dated December 27, 2007, again focused on suspicious order monitoring.[122] Distinct from the previous two, this letter detailed what constitutes timely reporting.[123] This letter also warned registrants about the use of rigid formulas to define whether an order is suspicious and that the use of rigid systems may cause a failure in detecting suspicious orders.[124]

The last letter in the series, dated June 12, 2012, reiterated what was stated in the December 2007 letter and again focused on suspicious order monitoring like the previous letters.[125] However, this letter focuses on communication of suspicious orders with the DEA field offices, the means necessitating reporting, and further steps that must follow reporting.[126] As such, the DEA specifically states, "Registrants who routinely report suspicious orders, yet fill these orders without first ascertaining that the order will not be diverted into other than legitimate medical, scientific, or industrial channels, are failing to maintain effective controls against diversion."[127]

B. Compliance Programs and the Mitigation of Punishments

In November 1991, the United States Sentencing Commission ("USSC") published the first version of the Federal Sentencing Guidelines for Organizations ("FSGO") with the purpose of "just punishment" and "deterrence."[128] "Just punishment" refers to punishment that corresponds to the degree of blameworthiness of the offender, while the "deterrence" model incentives are offered for organizations to detect and prevent crime.[129] The FSGO use a point system ("culpability score") to determine the sentencing range for each person or entity convicted of a federal crime.[130] There are then points assigned for each crime. The higher the offense level, the greater the points, and the harsher the sentence. Factors that increase punishment include: (1) tolerance of criminal activity; (2) history of criminal activity; (3) violation of a court order; and (4) obstruction of justice.[131] Meanwhile, two factors exist to mitigate the punishment: (1) self-reporting, cooperation, or acceptance of responsibility; and (2) sentencing credit for organizations that have an effective compliance and ethics program

[122] *See generally* DEA Letter, Dec. 27, 2007, *supra* note 100.
[123] *See id.*
[124] *See id.* at 2; *see also* W. VA. RED FLAGS REPORT, *supra* note 2, at 233.
[125] DEA Letter, June 12, 2012, *supra* note 100, at 1.
[126] *Id.*
[127] *Id.* at 2.
[128] Paula Desio, *An Overview of the Organizational Guidelines*, U.S. SENT'G COMM'N, https://www.ussc.gov/sites/default/files/pdf/training/organizational-guidelines/ORGOVERVIEW.pdf [https://perma.cc/W569-DRBV].
[129] *Id.*
[130] *See, e.g.*, 28 U.S.C. § 994.
[131] U.S. SENT'G GUIDELINES MANUAL § 7B1.1 (U.S. SENT'G COMM'N 2021) [hereinafter U.S. SENT'G GUIDELINES 2021].

designed to prevent and detect criminal conduct.[132]

The USSC outlined "Seven Elements," which later became "Eight Elements" for establishing an effective compliance program. For an organization to receive mitigation credit and have its compliance program deemed "effective," the following elements must be met:[133]

1. Organization and Resources
2. Due Diligence
3. Written Standards
4. Training & Communication
5. Monitoring, Auditing & Investigations
6. Corrective Actions
7. Enforcement (i.e., Discipline or other consequences for violating the standards)
8. Periodic Risk Assessment[134]

Because every organization is different in structure, culture, operation, and mission, each organization's compliance program will take a different form.[135] Therefore, it is imperative that each organization implements the elements in a way that best addresses its specific organizational needs to mitigate risks.[136]

When organizations fail to implement an effective compliance program, cases that could have been prevented—such as *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*—tend to occur.[137] In *Masters*, the court denied Masters Pharmaceutical, Inc.'s Petition for Review, seeking to overturn the DEA's revocation of Masters' registrant status. This case is of great importance as the court upheld the DEA Acting Administrator Chuck Rosenberg's decision that whenever an order for controlled substances was "discovered" by the SOMS computer program, that order was presumptively "suspicious."[138] Furthermore, based on the guidance provided by the Rannazzisi Letters, if an order is suspicious and it is discovered, then it should not be shipped to the customer.[139]

There are other methods used to discern whether an order is classified as suspicious. One of which includes the Park Doctrine, which is also

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[132] *See generally id.*
[133] *Id.*
[134] *Id.* at § 8B.2.1.
[135] *See id.*
[136] Desio, *supra* note 128 ("Criminal liability can attach to an organization whenever an employee of the organization commits an act within the apparent scope of his or her employment, even if the employee acted directly contrary to company policy and instructions. An entire organization, despite its best efforts to prevent wrongdoing in its ranks, can still be held criminally liable for any of its employees' illegal actions.").
[137] Masters Pharm, Inc. v Drug Enf't Admin., 861 F.3d 206 (D.C. Cir. 2017).
[138] *Id.* at 216.
[139] *See supra* note Desio.

referred to as the responsible corporate officer doctrine.[140] This doctrine is used to hold individual corporate officers responsible for any violation of federal law without any unlawful intent, knowledge of the violation, or any participation in the wrongdoing.[141] The government must prove: the corporate officer held a position of authority in the corporation; the officer had the ability to prevent the violation; and the officer failed to prevent the violation.[142] However, in *Masters Pharmaceutical*, employees rarely did their due diligence to investigate the flagged orders that were required to dispel the suspicion surrounding held orders.[143]

III. FOUNDATIONAL CHANGES TO ENSURE CONSISTENCY AND ACCOUNTABILITY

To establish consistency, it is necessary that the DEA creates its own Suspicious Order Monitoring program that all registrants are required to use and stop passing this requirement off to companies that receive little guidance and can manipulate the system. In *Masters Pharmaceutical*, the SOM system was only four days old when it was reviewed by the DEA.[144] With such little time before the review was conducted, it was apparent that the SOM system would not be sufficiently tested.[145] A remedy that would have prevented a defective SOM system would be if the SOM system was standardized among registrants. The DEA can stop "passing the buck" off to the registrants and instead design and operate an SOM system that works for all distributors, manufacturers, retailers, and prescribers.

After public comment, the DEA can design a system that considers the registrant's needs, meets statutory requirements, and alerts the DEA to suspicious orders immediately.[146] This "public comment" should entail an open dialogue and working sessions with as many registrants as would like to provide input to create an SOM that has "buy in" from the entire "closed system." If retailers or physicians must order through the DEA's system, it would send orders directly to the distributor or manufacturer of their choice, automatically keeping records of every order. Any order alerted as "suspicious" would automatically stop at the DEA, allowing it to prevent and investigate potential diversion.[147] If the DEA determines the order is not suspicious, the DEA will allow the order to proceed to its intended contact. Additionally, once the manufacturer or distributor sent the order, either

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[140] *See* United States v. Dotterweich, 320 U.S. 277, 8 (1943); *see also* United States v. Park, 421 U.S. 658, 17 (1975).
[141] *See Dotterweich*, 320 U.S. at 8; *see also Park*, 421 U.S. at 17.
[142] *Park*, 421 U.S. at 18.
[143] *Masters Pharm., Inc.*, 861 F.3d at 213.
[144] *Id.* at 225.
[145] *Id.*
[146] *See supra* text accompanying notes 109–12 (addressing the current "suspicious order" standard).
[147] *See supra* notes 103–09 and accompanying text (outlining statutory diversion requirements).

would have to input it into the same system, showing the order was shipped. This type of SOM designed and operated by the DEA would confirm all electronically-ordered prescriptions comply with their regulations.[148] Additionally, the new system would require handwritten prescriptions to be logged into the SOM by the pharmacy fulfilling the order prior to dispensing to the intended patient. This would allow doctors who rely on written prescriptions or are not "tech savvy" from falling through the cracks of direct DEA oversight. While this would be more difficult for the DEA to control, it would provide the distributors, manufacturers, retailers, and prescribers a better understanding of how to create an effective compliance program.[149]

When enforcing controlled substance laws, if the DEA finds a registrant violated the CSA, it may issue an order to show cause, asserting why the DEA should not revoke, suspend, or deny registration.[150] If the violation appears to pose an imminent threat to public health, the DEA may issue an immediate suspension order, which deprives the registrant of the right to distribute controlled substances immediately.[151] Orders to show cause and immediate suspension orders are collectively known as "registrant actions."[152]

The DEA can enforce suspected violations through a process collectively known as registrant actions. However, the DEA underutilizes this authority, which has led to large pharmaceutical manufacturers, distributors, and retailers failing to perform necessary due diligence.[153] Instead, it allows manufacturers like McKesson, Purdue, Insys, CVS, Walgreens, Mallinckrodt, and Cardinal Health to provide kickbacks to prescribers, or ship suspicious orders without providing due diligence to ensure diversion was not occurring.[154] For example, the DEA allowed

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[148] *See supra* text accompanying notes 109–12.

[149] *See supra* notes 133–36 and accompanying text (implementing a variation of the USSC's "Eight Elements" for establishing an effective compliance program).

[150] 21 C.F.R. § 1314.150; 21 U.S.C. § 824(a).

[151] 21 U.S.C. §§ 823–24; *see also* U.S. DEP'T OF JUST. OFF. OF INSPECTOR GEN. EVALUATION & INSPECTION DIV., I-2014-003, THE DRUG ENFORCEMENT ADMINISTRATION'S ADJUDICATION OF REGISTRANT ACTIONS 1 (2014), https://oig.justice.gov/reports/2014/e1403.pdf [https://perma.cc/JW2M-C327] [hereinafter REGISTRANT ACTIONS].

[152] *See* REGISTRANT ACTIONS, *supra* note 151.

[153] *See* U.S. DEP'T JUST. OFF. OF INSPECTOR GEN., 19-05, REVIEW OF THE DRUG ENFORCEMENT ADMINISTRATION'S REGULATORY AND ENFORCEMENT EFFORTS TO CONTROL THE DIVERSION OF OPIOIDS 1 (2019), https://oig.justice.gov/reports/2019/e1905.pdf [https://perma.cc/ZU5A-RFUQ] ("We found that DEA was slow to respond to the significant increase in the use and diversion of opioids since 2000. We also found that DEA did not use its available resources, including its data systems and strongest administrative enforcement tools, to detect and regulate diversion effectively. Further, we found that DEA policies and regulations did not adequately hold registrants accountable or prevent the diversion of pharmaceutical opioids. Lastly, we found that while the Department and DEA have recently taken steps to address the crisis, more work is needed.").

[154] *See* W. VA. RED FLAGS REPORT, *supra* note 2, at 60–65.

Mallinckrodt to use the term "peculiar order" to ship 37,817 orders between 2003 and 2011 while only reporting 33 as "suspicious."[155] It also allows manufacturers to change order amounts to fall below the threshold of "suspicious."[156] It also includes failing to follow the guidelines of knowing your customer and your customer's customer by placing sales and profits over a compliance program.[157] All these companies failed the American public, but it is not completely their fault nor the majority their fault.[158] The largest portion of blame should be placed squarely on the shoulders of the federal government and the regulators that have the responsibility and duty to ensure controlled substance laws are followed.[159]

A. Monetary Remedies to Encourage Deterrence

With a strong foundation in place, additional settlement remedies, including both monetary and non-monetary, are possible and may be effective in reducing damages currently caused by this crisis and even thwarting future crises.[160] Not only do many people use opioids to control chronic pain, but manufacturers of opioids typically produce other medications consumers need to engage in everyday life.[161] Accordingly, bankrupting them would do much more harm than good.[162]

The notion that a company can be "too big to fail" is an inaccurate one, as once "Titans of Industry" fail all the time, such as Lehman Brothers Holdings, Washington Mutual, WorldCom, General Motors, Enron, Chrysler, Thornburg Mortgage, Pacific Gas and Electric Co.[163] A recent example of a company that should have been left to its own demise is the 2009 bankruptcy of General Motors in which the U.S. government decided

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[155] Scott Higham, Sari Horwitz & Steven Rich, *Internal Drug Company Emails Show Indifference to Opioid Epidemic*, WASH. POST (July 19, 2019), https://www.washingtonpost.com/investigations/internal-drug-company-emails-show-indifference-to-opioid-epidemic-ship-ship-ship/2019/07/19/003d58f6-a993-11e9-a3a6-ab670962db05_story.html [https://perma.cc/FE8R-HNC7].

[156] *See* W. VA. RED FLAGS REPORT, *supra* note 2, at 105–06.

[157] *See* W. VA. RED FLAGS REPORT, *supra* note 2, at 39.

[158] *See generally id.*

[159] *See* 21 U.S.C. § 812; *see also supra* Parts I, II.

[160] Remedies can be provided in non-traditional ways similar to those provided in "special" courts like Veterans court, drug court, and other nontraditional judiciaries. *See* VALOR, Brochure, https://www.collincountytx.gov/supervision_corrections/Documents/VALOR%20Brochure.pdf [https://perma.cc/JL5E-HNV3]; *Drug Courts*, U.S. DEP'T JUST. (May 4, 2021), https://www.ojp.gov/feature/drug-courts/overview [https://perma.cc/9PZQ-93X5].

[161] *See generally Manufacturers*, MPR, https://www.empr.com/manufactures/letter/m/ [https://perma.cc/WXN5-8Q6A].

[162] *Id.*

[163] Christopher Tkaczyk, *The 10 Largest U.S. Bankruptcies*, CNN MONEY (Sept. 15, 2008), https://money.cnn.com/galleries/2009/fortune/0905/gallery.largest_bankruptcies.fortune/index.html [https://perma.cc/RUT5-HVTC] (Lehman Brothers (slide 1), Washington Mutual (slide 2), WorldCom (slide 3), General Motors (slide 4), Enron (slide 6), Chrysler (slide 8), Thornburg Mortgage (slide 9), Pacific Gas and Electric Co. (slide 10)).

that the automaker was "too big to fail" and spent approximately $50 billion dollars to secure a 61% equity stake in the company.[164] When it came time to recoup taxpayer's money, the federal government decided to sell the 61% stake for a loss of 22.4%, or a loss of $11.2 billion.[165] However, in the field of pharmaceutical manufacturers, there truly are three companies that are too big to fail.[166] AmerisourceBergen, Cardinal Health, and McKesson make up eighty-five percent of pharmaceutical distributions while all other companies combined make up the remaining fifteen percent.[167] This simple statistic is enough to determine that although these three industry giants targeted consumers for their own greedy agenda and actively contributed to diversion that has cost countless American lives, they truly are needed more than they need us.[168]

B. Non-Monetary Remedies to Encourage Deterrence

The Health and Human Services Office of Inspector General ("OIG") is required to exclude individuals and entities convicted of:

> (1) Medicare or Medicaid fraud, as well as any other offenses related to the delivery of items or services under Medicare or Medicaid;
> (2) Patient abuse or neglect;
> (3) Felony convictions for other health-care-related fraud, theft, or other financial misconduct; and
> (4) Felony convictions for unlawful manufacture, distribution, prescription, or dispensing of controlled substances.[169]

Additionally, the OIG has discretion to exclude individuals and entities for misdemeanor convictions related to health care fraud, other than Medicare or Medicaid fraud or misdemeanor convictions in connection with the unlawful manufacture, distribution, prescription, or dispensing of controlled substances.[170] The OIG can also suspend, revoke, or surrender a license to provide healthcare for reasons bearing on professional competence, professional performance, or financial integrity per its provision on unnecessary or substandard services.[171] Submitting false or

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[164] Eric Beech, *U.S. Government Says It Lost $11.2 Billion on GM Bailout*, REUTERS (Apr. 30, 2014, 10:03 AM), https://www.reuters.com/article/us-autos-gm-treasury-idusbrea3t0mr20140430 [https://perma.cc/MY89-8E4X].
[165] *Id.*
[166] W. VA. RED FLAGS REPORT, *supra* note 2, at 6
[167] Scott Higham & Lenny Bernstein, *The Drug Industry's Triumph Over the DEA*, WASH. POST (Oct. 15, 2017), https://www.washingtonpost.com/graphics/2017/investigations/dea-drug-industry-congress/ [https://perma.cc/3W9H-C93G].
[168] *See generally id.*
[169] *See* 42 U.S.C. § 1320a–7.
[170] *Id.*
[171] *Id.*

fraudulent claims to a federal health care program, engaging in unlawful kickback arrangements, and defaulting on health education loan or scholarship obligations all warrant exclusion as well.[172]

This tremendous power has been given to the OIG for the sole purpose of protecting the public and the federal government from unscrupulous individuals and entities.[173] The only issue is that it is rarely utilized for distributors, manufacturers, or retailers. This power to exclude is primarily used to punish physicians and health care organizations that commit False Claim Act ("FCA")[174] or Anti-Kickback ("AKS")[175] violations. It is of the utmost importance for the OIG to work closely with the DEA's Diversion Control Division to begin excluding not only the entities, but executive leadership or board members based on the responsible corporate officer doctrine.[176] As of now, entity leaders who are experts at determining return on investments are at risk of losing their freedom for inconsistent amounts of time.[177] While that is a deterrent for many people, it is not for all.

Deterrence will be even lower for executive level employees, considering the first successful Racketeer Influence and Corrupt Organization ("RICO") Act case against a pharmaceutical company. John Kapoor, founder and previous owner of Insys Therapeutics, received sixty-six months in prison and a $250,000 fine for RICO conspiracy, conspiracy to commit wire fraud, and conspiracy to violate the Anti-Kickback Law.[178] This case would have served as a better deterrent had the judge imposed a more stringent sentence.[179]

Many professional career fields from medical doctors, respiratory therapists, lawyers, nurses, psychiatrists, electricians, and real estate agents are required to obtain licenses to practice in their chosen field.[180] Here, amid

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[172] *Id.*

[173] *See generally About OIG*, U.S. DEP'T HEALTH & HUM. SERVS., https://oig.hhs.gov/about-oig/ [https://perma.cc/LPE8-7XNW].

[174] 31 U.S.C. §§ 3729–3733.

[175] 42 U.S.C. §§ 1320a–7b(b).

[176] *United States v. DeCoster, 828 F.3d 626, 632 (8th Cir. 2016).*

[177] *Compare Doctor Gets 40 Years in Prison for Prescribing Over 500,000 Opioid Doses*, GUARDIAN (Oct. 3, 2019, 8:22 AM), https://www.theguardian.com/us-news/2019/oct/03/doctor-joel-smithers-gets-40-years-in-prison-for-prescribing-over-500000-opioid-doses [https://perma.cc/P5EC-EWUQ], *with* Press Release, *Founder and Former Chairman of the Board of Insys Therapeutics Sentenced to 66 Months in Prison*, U.S. FOOD & DRUG ADMIN. (Jan. 23, 2020), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/founder-and-former-chairman-board-insys-therapeutics-sentenced-66-months-prison [https://perma.cc/FK7E-2SGY].

[178] *Founder and Former Chairman of the Board of Insys Therapeutics Sentenced to 66 Months in Prison*, *supra* note 177.

[179] *See id.* (prosecutors sought a fifteen-year sentence for John Kapoor).

[180] *Professional Certifications and Occupational Licenses: Evidence from the Current Population Survey*, U.S. BUREAU LAB. STATS. (June 2019), https://www.bls.gov/opub/mlr/2019/article/professional-certifications-and-occupational-licenses.htm [https://perma.cc/8D7A-HLY6].

an epidemic that claimed countless lives, anyone can obtain a position with tremendous power and influence that can directly impact the public welfare more than most professionally licensed career choices. As such, there is no logical reason why specific roles within organizations that are registrants for controlled substances are not required to obtain professional licensing.

Therefore, this Article proposes that all staff directly involved in the sales, marketing, finance, contracting, distribution, or whoever has any contact with the public part of the "closed loop" system, must obtain and maintain a professional license. If an individual is caught violating the law or ethical policies, they must retake classes and be given community service that is to be conducted explicitly with or in areas that are being ravaged by the opioid crisis.[181] Additionally, if they continue to violate policies and laws, their individual license must be revoked, and the individual is subject to being banned from ever working, investing, consulting, volunteering, or acting in any other capacity with products overseen by the DEA.[182] This will ensure that all licensed staff are held accountable for their decisions.

Volunteering for drug rehabilitation centers on a mandatory annual basis must be implemented for all registrant executive level employees and board members. Ideally, this will foster empathy for lives their organization impacts, which may be just enough to deter negatively impactful decisions. This remedy will not cost the federal government, state governments, or taxpayers any additional funds to implement, which is important as the opioid epidemic has already created a substantial financial burden for the victims, families, and society.[183] This requirement would be easily tracked and implemented by requiring all executive leadership and board members to volunteer at a drug rehabilitation clinic for a minimum of forty hours before becoming a registrant.[184] Volunteering in this capacity shall take place on an annual basis to ensure executive and board members can see the faces of those they impact.[185]

It is far too easy to get caught up in the success of an organization and find ways to mock those that you are victimizing.[186] In West Virginia alone, AmerisourceBergen distributed 248.16 million dosage units of Oxycodone and Hydrocodone between 2005 and 2016.[187] The sheer lack of compliance culture led to employees widely sharing an email about a Beverly Hillbillies

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[181] *See supra* Section III.B.
[182] *See supra* Section III.B.
[183] *See supra* Section II.A.
[184] *See supra* Section III.B.
[185] *See supra* Part II; *supra* Section III.B.
[186] Meryl Kornfield, *Drug Distributor Employees Emailed a Parody Song about 'Pillbillies,' Documents Show*, HERALD DISPATCH (May 23, 2020), https://www.herald-dispatch.com/news/drug-distributor-employees-emailed-a-parody-song-about-pillbillies-documents-show/article_da91c044-1a34-5067-9135-9a0a937728be.html [https://perma.cc/5RYR-98TN]. Several examples of that involve AmerisourceBergen Corp., who was one of the largest distributors of opioids, accounting for 13.2% of the United States distribution. *Id.*
[187] *See* W. VA. RED FLAGS REPORT, *supra* note 2, at 6.

parody, the Pillbillies, which detailed addicted individuals traveling from Appalachia to Florida to easily obtain opioids at pill mills within the state.[188] Another example is Mallinckrodt's national account manager, Victor Borelli, sending an email to a distributor customer stating, "[j]ust like Doritos keep eating. We'll make more."[189]

IV. CONCLUSION

The extraordinary number of regulations imposed on controlled substances and the amount of damage done is currently happening.[190] Unfortunately, the damage caused by the opioid epidemic is unparalleled with long lasting and indeterminable effects.[191] The biggest issue is that the requirements imposed on the registrants, while tremendous, are both vague and unrealistic.[192] The CSA gave the DEA the task of enforcing controlled substance laws.[193] In turn, the DEA has given that responsibility to the registrants via the "closed system."[194] While the "closed system" sounds great in theory, it is the equivalent of letting the fox guard the hen house.[195] When registrants violate the Controlled Substances Act, False Claims Act, Anti-Kickback Statute, laws and industry standards, the DEA throws its hands up, almost in disbelief, and gives violators a slap on the wrist. Meanwhile, the real victims, the public, are becoming addicted to prescriptions and illicit drugs and often dying in the streets.[196]

The greatest balancing act in this epidemic is the one that separates the abusers from the responsible, legal users. The current system does not provide any remedy in sight and that is because the DEA, legislators, and presidents, do not want to take responsibility for the disaster they caused.[197] It has been twenty-six years since Purdue Pharma introduced its "time release" OxyContin; still, the DEA does not understand why diversion is as

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[188] Kennie Bass, *Suspicious Deliveries and Opioid-Inspired Parody Songs Highlighted at Trial*, EYEWITNESS NEWS (May 13, 2021), https://wchstv.com/news/local/suspicious-deliveries-and-opioid-inspired-parody-songs-highlighted-at-trial [https://perma.cc/X33L-F3FR]. "Sunny Florida is the place you ought to be[.] So, they loaded up the truck and drove speedily. South, that is. Pain Clinics, cash 'n carry. A Bevy of Pillbillies! Well now its time to say Howdy to Jed and all his kin. And they would like to thank Rick Scott fer kindly inviting them," read the lyrics, referring to former Governor Rick Scott. *Id.* The song continues, "They're all invited back again to this locality. To have a heapin helpin of Florida hospitality. Pill Mills that is. Buy some pills. Take a load home. Y'all come back now, y'hear?" *Id.*

[189] Higham et al., *supra* note 155.

[190] *See supra* Section II.A.

[191] *See supra* Part II.

[192] *See supra* Section II.A.

[193] *See The Opioid Epidemic by the Numbers*, *supra* note 52 (providing statistics from the 2019 National Survey on Drug Use and Health, 2020 and the NCHS National Vital Statistics System, Provisional Drug Overdose Death Counts).

[194] 21 C.F.R. § 1306 (2010).

[195] *Id.*

[196] *See* W. VA. RED FLAGS REPORT, *supra* note 2, at 6.

[197] *See supra* Section III.B.

bad as it is.[198]

Designing a SOM controlled by the DEA that all registrants are required to use would result in mitigating diversion.[199] Creating meaningful registrant requirements to see firsthand what their products do to people in their very own community can foster empathy, or at the very least, bring situational awareness.[200] Punishing these bad actors appropriately, which is the role of the DEA and OIG, would create the deterrence needed to stop at least one bad actor when they perform a risk assessment in the future.[201] Simple solutions for a complex problem, posited as the "80/20 rule," is why the opioid crisis is the epitome of the Pareto Principle. The resolution of one cog, which in this case is the Controlled Substances Act and its enforcement, will create a resolution to the opioid epidemic itself.

[198] Purdue Pharma's special "time release" OxyContin can be easily overcome by crushing the pill, which would eliminate any type of special coating that allowed for a timed release.
[199] *See supra* Part III.
[200] *See supra* Section III.B.
[201] *See supra* Sections III.A, B.