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# The DOJ's Tools to Combat the Opioid Crisis: Do They Work?

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# I. INTRODUCTION

## A. THE OPIOID CRISIS

The United States is confronted by an enormous public health crisis relating to prescription opioid drugs. Although the total number of drug overdose deaths decreased by four percent from 2017 to 2018, the number of drug overdose deaths was still four times higher in 2018 than in 1999 with the death toll over 67,000 in the United States alone.[1] Of that, prescription opioids were involved in 32% of all opioid deaths in 2018.[2] Abuse of prescription opioid pain medications has become a substantial public health epidemic throughout the nation.[3] Prescriptions opioids are found on the streets in the United States more than any other developed nation.[4] An estimated 2.5 million Americans have an opioid use disorder and the epidemic continues to grow.[5]

This article will examine how federal law enforcement has responded to the opioid epidemic through a variety of legal tools. This article will focus on several initiatives including the Department of Justice's (DOJ) prosecutions under the False Claims Act (FCA), the Controlled Substances Act (CSA), the federal Anti-Kickback Statute (AKS), and the newly enacted Eliminating Kickbacks in Recovery Act of 2018 (EKRA). Seeing that this epidemic is complex, this article will focus specifically on one underlying cause: the over-prescription of opioids and, in particular, the gaps in federal regulations that present issues in enforcement as

[1] Centers for Disease Control and Prevention (CDC), *Understanding the Epidemic*. (last reviewed March 19, 2020). https://www.cdc.gov/drugoverdose/epidemic/index.html
[2] CDC, *supra* note 1
[3] Jeanette M Tetrualt & Jenna L. Butner, *Non-Medical Prescription Opioid Use and Prescription Opioid Use Disorder: A Review*., 88 Yale J. Biol. Med. 222, 227-33 (2015).
[4] *Id*.
[5] Ameet Sarpatwari, Michael S. Sinha & Aaron S. Kesselheim, *The Opioid Epidemic: Fixing a Broken Pharmaceutical Market*, 11 Harvard L. Pol'y Rew. 463, 463 (2017).

well as regulation of prescription opioids. Furthermore, this article will examine EKRA, a newly-enacted law intended to combat entities who specifically take advantage of those who are suffering with addiction. This examination will show that different legal tools are most appropriate to deal with issues at various places along the prescription drug supply chain.

### a. Causes of the Opioid Crisis

Because the opioid crisis is complex and multifaceted, it is important to note the various players in the system and how prescription drugs enter the market and reach users. Drug manufacturers, distributors, pharmacies, doctors, patients, and dealers each have a unique and significant role in the narrative of the current opioid crisis. The narrative often begins with pharmaceutical manufacturers who research, develop and promote the drug for particular uses.[6] Pharmaceutical distributors purchase prescription medicines and other medical products directly from the manufacturer for storage in warehouses and distribution centers across the country.[7] Distributors then deliver the drugs to state-regulated pharmacies, hospitals and other drug retailers.[8] For a patient to then get the medicine from a hospital or pharmacy, it must start with a prescription. Physicians make the clinical decisions as to who should or should not receive a medicine or what medicine is best for a particular patient. Along this supply chain, there are various opportunities for the drugs to be abused and diverted into illegal channels and used for non-medical uses.[9]

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[6] Thomas N. Palermo, *The Opioid Crisis*, American Bar Association. (2019). https://www.americanbar.org/groups/criminal_justice/publications/criminal-justice-magazine/2019/winter/opioid-crisis/

[7] Healthcare Distribution Alliance. *Pharmaceutical Distributors: Understanding Our Role in the Supply Chain*. https://www.hda.org/about/role-of-distributors (last visited May 1, 2020).

[8] *Id*.

[9] Congressional Research Service, *The Controlled Substance Act (CSA): A legal Overview of the 116th Congress, 2.* (Oct. 9,2019). https://fas.org/sgp/crs/misc/R45948.pdf

Opioid prescriptions in the United States quadrupled between 1999 and 2018. Epidemiologists view the progression of opioid use in three waves.[10] The first wave began in 1999 (which is why it is typically used as a starting point in most statistics) when there was an initial rise in prescription opioid overdose deaths.[11] The second wave started in 2010 when a very stark rise in heroin overdose deaths occurred.[12] The third wave arrived soon after in 2013 where another stark rise in overdose deaths occurred at the hands of synthetic opioids, particularly those involving illicitly manufactured fentanyl.[13] The National Institute of Drug Abuse reported that this was the sharpest increase with more than 28,400 overdose deaths in 2017.[14] These official mortality figures are likely undercounted, since the data do not include those who were revived by Narcan (an overdose reversing drug), but had already suffered brain injury due to lack of oxygen.[15] Many users die weeks later of pneumonia or other overdose-induced complications.[16]

While this article will focus more narrowly on the particular legal context that presents an opportunity to help alleviate the opioid crisis, it is important to recognize some of the broader forces that may also contribute to the epidemic. There are several causes to the opioid epidemic such as the reliance of pharmacotherapy treatments[17] and the limited access to drug treatment through Medicate and other insurance coverage, [18] but this is not the focus of this paper. Instead,

[10] CDC, *supra* note 1.
[11] *Id.*
[12] *Id.*
[13] *Id.*
[14] National Institute on Drug Abuse, New Jersey: Opioid-Involved Deaths and Related Harms. (April 2020). https://www.drugabuse.gov/opioid-summaries-by-state/new-jersey-opioid-summary
[15] Rachel L. Rothberg & Kate StithGuest. *Symposium: Law and the Opioid Crisis: The Opioid Crises and Federal Criminal Prosecution,* 46 J.L Med. & Ethics 292.
[16] *Id.*
[17] Victor Absil, *Efficient Prosecution of False Claims Act Violation May Help Relive the Current Opioid Crisis*. 45 American Journal of Law & Medicine 253, 255 (2019).
[18] *Id.*

this paper will focus on arguably the main underlying cause of the opioid epidemic – the over-prescription of drugs. [19]

American doctors prescribe three times more opioids than European doctors.[20] Opioid prescriptions have increased by more than 300 percent since 1999 while doctors prescribed about three hundred million opioids in 2015 alone.[21] When physicians prescribe an overabundance of opioids, abuse and overreliance become more likely and will eventually pose a danger to the overall public health. Studies have shown that "approximately half of opioid prescriptions are for indications and durations for which evidence of effectiveness is weak or nonexistent…."[22] If this is the case, it seems likely that the risk of abuse and reliance would outweigh the benefits of a the short-term opioid pain treatment. Prescription opioids can lead to addiction, produce negative mental and physical side effects, and are no more effective than non-opioid painkillers at treating many long and short-term issues.[23] While many prescription opioids do help people suffering from pain, experts have underestimated the potential for opioid misuse and addiction. A solution does not call for a complete elimination of prescription opioids, but rather, the elimination of inappropriate prescriptions, allocating funding for treatments that utilize counseling, and conducting further research to alternative treatments and into the conditions that give rise to chronic physical and mental pain.[24]

A subsequent issue to the overabundance of prescription opioids is the overpayment by government in health care expenditure. An overabundance has cost the government billions of

[19] Corey S. Davis, *The Law and Policy of Opioids for Pain Management, Addiction Treatment, and Overdose Reversal*, 1 Ind. Heal. L. Rev. 1, 1-22 (2017).
[20] *See* Absil at 256.
[21] Corey S. Davis & Derek Carr, *Physician continuing education to reduce opioid misuse, abuse and overdose: Many opportunities, few requirements*. 163 Elsevier 100,107 (2016).
[22] Davis and Carr, *supra* note 21, at 100.
[23] *Id.*
[24] *See* Absil at 257.

dollars in health care spending in false claims, criminal activity and decreased economic productivity of people with opioid use disorders.[25] Additionally, the government loses money when it pays for prescription claims that, if it knew were false, it would not have reimbursed the prescription. This article will focus next on the DOJ's response of the opioid epidemic through various legal remedies including the False Claims Act (FCA), which directly addresses the issue noted above.

## II. DOJ's INIATIVES

In 2016, the DOJ dedicated its United States Attorneys' Bulletin to "Addressing the Heroin and Opioid Crisis."[26] In the bulletin, then-Deputy Attorney General (DAG) Sally Quillian Yates emphasized the importance that any solution by the federal government "must be holistic".[27] This included the cooperation of several agencies such as the Drug Enforcement Agency (DEA), the Organized Crime Drug Enforcement Task Force Program, and the Bureau of Justice Assistance's Prescription Drug Monitoring Grant Programs.[28] The Trump administration maintained the opioid-related initiatives announced by Yates when President Trump declared the opioid crisis a nationwide "public health emergency."[29]

In addition to combatting drugs on the street, the DOJ took further measures to bring legal actions based on the investigation efforts of the U.S. Department of Health and Human Services (HHS), the Health Care Fraud Prevention Team, and Medicare Fraud Strike Force. The Medicare Fraud Strike Force Teams in particular brings together efforts of the Office of the

[25] Aaron M. Gilson & Paul G. Kreis, *The Burden of the nonmedical use of prescription opioid Analgesics*, 10 PAIN MED. 89, 95 (2009).
[26] U.S. Dep't of Justice, Executive Office for the United States Attorneys, "Addressing the Heroin and Opioid Crisis," *United States Attorneys' Bulletin* 64, no. 5 (2016): 1-91.
[27] *Id.*
[28] *Id.*
[29] The White House, *Ending America's Opioid Crisis* (2017) (President Trump's nationwide call to action declaring the opioid crisis a public health emergency and the administration applying an all-of-government approach to stopping the crisis).

Inspector General (OIG), DOJ, and FBI to successfully investigate and identify fraud relating to health care.[30]

One of the earliest and most notable enforcement efforts by the OIG was in 2007 during the investigation of Purdue Pharma – the company that manufactures the narcotic painkiller OxyContin. Purdue and three executives pled guilty "to criminal charges that they misled regulators, doctors and patients about the drug's risk of addition and its potential to be abused."[31] Because of the DOJ's authority to bring both civil and criminal charges, the company agreed to pay over $600 million in fines and the executives a total of $34.6 million.[32] Experts believe that the power opioid painkiller strength and addictive potential contributed to the current opioid epidemic, which may be why it was the largest settlement paid by a pharmaceutical manufacturer at the time.[33] The DOJ continues to pursue these civil and criminal actions against fraudulent medical practices in a fight to combat the growth of the opioid epidemic.[34] The DOJ's legal tools and initiatives have displayed their effectiveness in prosecuting bad actors in the health care supply chain. However, this article will reveal several gaps in the laws that federal prosecutors rely on in prosecuting those who are exploiting the crisis.

## A. THE FALSE CLAIMS ACT

### a. Background of the FCA

[30] HHS Office of the Inspector General, *Medicare Fraud Strike Force.* https://oig.hhs.gov/fraud/strike-force/
[31] CNN Money, *Purdue in $634 million settlement over OxyContin*, (July 20, 2007). https://money.cnn.com/2007/07/20/news/companies/purdue/index.htm
[32] *Id.*
[33] Jamie Ducharme, Time, *Allegations Against the Maker of OxyContin Are Piling Up. Here's What They Could Mean for the Billionaire Family Behind Purdue Pharma.* (February 22, 2019). https://time.com/5520159/purdue-pharma-lawsuits/
[34] Press Release, U.S. Dep't of Justice (DOJ), Office of Pub. Affairs, *Justice Department Celebrates 25th Anniversary of False Claims Act Amendments of 1986*. (Jan. 31, 2012). https://www.justice.gov/opa/pr/justice-department-celebrates-25th-anniversary-false-claims-act-amendments-1986

The first relevant law that this article will address in the attempt to combat the opioid crisis is the FCA. The FCA is arguably among the most powerful weapons the government has in its arsenal to combat healthcare fraud and abuse.[35] The FCA was initially passed to impose civil liability for fraudulent claims submitted to the government. Eventually the practice of using private citizens to sue on behalf of the government proved to be an efficient law enforcement strategy.[36] FCA prosecutions permitted the government to seek treble damages and use the *qui tam*, or whistleblower, provision to incentivize whistleblowers to come forward with allegations of fraud.[37] A large portion of FCA recovery has come from settlements from health care companies.[38]

The False Claims Act imposes civil liabilities for violations that occur when an individual: (1) "knowingly presents or causes to be presented, a false or fraudulent claim for payment or approval" to the federal government, including a false Medicare or Medicaid claim; (2) "knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim."[39] Examples of Medicare, Medicaid, and other federal claims that violate the FCA include claims for health care services not actually provided, claims that misrepresent the level of health care services that were provided, and claims for unnecessary health services.[40] Knowing conduct includes conduct involving actual knowledge of a falsehood

[35] Robert Salcido, *Mixing Oil and Water: The Government's Mistaken Use of the Medicare Anti-Kickback Statute in False Claims Act Prosecutions*, 6 Annals health L. 105 (1997).
[36] Jr. Helmer, James & Robert Clark Neff, *War Stories: A History of the Qui Tam Provisions of the False Claims Act, The 1986 Amendments to the False Claims Act, and the Application*, 18 Ohio North. Univ. Law. Rev. 35, 35 (1991).
[37] Press Release, *supra* note 34.
[38] Press Release, U.S. Dep't of Justice, Office of Pub. Affairs, *Justice Dep't Recovers over $3 Billion from False Claims Act Cases in Fiscal Year 2019.* (Jan. 9, 2020). https://www.justice.gov/opa/pr/justice-department-recovers-over-3-billion-false-claims-act-cases-fiscal-year-2019
[39] 31 U.S.C. §3729(a)(1)(A)-(B) (2012).
[40] Stacey A. Tovino, *Fraud, Abuse, Opioids*, 67 U. Kan. L. Rev. 901, 921 (2019).

as well as conduct involving deliberate ignorance or reckless disregard of the truth.[41] The act does not require specific intent to defraud.[42]

FCA claims may be classified as factually false or legally false. Factually false claims include claims that are false on their face, such as claims for nonexistent care provided to fictitious patients or claims supported by falsified medical records.[43] Legally false claims, at first glance, may appear to be facially, technically accurate in the sense that a provider may have seen a patient in the office, however it becomes legally false because a provider may have failed to meet a regulation in connection to the office visit.[44] Legally false claims may be further divided into express false certifications and implied false certifications, depending on the type of certification made (or not) on the claim or invoice.[45] Express false certifications occur when a claimant makes an "explicitly false certification of compliance with an underlying program condition, such as by signing a false certification statement" on a claim.[46] In the absence of such express certifications, an implied false certification occurs when a claimant submits a reimbursement claim without disclosing that the claimant is in violation of a legal requirement that affects the claimant's eligibility.[47]

In 2016 the Supreme Court addressed the circuit split regarding whether the government could use an implied false certification as a basis for a FCA violation in *Universal Health*

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[41] *Id*. at 922.
[42] 31 U.S.C. 3729(b)(1) (2012).
[43] Christopher L. Martin, Jr., *Reining in Lincoln's Law: A Call to Limit the Implied Certification Theory of Liability Under the False Claims Act, 101* CAL**.** L. Rev. 227, 230 (2013) ("Courts originally interpreted the phrase 'false or fraudulent claim' in a limited fashion to mean a 'factually false claim,' which is a claim for payment containing 'an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided.'").
[44] *See* Tovino at 922.
[45] Joan H. Krause, *Reflections on Certification, Interpretation, and the Quest for Fraud that "Counts" under the False Claims Act,* 2017 U. Ill. L. Rev. 1811, 1812-13 (2017).
[46] *Id*. at 1817.
[47] *Id.*

*Services Inc. v. United States ex rel. Escobar*.[48] The Court held that the implied certification theory can serve as a basis for FCA liability.[49] When a claim is submitted to the government, there is an implied certification that all material laws and regulations have been complied with.[50] If a noncompliant claim has been submitted, it would then materially influence the government's decision to pay and thus the FCA would be implicated.[51] It is important to also note that the FCA violation is undermined when the law being violated is not material to the government's decision to pay.[52] The FCA's application hinges off of the statute's materiality element. Whether or not a claim is considered "false", as interpreted by the Supreme Court, depends on whether the government would have paid for the claim.[53] The Act defines "material" as having a natural tendency to influence or is capable of influencing payment.[54]

Under the FCA's *qui tam* provisions, a private person, known as "relator," may enforce the statute by filing a complaint, under seal, setting forth allegations of fraud committed against the government.[55] The government will then investigate these allegations and the DOJ can intervene in the action and lift the seal from the complaint assuming the primary responsibility for prosecuting the claim.[56] The FCA is popular among fraud prosecutions because if the government prevails on the merits, it is awarded treble damages plus penalties for each false claim. [57] In addition, the relator or whistleblower may recover 15 to 25% of the government's recovery, plus legal fees and expenses.[58] For the FCA to attach to criminal penalties, the

[48] *See Universal Health Services v. U.S. ex rel. Escobar,* 579 US 1, 14 (2016).
[49] *Id*. at 11.
[50] *Id*.
[51] *Id*.
[52] Absil at 260.
[53] *Universal Health Services* at 14.
[54] *See* 31 U.S.C. §3729(b)(4) (2012).
[55] Salcido at 106.
[56] *Id*.
[57] *See* 31 U.S.C. § 3729(a) & 3730(d)(1) (2012).
[58] *See* 31 U.S.C. § 3730(d)(2) (2012).

fraudulent claim submitted must also implicate a federal criminal statute such as the Anti-kickback statute, which will be discussed later in this article.[59]

**b. Applying the FCA in the Context of Opioids**

False claims submitted to the government are a key gateway for prescription opioids that are not medically indicated to enter the community.[60] Although *Universal Health Services*, received significant attention in regards to the legally false certification theory of FCA liability, health industry participants that prescribe or dispense opioids violate more traditional provisions within the FCA.[61] Prescription opioids, when not medically indicated, enter the streets when a physician prescribes opioids that are not considered a "medical necessity" implicating a factually false claim.[62] Medicare and Medicaid programs only provide payment for those healthcare services that are "reasonable and necessary for the diagnosis or treatment of illness or injury."[63]

The FCA is violated when it can be proven that the defendant submitted a claim for an item or service when the defendant knew those items and services were not medically necessary or where the defendant knowingly falsified medical records to make a medically unnecessary item or service appear necessary.[64] For example, if a physician knowingly lies to the government about the medical necessity or did not properly document what is medically necessary when submitting a claim, the FCA is implicated.[65]

In January 2018, Matthew Anderson, a chiropractor who worked in Tennessee, agreed to pay $1.45 million plus interest to resolve FCA violations and contributing to the state's opioid

[59] *Id.*
[60] Absil at 262.
[61] Tovino at 928.
[62] Michael W. Youtt, H. Victor Thomas & Adam Robison, *False Claims Act Actions - The Developing Case Law regarding If and When Opinions of Medical Necessity Can Be Fraudulent*, 27 Health Law. 36, 36 (2015).
[63] 42 U.S.C. § 1395 (a)(1)(A); 42 C.F.R. § 440.230(d)
[64] Youtt at 36.
[65] *Id.* at 39.

epidemic.[66] The government alleged that the defendant and his management company instructed employees of his four clinics to up-code office visits by assigning an inaccurate billing code increase Medicare reimbursement.[67] As a result Anderson caused pharmacies to submit requests for Medicare payments for pain killers, including opioids, which were dispensed based upon the defendant's prescriptions [68] "Pill mills" such as this billed medically unnecessary services to Medicare, defrauded the government and contributed to opioid abuse and addiction. Fortunately, the FCA creates liability not just for those who submitted false claims, but also for those who "cause" false reimbursement claims to be made or "cause" false statements to be made in connection with claims for reimbursement.[69]

However, "expressions of opinion, scientific judgements , or statements as to conclusions about which reasonable minds may differ" cannot be actionable.[70] Courts are also in agreement that mistaken or negligent certifications or statements regarding medical necessity are not actionable.[71] However, when a physician prescribes an unnecessary drug, it directly contributes to the overabundance of opioids in the hands of who may not need them, effectively enabling prescription opioid use disorders.[72]

The medical necessity requirement serves one of the FCA's limitations in enforcement and prosecution. Courts have been hesitant when invaliding a physician's scientific or medical

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[66] Press Release, U.S. Dep't of Justice, Office of Pub. Affairs, Tennessee Chiropractor Pays More Than $1.45 Million to Resolve False Claims Act Allegations (Jan. 24, 2018), https://www.justice.gov/usao-mdtn/pr/tennessee-chiropractor-pays-more-145-million-resolve-false-claims-act-allegations

[67] *Id.*

[68] *Id.*

[69] 31 U.S.C. § 3729(a)(1)(A), (B) (2012) (creating liability for "any person who... knowingly **...** *causes* to be presented **...** a false or fraudulent claim for payment or approval" or "knowingly **...** *causes* to be made **...** a false record or statement material to a false or fraudulent claim.") (emphasis added).

[70] *See* Youtt at 38.

[71] *Id.*

[72] *See* Absil at 262.

judgment in fear of undermining their profession.[73] Instead, courts have consistently declined to find that a contractor's exercise of scientific or professional judgment as to an applicable standard of care falls within the scope of the FCA.[74] A scientific dispute on what is "medically necessary" for a patient is not always a fraud case and reasonable disagreements in the medical or scientific methodology simply do not give rise to FCA liability.[75] As stated above, in order invoke FCA liability in this context, it must be proven that a defendant submitted a claim for government reimbursement that was medically unnecessary, such as the defendant in Tennessee noted above. This limitation may allow for physicians and doctors to hide behind the cloak of their medical opinions, expressions, and scientific work to justify their fraudulent claims.

## B. THE CONTROLLED SUBSTANCE ACT

### a. Background of the CSA

This article will now shift to its second focus: The Controlled Substance Act and its effectiveness in combatting the opioid epidemic. The primary federal law governing the manufacture, distribution, and use of prescription and illicit opioids is the Controlled Substance Act (CSA).[76] The Drug Enforcement Agency (DEA), a law enforcement agency within the DOJ, is principally responsible for administering and enforcing the CSA.[77] The CSA provides a framework through which the federal government regulates the manufacture, distribution, importation, exportation, and use of certain substances which have the potential for abuse or psychological or physical dependence, including both illicit and prescription opioids.[78]

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[73] *See* Youtt at 38.
[74] *Luckey v. Baxter Healthcare Corp*, 2 E Supp. 2d. 1034, 1047 (N.D. Ill. 1998), aff'd, 183 F3d. 730 (7th Cit. 1999).
[75] *See* Youtt at 39
[76] Congressional Research Service, *Legal Authorities Under the Controlled Substances Act to Combat the Opioid Crisis.* (December 18, 2018). https://crsreports.congress.gov/product/pdf/R/R45164/6
[77] *Id*.
[78] *Id*.

The CSA classifies various plants, drugs, chemicals into one of five schedules based on the substances' medical use, potential for abuse, and safety or dependence liability.[79] Schedule I contains substances, such as the hallucinogen lysergic acid diethylamide, better known as LSD, and the illicit opioid heroin, that have "a high potential for abuse" with "no currently accepted medical use in the treatment in the U.S." and that cannot safely be dispensed under a prescription.[80] Schedules II, III, IV, and V include substances that have recognized medical uses, such as prescription opioids like oxycodone, codeine, and morphine, and may be manufactured, distributed, prescribed, dispensed, and possessed in accordance to the CSA.[81]

The CSA also details who must register with the DEA in order to receive authorization to handle the substances.[82] These "registrants" include manufacturers, distributors, doctors, hospitals, pharmacies, and scientific researchers.[83] This creates a "closed system" of lawful distribution among registered handlers of controlled substances. In addition to this, the CSA requires that the DEA establish a quota system that restricts the total amount of certain controlled substances that may be annually produced or manufactured.[84] The DEA establishes quotas for the maximum amount of each basic class of Schedule I and II controlled substances that can be produced each year as well as quotas for individual manufacturers who must apply to obtain quotas for specific classes of controlled substances.[85] This essentially controls the amount of controlled substances that can be put into the market and avoiding the overproduction of controlled substances.

[79] *See* 21 U.S.C. §§ 801- 904 (2012).
[80] 21 U.S.C. § 812(b).
[81] *Id.*
[82] *Id*.
[83] *Id*.
[84] 21 U.S.C. §826(a).
[85] 29th Annual National Institute on Health Care Fraud, 10 (2019).

Additionally, the CSA provides the legal standards through which the federal government prevents diversion of these substances from their legitimate uses and purposes. The DEA uses the CSA as a guide to avoid controlled substances which may have lawful uses from entering into illicit channels.[86] To track this, the CSA and its implementing regulations subject registrants to strict requirements regarding recordkeeping, maintaining the security of inventories, and reporting to the DEA.[87] As part of the registrant's monitoring process and to ensure compliance with the CSA, the DEA conducts three types of investigations – regulatory, complaint , and criminal.[88] A registrant's failure to meet the obligations set forth by the CSA can result in the diversion of controlled substances, which, in turn, can contribute to drug abuse and addiction.[89]

Like most medicine, prescription opioid pain relievers are safe and effective when used as directed, but these highly addictive substances can pose serious risks of addiction or death if they are abused, misused, or diverted. These opportunities for abuse or diversion can occur as drug flow through the prescription drug supply chain. [90] This supply chain is the means through which prescription drugs are ultimately delivered to patients with legitimate medical needs. The typical goes as followed: prescription drugs are produced by manufacturers; are purchased and stored by distributors, who take orders and deliver them to customers such as pharmacies; and ultimately are dispensed by pharmacies to patients who have a prescription from a practitioner.[91]

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[86] Improving Predictability and Transparency in DEA and FDA Regulation: Hearing Before the H. Comm. On Energy & Commerce, Subcomm. On Health, 113th Congress 1 (2014) (statement by Joseph T. Rannazzisi, DEA).
[87] *See*, e.g., 21 C.F.R. § 1304.11(a) ("Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken...."); *see also id*. § 1301.71(a) ("All applicants and registrants shall provide effective controls to guard against theft and diversion of controlled substances."); *see* 21 U.S.C. § 832 ("Each registrant shall—design and operate a system to identify suspicious orders for the registrant … and upon discovering a suspicious order or series of orders, notify the Administrator of the Drug Enforcement Administration….").
[88] *See supra* note 84, 11-12.
[89] *See supra* note 85.
[90] *See supra* note 84, 6.
[91] *Id.* at 8.

Along this supply chain, there are various opportunities for the drugs to be abused and diverted into illegal channels and used for non-medical uses. A common example of diversion is when an individual may visit multiple practitioners posing as a legitimate patient, referred to as a "doctor shopper," to obtain prescriptions for drugs for themselves or others.[92] In other more obvious cases, diversion can occur when a criminal enterprise robs distributors and pharmacies of prescription drugs to illicitly sell to others for a profit.[93]

**b. Enforcing the CSA in the Context of Opioids**

The CSA provides the DEA with a variety of criminal, civil, and administrative tools to hold manufacturers, distributors, pharmacies, and physicians accountable for violations of the CSA's regulatory requirements.[94] Registrants who fail to adhere to the CSA requirements may face administrative consequences, civil and criminal fines, and even the possibility of imprisonment.[95]

The CSA makes it an offense to "knowingly" possess a "controlled substance" with the intent to distribute it. In *McFadden v. United* States, the Supreme Court explained that "the word knowingly applies not just to the statute's verbs but also to the object of those verbs – 'a controlled substance.'"[96] In CSA cases, the federal government has the burden to prove the element of mens rea of "knowing" beyond reasonable doubt. This means that the government must prove that the defendant "knew" that they possessed a controlled substance.[97] A violation of the CSA's registration requirements – including "failure to maintain records or detect and report suspicious orders, noncompliance with security requirements, or dispensing controlled

[92] *Id*.
[93] *Id*.
[94] *See* 21 U.S.C. § 842(a)(6).
[95] *Id*.
[96] *McFadden v. U.S.*, 576 U.S. 186, 190 (2015).
[97] *Id*.

substances without the necessary prescriptions." [98] These violations do not typically constitute a criminal offense unless the violation is committed knowingly. In that event, the DOJ has the authority to bring criminal charges against both individual and corporate registrants.[99]

Furthermore, the Act's trafficking provisions allow for prosecution of the illegal distribution of controlled substances. Although this may primarily involve the illegal distribution of recreational drugs, the CSA applies to illicit activities involving pharmaceutical or non-pharmaceutical controlled substances.[100] "Notably, the CSA's registration system and its trafficking regime are not mutually exclusive, and participation in the registration system does not insulate registrants from the statute's trafficking penalties." For example, a registered physician may be prosecuted under the CSA for illegally prescribing and distributing prescription drugs. This provision and interpretation of the CSA has been exponential in combatting the overabundance of prescription opioids in the community. *In United States v. Moore*, the Supreme Court rejected a claim that the CSA, "must be interpreted in light of a congressional intent to set up two separate and distinct penalty systems," one for registrants and one for non-registrants.[101] The Court held that physicians registered under the Act can be prosecuted under the drug trafficking provision "when their activities fall outside the usual course of professional practice."[102] In other words, when physicians are acting less like medical doctors treating patients and more like a large-scale drug pusher.

The decision in *Moore* also upholds convictions of pharmacists who signed thousands of prescriptions for sale though an online pharmacy, and a practitioner who "freely distributed

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[98]Congressional Research Service, *supra* note 9.
[99] *Id*.
[100] *See* 21 U.S.C. §§ 841, 844 (criminalizing the manufacture, distribution, and possession of "a controlled substance," except as authorized by the CSA).
[101] *United States v. Moore,* 423 U.S. 122, 133 (1975).
[102] *Id*. at 124. (The defendant in *Moore* was a registered doctor who distributed large amount of methadone with inadequate patient exams and no precautions against misuse or diversion.)

prescriptions for large amounts of controlled substances that are highly addictive, difficult to obtain, and sought after for nonmedical purposes…"[103] However, one limitation to prosecuting bad actors under *Moore* requires "more than a showing of mere professional malpractice." For example, the Ninth Circuit held that a prosecution must prove that the defendant "acted with intent to distribute drugs and with intent to distribute them outside the course of professional practice," suggesting that intent must be established with respect to the nature of the defendant's failure to abide by professional norms.[104]

The DOJ's prosecution of criminal trafficking charges against doctors and pharmacies has proved essential in combatting diversion and ensuring proper regulation of the CSA. This has also been seminal in combatting the overabundance of prescription opioids leading to addiction and abuse. However, in April 2019, the DOJ used the CSA for the first time to bring criminal trafficking charges against a drug distributor .[105] The DOJ successfully prosecuted two executives of Rochester Drug Cooperative (RDC) on the company's sale of the opioids oxycodone and fentanyl to pharmacies that illegally distributed and diverted the drugs.[106] RDC was charged with unlawfully distributing oxycodone and fentanyl, defrauding the DEA, and failing to report suspicious order to the DEA.[107] The DOJ entered into a deferred prosecution agree and consent decree with RDC, which has admitted to its misconduct.[108] In addition, the pharmaceutical paid a substantial penalty, agreed to be supervised by a monitor and make significant reforms to its compliance program.[109]

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[103] *See United States v. McIver*, 470 F.3d 550, 564 (4th Cir. 2006).
[104] *United States v. Feingold*, 454 F.3d 1001, 1008 (9th Cir. 2006).
[105] *See* U.S. v. Rochester Drug Co-operative, U.S. v. Laurence Doud III, Press conference remarks of U.S. Attorney Geoffrey S. Bernam as delivered (Apr. 23, 2019), https://www.justice.gov/usao-sdny/page/file/1164191/download
[106] *See* Press Conference Remarks.
[107] *Id.*
[108] *Id.*
[109] *Id.*

Lastly, CSA cases may also be prosecuted alongside the FCA. Several health industry players have settled FCA allegation predicated on violating of material statutes and regulations such as the provisions within the CSA.[110] In 2015, PharMerica Corporation agreed to pay the government $31.5 million "to resolve a lawsuit alleging the pharmacy violated the CSA by dispensing Schedule II controlled drugs without a valid prescription and the FCA by submitting false claims to Medicare for improperly dispensed drugs."[111] Many of those prescriptions include oxycodone and fentanyl, which the pharmacies dispensed without a CSA-required physician prescription.[112]

The trend of criminally prosecuting pharmaceuticals under the CSA by the DOJ continued. Similarly in July 2019, the DOJ successfully prosecuted the pharmaceutical distributor Miami-Luken, Inc. for conspiracy to violate CSA's trafficking provisions.[113] The threat of the CSA to all players on the drug supply chain has been effective in combatting the overabundance and misuse of prescription opioids.[114] In theory, the CSA can be used to prosecute any player in the supply chain that is required to become a registrant with the DEA. There have been proposals targeting the "imminent danger" requirement. Specifically the bill would lower the threshold for what constitutes imminent danger, requiring "probable cause that death, serious bodily harm, or abuse" will occur in the absence of an immediate suspension of DEA registration.[115] The opioid epidemic has been driven by the greed of pharmaceutical

[110] *See* Tovino at 930.
[111] Press Release, U.S. Dep't of Justice, Office of Pub. Affairs, Long-Term Care Pharmacy to Pay $31.5 Million to Settle Lawsuit Alleging Violations of Controlled Substances Act and False Claims Act (May 14, 2015), https://www.justice.gov/opa/pr/long-term-care-pharmacy-pay-315-million-settle-lawsuit-alleging-violations-controlled.
[112] Id.
[113] Congressional Research Service, *supra* note 9, 18.
[114] *Id*.
[115] *See id*. at 21.

manufacturers, distributors, and physicians who exploit those with prescription drug abuse and fuel the opioid epidemic.

In recent years, we have already seen several legislative proposals enacted into law to prevent the illicit distribution of opioids. In 2016, Congress enacted the Comprehensive Addiction and Recovery Act (CARA) and the 21st Century Cures Act (Cures Act) which authorizes grants for educational programs to address the opioid crisis in areas including abuse prevention, law enforcement, and treatment. These Acts also provided additional funding to states combatting opioid addiction.[116] However, in 2018, Congress went even further to enact the SUPPORT Act (Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act).[117] This Act included amendments to the CSA to include provisions expanding access to medication-assisted treatment (MAT), revising the factors DEA considers when establishing opioid production quotas, and codifying the definition of "suspicious order."[118]

To further address the opioid crisis, there are several gaps in the CSA that can still be filled. The CSA can allow for stricter requirements for registrants, specifically medical practitioners, to certify that they will not prescribe more prescription opioids than necessary for the treatment of short-term pain.[119] The John S. McCain Opioid Addiction Prevention Act has already been proposed to limit a prescription of no more than a seven-day supply of opioids for

[116] Pub. L. No. 115-271, 132 Stat. 3894 (2018); see also CRS Report R45449, *The SUPPORT for Patients and Communities Act* (P.L.115-271): Medicare Provisions, coordinated by Suzanne M. Kirchhoff; CRS Report R45423, *Public Health and Other Related Provisions in P.L* 115-271, *the SUPPORT for Patients and Communities Act*, coordinated by Elayne J. Heisler and Johnathan H. Duff; CRS Report R45405, *The SUPPORT for Patients and Communities Act* (P.L. 115-271): *Food and Drug Administration and Controlled Substance Provisions*, coordinated by Agata Dabrowska.
[117] *Id*.
[118] *Id*.
[119] Congressional Research Service, *supra* note 9, 21.

the treatment of acute pain.[120] Moreover, with the growing rise of the synthetic opioid, fentanyl, amending the CSA by reducing the amounts of fentanyl needed for a trafficking offense and increasing penalties to offences involving the drug would lead to more bad actors facing criminal liability.[121]

## C. THE FEDERAL ANTI-KICKBACK STATUTE

### a. Background of the AKS

The third federal law that this article will explore is the federal Anti-Kickback Statute (AKS). This federal law prohibits the knowing and willful solicitation, receipt, offer, or payment of any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overly or covertly, in case or in kind, in return for the referral of any individual for the furnishing of any item or service for which payment may be made in whole or in part under a federal health care program, such as Medicare or Medicaid.[122] The AKS also prohibits remuneration knowingly and willfully exchanged in return for "purchasing, leasing, order or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a federal health program.[123]

The goal of the AKS is premised upon the concern that health care kickbacks can lead to corruption of professional medical decision making, patient steering, overutilization of health care items (such as opioids), services, and supplies, increased costs to federal health care

[120] H.R. 1614, 116th Cong. (2019); S. 724, 116th Cong. (2019).
[121] H.R. 1781, 115th Cong. (2017); The amendment would have allowed for temporary scheduling of a substance if the DEA Administrator found that "the drug or other substance satisfies the criteria for being considered a synthetic opioid" and "adding such drug or other substance to the definition of synthetic opioids will assist in preventing abuse or misuse of the drug or other substance."
[122] 42 U.S.C. §§1320a-7b(b)(1)(A), (b)(2)(A) (2012).
[123] 42 U.S.C. §1320a-7b(b)(1)(B), (b)(2)(B) (2012).

programs, and unfair competition among doctors and health care facilities.[124] The Department of Health and Human Services makes it clear to physicians that it may be acceptable to reward those who refer business in some industries, but in the federal health care programs, paying for referrals is a crime.[125] In *United States v. Patel*, the Seventh Circuit issued an important ruling regarding the meaning of the term "refer."[126] Although prior courts largely agreed that a "referral" means sending patients to a certain provider, the Seventh Circuit adopted a broader interpretation, holding that a physician makes a referral for a purposes of the AKS when he or she makes a "certification or recertification" that care is necessary, even if the physician never steered patients to the particular provider.[127] This expansion is important because it gives prosecutors broader range to charge physicians with an AKS violation because they did something that allowed a patient to receive care from a provider when they otherwise would not without the physicians referral.

An AKS violation is punishable as a felony. Individuals convicted of an AKS violation shall be fined not more than $100,000, imprisoned for not more than 10 years, or both.[128] With respect to violations, a prosecutor must not prove actual knowledge or specific intent to commit a violation of the AKS. Instead, the government has a lower burden and must only prove that the individual "knowingly and willfully" intending to do something wrong.[129] A violation of the AKS can also subject a defendant to exclusion from future participation in federal health care

[124] A Roadmap for New Physicians: Fraud and Abuse Laws, U.S. Dep't Health & Human Servs., Off. Inspector Gen., https://oig.hhs.gov/compliance/physician-education/index.asp (last visited Apr. 5, 2020) (listing concerns raised by health care kickbacks).
[125] *See id.* at 4.
[126] *See United States v. Patel*, 778 F.3d 607, 609 (7th Cir. 2015).
[127] *Id*. at 612–18.
[128] 42 U.S.C. § 1320a-7b(b)(1), (2)
[129]42 U.S.C. § 1320a-7b(h); *see also United States v. Greber*, 760 F.2d 68, 72 (3d Cir. 1985) (establishing the "one purpose" rule which states that as long as there was only one purpose to induce the ordering of services, then the Anti-Kickback Statute has been violated).

programs as well as civil monetary penalties.[130] The AKS covers the payers of the kickbacks – those who offer or pay remuneration – as well as the recipients of kickbacks – those who solicit or receive remunerations.[131] Each party's intent is a key element of their liability under the AKS.

**b. Enforcement of the Anti-Kickback Statute in the context of Opioids**

The AKS is used to combat the opioid epidemic form several angles, whether it be street level dealing by physicians or corporate greed by pharmaceutical companies. Both physicians and non-physicians violate the Anti-Kickback Statute if they receive remuneration from pharmaceutical companies in the exchange for opioids prescriptions. On the other hand, the AKS is also enforced against those same companies who offer illegal remunerations to physicians for unnecessary prescriptions and promotions.

One of the most notable health care fraud prosecutions in recent years was against Insys Therapeutics Inc., who played a large role in increasing the over prescription of opioids across the country. Former executives and managers of Insys Therapeutics, were charged with conspiracy to violate the Anti-Kickback Statute Law in relation to a nationwide conspiracy to bribe medical practitioners to unnecessarily prescribe their fentanyl-based pain medication and defraud payers of the medication, including insurers.[132] These top executives of Insys paid kickbacks and committed fraud to sell a highly potent and addictive opioid that led to abuse and life threatening respiratory depression of many patients.[133]

In turn, there have been a number of cases in which physicians were convicted of violating the AKS for receiving or accepting remunerations from pharmaceutical companies in

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[130] 42 U.S.C. § 1320a-7(b)(7)
[131] *See* A Roadmap for New Physicians: Fraud and Abuse Laws
[132] Press Release, U.S. Dep't of Justice, U.S. Attorney's Office, Dist. of Mass., *Pharmaceutical Executives Charged in Racketeering Scheme.* (Dec. 8, 2016). https://www.justice.gov/usao-ma/pr/pharmaceutical-executives-charged-racketeering-scheme
[133] *Id.*

turn for prescribing prescription opioids.[134] For example, in November 2019, a New Jersey/Pennsylvania doctor pled guilty to accepting bribes and kickbacks from Insys Therapeutics, in exchange for prescribing more than 28 million micrograms of Subys, a powerful opioid narcotic.[135] Kenneth Sun, M.D, participated in a scheme to receive over $140,000 in bribes and kickbacks from Insys in exchange of prescribing large volumes of Subys. Subys contains fentanyl, a synthetic opioid pain reliever which is approximately 50 to 100 times more potent than morphine.[136] Sun admitted of proscribing Subys to patients for whom Subys was medically unnecessary, not eligible for insurance reimbursement and unsafe.[137] The scheme involving both Insys and Sun disguised the bribes and kickbacks as "honoraria" for education presentation regarding the narcotic that Sun purportedly provide to other doctors.[138] These presentations were a sham. Sun admitted that he defrauded the government by causing Medicare to pay more than $847,000 for Subys prescriptions that were medically unnecessary, procured through the payment of kickbacks and bribes and not eligible for Medicare reimbursement.[139]

Kenneth Sun is not the only doctor who has received remunerations in exchange for prescribing Subys. In January of this year, a Manhattan doctor was sentence to nearly 5 years in prison for accept bribes and kickbacks from Insys Therapeutics. Dr. Alexandru Burdecea began prescribing Subys in 2015 – a drug that he previously never prescribed before – in exchange for

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[134] Press Release, U.S. Dep't of Justice, Office of Pub. Affairs, *New Jersey/Pennsylvania Doctor Pleads Guilty to Accepting Bribes and Kickbacks in Exchange for Prescribing Powerful Fentanyl Drug*. (Nov. 22, 2019) https://www.justice.gov/opa/pr/new-jerseypennsylvania-doctor-pleads-guilty-accepting-bribes-and-kickbacks-exchange; Press Release, U.S. Dep't of Justice, Office of Pub. Affairs, *New Jersey Chiropractor Agrees to Pay $2 Million to Resolve Allegations of Unnecessary Knee Injections and Knee Braces and Related Kickbacks.* (Apr. 6. 2020). https://www.justice.gov/opa/pr/new-jersey-chiropractor-agrees-pay-2-million-resolve-allegations-unnecessary-knee-injections; https://www.justice.gov/usao-sdny/pr/manhattan-doctor-sentenced-nearly-five-years-prison-accepting-bribes-and-kickbacks;

[135] Press Release, *supra* note 134.

[136] *Id.*

[137] 27 No. 6 FDA Advertising & Promotion Manual Newsl. *Insys Sale Rep Sentenced to Probation; Doctor indicted in Separate Case.* 9

[138] *Id.*

[139] *Id.*

bribes from Insys and became the 14th highest prescriber of the drug in the country with a net sale of the drug of approximately $621,345 in that quarter.[140] Burdecea was one of five doctors who were convicted of participating in Insy's "Speakers Bureau." This scheme involved a roster of doctors across the country who would conduct programs purported aimed at educating other practitioners about Subys.[141] However, in reality, the Speakers Bureau was used to induce doctors who served as speakers to prescribe large amounts of the drugs and paying them in Speakers fees.[142]

Physicians who receive remunerations from pharmacies or laboratories also violate the Anti-Kickback Statute.[143] In 2014, Dr. Carl Dennis Fowler, was convicted of violating the AKS when he received remuneration from a pharmacist in exchange for opioid prescriptions.[144] Dr. Fowler wrote numerous prescriptions for OxyContin and oxycodone, without regard to whether the drugs were medically necessary and filled to Patel Pharmacies, which were later resold on the street market.[145] In return, Dr. Fowler received kickbacks for writing the prescriptions that were filled to Patel Pharmacies and that were billed to Medicare and Medicaid.[146] Further, physicians who also receive remunerations in return for referring government program patients to particular laboratories for opioid and other drug testing services implicate the AKS.[147] In 2017, a

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[140] Press Release, *Manhattan Doctor Sentenced to Nearly Five Years In Prison For Accepting Bribes And Kickbacks In Exchange For Prescribing Fentanyl Drug* (January 27, 2020). https://www.justice.gov/usao-sdny/pr/manhattan-doctor-sentenced-nearly-five-years-prison-accepting-bribes-and-kickbacks

[141] *Id.*

[142] *Id*.

[143] *See* Tovino at 914.

[144] Press Release, U.S. Dep't of Justice, U.S. Attorney's Office, E. Dist. of Mich., *Jury Convicts Doctor, Pharmacist, Marketer in Health Care Fraud Scheme* (Mar. 7, 2014) https://www.justice.gov/usao-edmi/pr/jury-convicts-doctor-pharmacist-marketer-health-care-fraud-scheme

[145] *Id*.

[146] *Id*., *see also* Salcido at 118. (Most if not all Anti-Kickback prosecutions are overlapped with FCA actions. If it is a violation of the AKS, it is generally a per se violation of the FCA); *see also, United States ex rel. Thompson v. Columbia /HCA Healthcare Corp*., 20 F.Supp.2d 1017 (S.D. Tex. 1998) (interpreting and allowing the FCA to be used in conjunction with the AKS providing a long range of remedies to prosecute bad actors who take part in illegal kickbacks and filing false claims using patients using government health care programs).

[147] *See* Tovino at 915.

Pennsylvania doctor was sentenced to 84 months in prison and $2.3 million in restitution for referring his Medicare and Medicaid patients to a lab in which he was in a joint venture with.[148]

Under the AKS, the fraudulent use of government money matters. Similar to the FCA, the Act is concerned with defrauding federal health programs such as Medicare and Medicaid. Under the AKS, even if a service is given by the physician or laboratory, a falsity still exists because it is tainted by a kickback at the cost of federal health care programs. However, the requisite that there a federal health care program must be involved and the defrauding of government money must occur may also be limitation to AKS prosecutions. This limitation and a possible remedy will be explored in the next section discussing the enactment of EKRA.

## D. THE ELIMINATING KICKBACKS IN RECOVERY ACT

### a. Background of EKRA

The federal government has enacted a massive new initiative to address the nation's opioid crisis and health care fraud that accompanies it. President Trump signed into law the SUPPORT for Patients and Communities Act in 2018, which is a comprehensive legislative initiative comprised of 70 individual bills intended to address the opioid crisis and substance abuse.[149] The SUPPORT Act appropriates millions of dollars from the Treasury and federal Supplementary Medial Insurance Trust Fund to support federal agencies in their initiatives to combat the opioid epidemic.[150] This next section will focus specifically on Sections 8121 and 8122 part of the SUPPORT Act that establishes the Eliminating Kickbacks in Recovery Act of 2018 (EKRA). Of the many consequential provisions, EKRA is one that could have a significant impact on those involved in addiction recovery efforts and treatment facilities. Section 8122 now

[148] *Id.*
[149] *See* Support for Patients and Communities Act, Pub. L. No. 115-271, § 7031, 132 Stat. 3894 (2018).
[150] *Id*.

makes it a federal crime to pay for referrals to recovery homes, clinical treatment facilities and laboratories.[151] Violations would be punishable with criminal penalties such as monetary fines, imprisonment, or both

The Eliminating Kickback in Recovery Act is designed to build on the prohibitions set forth in the federal Anti-Kickback Statute. EKRA prohibits anyone from knowingly and willfully: (1) soliciting or receiving any remuneration in return for referring a patient to a recovery home, clinical treatment or laboratory; or (2) paying or offering an remuneration to: (1) induce a referral of an individual to a recovery home, clinical treatment facility, or laboratory in exchange for an individual using the services of the recovery home, clinical treatment facility or laboratory.[152] In other words, EKRA is narrower in this sense as it only applies to referrals of certain types of facilities, namely recovery homes, clinical treatment facilities, and laboratories. EKRA does not preempt the Federal AKS or state law on the subject matter. So, in terms of practicality, ERKA cannot be used when the AKS applies.[153]

EKRA addresses Congress's growing concerns about patient brokering in connection with substance abuse treatment centers. Patient brokers are those who profit off of patients seeking substance abuse treatment through "illicit referrals," including "patient brokers who take advantage of patients with opioid use disorders by referring these patients to substandard or fraudulent providers in exchange for kickbacks."[154] The legislative intent was clear: Congress included EKRA to the bill to crack down on individuals and companies taking advantage of and

[151] *See* Eliminating Kickbacks in Recovery Act of 2018 §§ 8121-8122.
[152] *Id*.
[153] Tony Maida & James A. Cannatti III, *Historic Opioids Package Pending: Congress Creates Drug Recovery and Treatment Anti-Kickback Law*, McDermott Will & Emery. (Oct. 4, 2018). https://www.mwe.com/pdf-download/?language=en&type=insights&slug=19123.
[154] *See* 164 Cong. Rec. H9244, H9249 (September 28, 2018).

exploiting vulnerable patients seeking addiction treatment,[155] as well as to close the gap left by the Federal AKS.[156]

This provision is also significant because although there are similarities with the Federal AKS, there are several defining distinctions. The Federal AKS already prohibits an individual to knowingly and willfully provide anything of value in return for or to induce or reward referrals of patients covered by federal health care programs. Rather than amend the Federal AKS, EKRA creates a new, separate provision that makes remuneration illegal as to patients covered by private health care plans as well.[157] Senator Amy Klobuchar (D-MN), one of three senators who introduced this bill, noted that such kickbacks are already illegal under federal health care plans, "but there is no Federal law to prohibit them in private health insurance plans."[158] She states, "when people are struggling with addiction, their focus should be on getting well, not worrying whether treatment facilities are trying to take advantage of them to make more money."[159] The DOJ explained why EKRA's expansion to people on private health insurance was needed: "Patients in substance abuse treatment facilities are not usually Medicare beneficiaries, but often people on private insurance, or often times people in their twenties, who are still on their parents' plans."[160] Patients who are most vulnerable who are suffering from addiction and substance abuse are essentially "treated as cash registers…"[161] However, although EKRA is well-intentioned, the following subsection will discuss some of the limitations in the language of the statute that have raised concerned for stakeholders as well as enforcers of act.

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[155] Katherine Lauer et. al., *Eliminating Kickbacks in Recovery Act: Implications for Laboratory Sales Force Arrangements*, 21 J. Health Care Compliance 25 (2019).
[156] Maida, *supra* note 153.
[157] Laurer, *supra* note 155.
[158] 164 Cong. Rec S6467, S6473 (2018).
[159] *Id*.
[160] *See* Tovino at 938.
[161] *Id*.

### b. Limitations to ERKA

First, the statute contains broad definitions that may cause discrepancies in enforcement. EKRA defines "recovery home" as "a shared living environment that is, or purports to be, free from alcohol and illicit drug use and centered on peer support and connection to services that promote sustained recovery from substance use disorders."[162] "Clinical treatment facility" is defined as "a medical setting, other than a hospital, that provides detoxification, risk reduction, outpatient treatment and care, residential treatment, or rehabilitation for substance use, pursuant to licensure or certification under state law."[163] "Laboratory" is defined to include all clinical laboratories, and thus all referrals for clinical laboratory tests implicate EKRA regardless of whether the tests relate to substance abuse testing or treatment.[164]

The definitions of "recovery home" and "clinical treatment facility" appear to lend support to the legislative intent of the SUPPORT Act, however the broad definition of "laboratories" does not, and may lead to unintended consequences in enforcement. Importantly, EKRA does not define the term "referral." "Because its prohibition against kickbacks is limited to remuneration paid in exchange for referrals or an individual's use of services, an authoritative interpretation of the term 'referral' under EKRA is necessary to determine the scope of the law."[165] Based on these definitions, EKRA establishes a new "public and private payor intent-based criminal anti-kickback law that prohibits any form of remuneration in exchange for referrals to, or an individual's use of, all entities that meet the definitions of recovery homes,

[162] 18 U.S.C. § 220(e)(5).
[163] 18 U.S.C. § 220(e)(2).
[164] 18 U.S.C. § 220(e)(4).
[165] Reesa N. Benkoff & Dustin T. Wachler, *EKRA: Enactment and Implications of the SUPPORT Act's New All-Payor Federal Anti-Kickback Law*. American Bar Association. (Mar. 1, 2019) https://www.americanbar.org/groups/health_law/publications/aba_health_esource/2018-2019/march/ekra/

clinical treatment facilities, and laboratories"– including referrals to laboratories unrelated to substance abuse testing or treatment.[166]

Confusion in enforcement may start with the statutory interpretation of the term "referral." Under the AKS, although not defined, a referral, has been traditionally viewed to apply to provider referrals. This is similar under EKRA, but it omits the statutory language that the federal government has historically used under the AKS to apply that law to marketing and sales activities.[167] The lack of a definition for "referral" will likely cause the DOJ to come up with regulation to clarify the meaning under EKRA so that it applies to marketing and sales agents consistent with its legislative intent.[168] EKRA's broad statutory language in its prohibition of remuneration in exchange for an individual using the services of a recovery home, clinical treatment facility or lab is written that it may also apply to remuneration received by a patient for his/her receipt of services by such an entity.[169] This discrepancy may diverge from the Act's legislative intent as well.

Furthermore, under EKRA, many existing relationships in the healthcare industry will need to be modified in order to comply with the statute and to avoid risk of criminal liability. In the context of laboratories, EKRA's broad language appears at first keen to prohibit laboratories from paying commissions to an employed sales force, however to end commission-based compensation for laboratory sales personnel would dramatically impact a common practice among labs.[170] It is common practice among laboratories to use employed sales representatives to recommend or arrange for providers to purchase their services, and pay employees based on the

[166] *Id*.
[167] *Id.*
[168] *Id*.
[169] *Id.*
[170] *See* Lauer at 27.

volume or value of business they generate.[171] Prior to EKRA, this practice was uncontroversial because the AKS excepts, "any amount paid by an employer to an employee (*bonafide* employment relationship) for employment in the provision of covered items or serviced.[172] However, EKRA does not have a parallel exception and its broad definition of "laboratories" does not limit these circumstances to drug-related testing.

Due to EKRA's recent enactment only two years ago, there have not been many convictions under this law for its impact to be determined yet. What is presumably the nation's first EKRA conviction occurred early January 2020 in Kentucky, when Theresa Merced admitted in federal court that she solicited kickbacks from a toxicology laboratory in exchange for urine drug testing referrals.[173] Merced was the office manager of a substance abuse treatment clinic and solicited kickbacks from the CEO of a toxicology lab in exchange for urine drug test referrals.[174] The 80-year-old woman is scheduled to be sentenced on May 1, 2020, and faces up to 20 years in prison and a maximum fine of $250,000.[175]

### c. EKRA's Effectiveness on Combatting the Opioid Crisis

The Eliminating Kickbacks in Recovery Act seems to be well intended. It is Congress's attempt to address kickback schemes that fall short of the Federal AKS in connection with patient brokering activities associated with substance abuse treatment and recovery efforts. It provides the federal government another legal tool that can be used in prosecuting those who exploit those suffering with addiction and drug abuse by referring them to insufficient or

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[171] *Id*.
[172] 42 U.S.C. §1320 7b(b)(3)(B)
[173] Press Release, *Jackson Woman Pleads Guilty to Soliciting Kickbacks Making False Statement to Law Enforcement Agents, and Tampering with Records.* (Jan. 10, 2020). https://www.justice.gov/usao-edky/pr/jackson-woman-pleads-guilty-soliciting-kickbacks-making-false-statements-law
[174] *Id*.
[175] *Id*.

fraudulent providers in return for kickbacks.[176] However, because of the law's broadly drafted definitions, there may be statutory consequences that exceed the initial legislative intent.[177] While EKRA was in fact enacted to prohibit patient brokering of substance abuse patients on behalf of substance abuse treatment providers and facilities, EKRA also applies to referrals to laboratories unrelated to substance abuse treatment.[178]

It is important to note that although these definitions raise concerns for enforcement, its expansion to prosecute actors who offer and receive kickbacks outside of the federal health care setting is a step in the right direction in eliminating any gaps that existed under the Federal AKS. However because of EKRA's expansive reach to the private health industry, many existing relationships in the health care industry will need to be modified to comply with the new law and to avoid risk of criminal liability.[179] The entire SUPPORT act is a wide-ranging provision that is intended to add to the roster of tools intended to cure the opioid crisis.[180] As more cases are prosecuted by the DOJ under EKRA, its legal effectiveness as well as its deficiencies will be determined.

## III. CONCLUSION

This article has identified and discussed several legal tools that the federal government uses to combat the over-prescription of drugs and the growing opioid crisis plaguing the United States. The False Claims Act, although not designed to be an anti-fraud statute, has played a critical role in prosecuting bad actors across the health care supply chain. The FCA creates liability not just for those who submitted false claims, but also for those who "cause" false

[176] Benkoff, *supra* note 165.
[177] *Id*.
[178] *See id*.; *See also* 18 U.S.C. § 220(a); 18 U.S.C. § 220(e)(4).
[179] Benkoff, *supra* note 165; *see also* Maida, *supra* note 153.
[180] *See* Lauer at 30.

reimbursement claims to be made or "cause" false statements to be made in connection with claims for reimbursement. Thus, the FCA is able to prosecute individual physicians filing false claims to pharmaceutical companies who cause a doctor to file a false claim. With its *qui tam* provision, also known as its whistleblower powers, the federal government can initiate investigations as well as impose civil monetary penalties on bad actors. Because of the its treble damages provision, some of the largest settlements under the FCA have been by pharmaceutical manufacturers, like Pfizer and Insys Therapeutics Inc.[181] Like many federal provisions, the FCA has its limitations. For one, the government can only prosecute false claims involving the defrauding of a federal health care program. Claims involving the private health insurances do not fall under the realm of the FCA. As EKRA is to the AKS, it would be interesting to see an amendment or legislative counterpart to the FCA that covers false claims as to private health insurance business. Moreover, factually false claims, including claims for medical services never provided certainly can increase unnecessary costs to federal health care programs. However, it can be argued that these false claims do not contribute to the patient injury side of the opioid crises because there were no patients actually prescribed the opioids.[182] Despite this, the FCA is viewed as one an important tool in combatting the opioid epidemic.[183]

The article then examines the effectiveness of the Controlled Substance Act in combatting the opioid crisis. The CSA, which classifies both prescription and illicit drugs into schedules based on its potential for abuse, imposes criminal penalties on those who illegally

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[181] Press Release, *supra* note 34.
[182] *See* Tovino at 936.
[183] Nekia Hackworth Jones, *The DOJ's Latest Opioid Crime-Fighting Tool: The Civil False Claims Act*, L.J. Newsletter (July 2018) http://www.lawjournalnewsletters.com/2018/07/01/the-dojs-latest-opioid-crime-fighting-tool-the-civil-false-claims-act/?slreturn=20200412191456 (stating "[t]he U.S. Department of Justice is now using the False Claims Act traditionally a civil enforcement tool-to combat the United States' sweeping opioid epidemic", and "[t]he use of the FCA is part of a larger DOJ strategy to develop multi-faceted solutions for this public health emergency.").

possess, distribute, manufacture or prescribe controlled substances without being a proper registrant of the DEA. The CSA's prosecutions are not limited to registrants under the DEA. The CSA has been successful in the prosecutions of individual physicians and pharmacies who act as drug dealers and pill mills through the over-prescription of opioids. The CSA is also seminal in controlling the amount of controlled substances that may enter into the market. Manufacturers and distributors who are in violation of the overproduction of opioids are successfully prosecuted under the CSA. The threat of criminal penalties and the threat of losing DEA registrant status has been key to deterring bad actors from violating the CSA and an efficient tool to combat the opioid crisis.

The article then explores the Federal Anti-Kickback Statute, which prohibits the remuneration of anything of value in return for the referral of patients or medical services. The federal government uses the AKS as a tool to cut off opioid over-prescribing and over-referring induced by remuneration. The AKS has been successful in prosecuting large pharmaceutical companies and their executives, as well as individual doctors or pharmacies who accept remuneration in return for their prescriptions. The AKS has been effective in combatting opioid-related health care fraud, abuse and for protecting patients in cases in which a prescriber's medical judgement has been tainted by illegal kickbacks.[184] Additionally, the AKS has been an effective tool for purposes of prosecuting bad actors like Dr. Kenneth Sun[185], whose opioid prescriptions were fueled by greed. It must be noted that the AKS also has its limitations in their application to federal (versus private) health care program business. Like the FCA, the federal

[184] *See* Tovino at 933.
[185] Press Release, *supra* note 134.

AKS does not apply to patient recruiters who offers to pay for remunerations from private health insurance business.[186]

Lastly, the article briefly explored the Eliminating Kickbacks in Recovery Act of 2018. This act was incorporated in SUPPORT for Patients and Communities Act. EKRA is designed to focus on health care fraud (specifically kickbacks) in the context of opioids and crack down on those bad actors who exploit patients struggling with addiction by referring them to insufficient facilities or treatments in return for remunerations.[187] Although this act does not prosecute bad actors who put medically unnecessary opioids in the hands of more users, it combats those who are exploiting drug addicts who are seeking help with their addiction. Importantly, EKRA fills in the gaps left by the AKS by making remunerations illegal as to patients covered by private health insurance. Because ERKA is relatively new, there have not been many cases surrounding the legislation yet. However, as more cases arises, it will allow us to determine is effectiveness and capability in the overall fight against the opioid crisis.

[186] *Supra* note 184.
[187] Benkoff, supra note 165.