# Fraud, Abuse, and Opioids

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## I. INTRODUCTION

Legislation, regulation, scholarship, and journalism addressing the opioid crisis has focused on a number of front-end management strategies, including opioid production quotas,[1] opioid taxes,[2] drug labeling,[3] risk evaluation and mitigation strategies,[4] marketing restrictions,[5] opioid

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1. *See* Scott Burris et al., *Stopping an Invisible Epidemic: Legal Issues in the Provision of Naloxone to Prevent Opioid Overdose*, 1 DREXEL L. REV. 273, 286 (2009) (discussing production quotas as well as eradication programs, border controls, and street-level disruptions as supply-side interventions that can help interfere with the production and distribution of opioids and other drugs).

2. *See, e.g.*, Editorial, *Kill Cuomo's Cockamamie 'Opioid Tax'*, N.Y. POST (Mar. 22, 2018), https://nypost.com/2018/03/22/kill-cuomos-cockamamie-opioid-tax/ [https://perma.cc/U2HH-L58C] (criticizing Governor Andrew Cuomo's proposed two-cents-per-milligram opioid tax, also known as an "opioid epidemic surcharge" and questioning whether pharmaceutical companies would actually pay the tax).

3. Patricia J. Zettler, Margaret Foster Riley & Aaron S. Kesselheim, *Implementing a Public Health Perspective in FDA Drug Regulation,* 73 FOOD & DRUG L.J. 221, 247–55 (2018) (discussing the FDA's influence of provider and patient behavior through drug labeling).

4. Hilary Homenko, *Rehabilitating Opioid Regulation: A Prescription for the FDA's Next Proposal of an Opioid Risk Evaluation and Mitigation Strategy (REMS)*, 22 HEALTH MATRIX 273, 290–312 (2012) (discussing the FDA's authority to require a risk evaluation and mitigation strategy (REMS) as part of a drug approval application; applying REMS to the opioid crisis).

5. *See, e.g.*, Ameet Sarpatwari, Michael S. Sinha & Aaron S. Kesselheim, *The Opioid Epidemic: Fixing a Broken Pharmaceutical Market*, 11 HARV. L. & POL'Y REV. 463, 472–73 (2017) (arguing that ineffective penalties for illegal marketing incentivized opioid manufacturers to make misleading claims).

insurance coverage limitations,[6] physician prescribing practices,[7] prescription drug monitoring programs,[8] prescription safety alert systems,[9] maximum initial opioid prescription quantities,[10] continuing opioid education for opioid prescribers,[11] and temporary restraining orders for improper opioid prescribers.[12] Back-end crisis-management strategies,

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6. *See, e.g.*, Stacey A. Tovino, *State Benchmark Plan Coverage of Opioid Use Disorder Treatments and Services: Trends and Limitations*, 70 S.C. L. REV. (forthcoming 2019) (surveying state benchmark plan coverage of opioid use disorder treatments and services and identifying trends and limitations relevant thereto); Lev Facher, *Tapered to Zero: In Radical Move, Oregon's Medicaid Program Weighs Cutting Off Chronic Pain Patients from Opioids*, STAT (Aug. 15, 2018), https://www.statnews.com/2018/08/15/oregon-medicaid-tapering-opioids/ [https://perma.cc/MQL2-QN6N] (reporting Oregon officials' consideration of a proposal that would end Medicaid coverage of opioids for Medicaid beneficiaries with chronic pain); Brett Kelman, *Blue Cross Will Stop Covering OxyContin in Tennessee Next Year*, TENNESSEAN (Sept. 6, 2018), https://www.tennessean.com/story/news/health/2018/09/06/blue-cross-stop-covering-oxycontin-tennessee-opioid-epidemic/1109915002/ [https://perma.cc/B2QX-XARG] ("The largest health insurance company in Tennessee will stop covering OxyContin prescriptions next year as part of sweeping policy changes intended to combat opioid addiction and make pain pills less valuable on the black market.").

7. *See generally* Kelly K. Dineen, *Definitions Matter: Defining Inappropriate Prescribing to Shape Effective Opioid Policy and Reduce Patient Harm*, 67 U. KAN. L. REV. __ (2019) (assessing opioid prescribing policy and the lack of definitions for inappropriate prescribing; offering a new framework for inappropriate prescribing); Kelly K. Dineen & James M. Dubois, *Between a Rock and a Hard Place: Can Physicians Prescribe Opioids to Treat Pain Adequately While Avoiding Legal Sanction?*, 42 AM. J.L. & MED. 7 (2016) (reviewing cases of inappropriate prescribing and suggesting a new framework for describing and categorizing inappropriate prescribers); Kelly K. Dineen, *Addressing Prescription Opioid Abuse Concerns in Context: Synchronizing Policy Solutions to Multiple Complex Public Health Problems*, 40 L. & PSYCHOL. REV. 1 (2016) (examining prescription opioid policy in light of available morbidity and mortality data and suggesting areas of policy priority that better align with evidence).

8. *See, e.g.*, Jennifer Oliva, *Prescription Drug Policing: The Right to Protected Health Information Privacy Pre- and Post-*Carpenter, 69 DUKE L. REV. (forthcoming 2019) (arguing that courts are more likely to rule that warrantless Drug Enforcement Agency (DEA) searches of sensitive health care data stored in prescription drug monitoring program (PDMP) databases violate the Fourth Amendment post-*Carpenter v. United States*).

9. *See, e.g.*, Jessica Davis, *Nationwide Prescription Safety Alert System Proposed by House Bill*, HEATHCARE IT NEWS, (Aug. 31, 2018, 2:57 PM), https://www.healthcareitnews.com/news/nationwide-prescription-safety-alert-system-proposed-house-bill [https://perma.cc/5UHR-HW6M] (discussing House Representatives Tom MacArthur, Barbara Comstock, and Ann Kuster's introduction of new legislation to create a nationwide Prescription Safety Alert System to help prevent patient opioid abuse).

10. An Act Relating to Regulation of Opioid Drugs, OKLA. STAT. tit. 63 § 2-309I (Westlaw though 2018 Legis. Sess.) (prohibiting practitioners from issuing an initial prescription for an opioid drug in a quantity exceeding a seven-day supply for treatment of acute pain in an adult patient or a patient under the age of eighteen; further requiring any opioid prescription for acute pain to be for the lowest effective dose of the immediate-release version of the opioid drug).

11. OKLA. STAT. tit. 59, § 161.10a (Westlaw though 2018 Legis. Sess.) (requiring Oklahoma licensed physicians who have DEA numbers to take at least one hour of continuing education in the area of pain management or opioid addiction prior to license renewal).

12. *See* Alex Ebert, *DOJ Restraining Orders Strip Docs' Opioid Prescribing Rights*, BLOOMBERG L. NEWS (last updated Aug. 22, 2018, 3:17 PM), https://www.bloomberglaw.com/document/X3SFRFPC000000?bna_news_filter=health-law-and-business&jcsearch=BNA%252000000016562c8d309a5757aeef3520002#jcite [http://perma.cc/U3DG-WPFW] (reporting that the U.S.

including needle exchange programs,[13] safe injection sites,[14] naloxone availability,[15] medication-assisted treatment,[16] mobile health care services,[17] national recovery housing best practices,[18] integrated treatment for individuals with co-occurring mental disorders,[19] information sharing with families and caregivers during opioid overdoses,[20] insurance coverage of opioid addiction and overdose treatments,[21] opioid treatment insurance parity,[22] and even sharply-written letters by medical examiners

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Department of Justice (DOJ) is using civil temporary restraining orders to prevent physicians from writing improper opioid prescriptions while under investigation for illegal conduct; also reporting that the DOJ used the emergency orders against two Ohio physicians who were allegedly caught giving opioids to undercover patients who did not need the opioids).

13. *See* Melissa Vallejo, *Safer Bathrooms in Syringe Exchange Programs: Injecting Progress into the Harm Reduction Movement*, 118 COLUM. L. REV. 1185, 1211–24 (2018) (advocating for safe bathrooms as part of syringe exchange programs).

14. *See, e.g.*, Alex H. Kral & Peter J. Davidson, *Addressing the Nation's Opioid Epidemic: Lessons from an Unsanctioned Supervised Injection Site in the U.S.*, 53 AM. J. PREVENTIVE MED. 919, 919–21 (2017) (defining safe injection sites as "legally sanctioned locations that provide a hygienic space for people to inject pre-obtained drugs while observed by trained staff"; noting that such sites have the dual aims of increasing the safety of individuals who inject drugs and reducing the public nuisance associated with public injection).

15. Corey S. Davis & Derek H. Carr, *The Law and Policy of Opioids for Pain Management, Addiction Treatment, and Overdose Reversal*, 14 IND. HEALTH L. REV. 1, 26–37 (2017) (examining naloxone access).

16. *See, e.g.*, Page M. Smith, *Implementing Medicaid Health Homes to Provide Medication Assisted Treatment to Opioid Dependent Medicaid Beneficiaries*, 106 KY. L.J. 111, 123–43 (2017-2018) (assessing the application of the Medicaid health home model in terms of delivering medication assisted treatment to Medicaid recipients).

17. *See, e.g.*, Jacob Dawson, *Public Gives Input on Federal Grant to Combat Opioids in N.H.*, CONCORD MONITOR (Aug. 14, 2018), https://www.concordmonitor.com/Public-gives-input-to-DHHS-about-opioid-grant-funds-19451667 [https://perma.cc/V32X-ACWH?type=image] (reporting public input regarding the opioid crisis; noting public desire for better mobile services).

18. SUPPORT for Patients and Communities Act, Pub. L. No. 115-271, § 7031, 132 Stat. 3894 (2018) (requiring the Secretary of the federal Department of Health and Human Services (Secretary), in consultation with other individuals and entities, to identify or facilitate the development of best practices, which may include model laws for implementing suggested minimum standards for recovery housing).

19. *See, e.g.*, Allison Petersen et al., *State Legislative Responses to the Opioid Crisis: Leading Examples*, 11 J. HEALTH & LIFE SCI. L. 30, 66 (2018) (discussing targeted case management, including insurance coverage thereof, for patients with co-occurring mental health and substance use disorders, including opioid use disorder).

20. SUPPORT for Patients and Communities Act § 7052 (requiring the Secretary to annually notify health care providers regarding permitted disclosures under federal health privacy laws during emergencies, including opioid overdoses, of certain health information to families, caregivers, and health care providers).

21. *See, e.g.*, Sara Hansard, *Health Insurer Uses Prevention, Therapy to Fight Opioid Crisis*, BLOOMBERG L. NEWS (Aug. 10, 2018, 1:17 PM), https://www.bloomberglaw.com/document/XDE7AN4K000000?bna_news_filter=health-law-and-business&jcsearch=BNA%252000000016 51f48d5faaf759f5cacde0002#jcite [https://perma.cc/5JFV-5FMV] (noting that Philadelphia-based Independence Blue Cross ended prior authorization requirements for insurance coverage of opioid use disorder treatments and made lifesaving drugs available for insureds who had overdosed on opioids).

22. SUPPORT for Patients and Communities Act § 5021 (requiring mental health and substance

to prescribing physicians following a patient's death due to overdose[23] have also received significant attention. Less attention has been paid, however, to the role of health care fraud and abuse authorities in combating the opioid crisis. This Article helps to fill this gap in the literature by analyzing recent government enforcement actions involving two health care fraud and abuse authorities, including the federal Anti-Kickback Statute and the federal civil False Claims Act, in cases involving opioids.[24]

Part II of this Article examines recent government enforcement actions involving the federal Anti-Kickback Statute, which prohibits (among other conduct) the exchange of remuneration for opioid prescriptions, patient referrals for drug testing services, and patient referrals for addiction treatment services if such prescriptions or services are reimbursed in whole or in part by a federal health care program.[25] Part III of this Article examines recent government enforcement actions involving the federal civil False Claims Act, which prohibits (among other conduct) factually and legally false opioid prescription claims, drug testing

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use disorder coverage under the Children's Health Insurance Program (CHIP) to be provided at parity with physical health coverage).

23. *See, e.g.*, Margot Sanger-Katz, *Here's a Cheap Way to Fight Drug Misuse: Send Doctors a Sharp Letter*, N.Y. TIMES (Sept. 5, 2018), https://www.nytimes.com/2018/09/05/upshot/letters-to-doctors-opioid-research.html [https://perma.cc/T97N-ZVTU] ("Two studies find that nudges [sharply-written letters to prescribing physicians following a patient's death from opioids] can lead to more scrupulous prescribing.").

24. Beyond the scope of this limited symposium Article are cases involving violations of federal and state laws other than the federal Anti-Kickback Statute and the federal civil False Claims Act. *See, e.g.*, Leslie A. Pappas, *Pharmacy's Sloppy Record Keeping Results in $100K Fine*, BLOOMBERG L. NEWS (Aug. 10, 2018), https://www.bloomberglaw.com/document/XAQPGJ04000000?bna_news_filter=health-law-and-business&jcsearch=BNA%2520000001651ff7dfa0a5ed7ff7f8fc0000#jcite [https://perma.cc/H9WL-ME92] (reporting that AccuServ Pharmacy and its owner, pharmacist Marvin P. Sheffler, agreed to pay $100,000 in civil penalties to resolve allegations that it failed to properly keep track of prescription opioids and other addictive drugs in accordance with the Controlled Substances Act, which establishes strict record-keeping requirements applicable to addictive prescription medications); Eliminating Kickbacks in Recovery Act of 2018, in the SUPPORT for Patients and Communities Act § 8121 (making illegal the knowing and willful solicitation or receipt, or offer or payment, of remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for the referral of a patient or patronage to a recovery home, clinical treatment facility, or laboratory or to induce a referral of an individual to a recovery home, clinical treatment facility, or laboratory for which payment may be made under any public or private health care benefit program; establishing criminal penalties of not more than $200,000, imprisonment of not more than ten years, or both, for each such occurrence); 18 U.S.C. § 1347(a) (2012) (making illegal the knowing and willful execution of, or attempt to execute, a scheme or artifice designed to: (1) "defraud any [public or private] health care benefit program;" or (2) obtain, by "false or fraudulent pretenses, representations, or promises, any of the money owned by or under the custody or control of any public or private health care benefit program"; establishing criminal penalties for violations thereof, including fines and imprisonment).

25. *Infra* Part II.

claims, and addiction treatment claims when such claims are submitted for payment to a federal health care program.[26] Finally, Part IV addresses the role of the Anti-Kickback Statute and the False Claims Act in combating the opioid crisis and highlights new government initiatives in this area, including: (1) the Prescription Interdiction & Litigation Task Force, created by the Department of Justice in February 2018; (2) the Eliminating Kickbacks in Recovery Act, signed into law by President Trump in October 2018; and (3) a mega anti-fraud program known as the Unified Program Integrity Contractor, announced by the Centers for Medicare and Medicaid Services in November 2018.[27]

## II. THE ANTI-KICKBACK STATUTE

### *A. Background*

The federal Anti-Kickback Statute, also known as the Illegal Remuneration Statute, prohibits the knowing and willful solicitation, receipt, offer, or payment of any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash 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,[28] such as Medicare,[29] Medicaid,[30] and Tricare.[31] The Anti-Kickback Statute also prohibits remuneration knowingly and willfully exchanged in return for "purchasing, leasing,

26. *Infra* Part III.

27. *Infra* Part IV.

28. 42 U.S.C. §§ 1320a-7b(b)(1)(A), (b)(2)(A) (2012) (limiting the application of the Anti-Kickback Statute to federal health care program business).

29. Medicare is federally administered insurance program that Americans pay into throughout their working lives and enroll in after they retire or acquire a disability. Medicare provides "basic protection against the costs of hospital, related post-hospital, home health services, and hospice care" for individuals who are age sixty-five or over; individuals under age 65 who have been entitled for not less than twenty-four months to Social Security Disability Insurance benefits; and certain individuals who have end stage renal disease. *See* 42 U.S.C. §§ 1395–1395lll (2012 & Supp. 2017) (governing Medicare).

30. Medicaid is a joint federal and state program that, together with the Children's Health Insurance Program, provides health insurance coverage to over 72.5 million Americans, including low income families, qualified pregnant women and children, and individuals receiving Supplemental Security Income (SSI). States may choose to cover other individuals, such as individuals receiving home and community-based services and children in foster care who are not otherwise eligible for Medicaid. *See* 42 U.S.C. §§ 1396–1396w-5 (2012 & Supp. 2017) (governing Medicaid).

31. Tricare (formerly known as CHAMPUS) is a health insurance program carried out by the U.S. Department of Defense that furnishes medical and dental care to members and veterans of the armed forces as well as their family members. *See* 10 U.S.C. §§ 1071–1110 (2012 & Supp. 2017) (governing Tricare).

ordering 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 care program."[32]

The Anti-Kickback Statute is premised on the concern that health care kickbacks can lead to corruption of medical decision making; patient steering; overutilization of health care items, services, and supplies; increased costs to federal health care programs; and unfair competition.[33] A violation of the Anti-Kickback Statute is punishable as a felony. Individuals convicted of violating the Anti-Kickback Statute shall be fined not more than $100,000, imprisoned for not more than ten years, or both.[34] A prosecutor is not required to prove a defendant's actual knowledge of, or specific intent to violate, the Anti-Kickback Statute in order to successfully prosecute the defendant.[35] A violation of the Anti-Kickback Statute can also subject a defendant to exclusion from participation in federal health care programs as well as civil monetary penalties.[36]

Over time, federal courts have interpreted key provisions within the Anti-Kickback Statute.[37] In 1985, for example, the United States Court of Appeals for the Third Circuit established the "one purpose" rule in the case of *United States v. Greber*.[38] *Greber* involved a cardiologist (Defendant)

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32. 42 U.S.C. § 1320a-7b(b)(1)(B), (b)(2)(B) (2012).

33. *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 [https://perma.cc/25W7-7H6L] (last visited Mar. 18, 2019) (listing concerns raised by health care kickbacks).

34. 42 U.S.C. § 1320a-7b(b)(1), (2) (as amended by the Bipartisan Budget Act of 2018, Pub. L. No. 115-123, § 50412(a), (b), 132 Stat. 64 (Feb. 9, 2018) (increasing the fines and sentences applicable to violations of the Anti-Kickback Statute)).

35. 42 U.S.C. § 1320a-7b(h) ("With respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section.").

36. 42 U.S.C. § 1320a-7(b)(7) (authorizing the Secretary of HHS to exclude any individual from federal health care programs if the individual violates the Anti-Kickback Statute); *id*. § 1320a-7a(a)(7) (stating that any individual who violates the Anti-Kickback Statute shall, in addition to any other penalties that may be imposed, be subject to civil money penalties).

37. *See* United States v. Kats, 871 F.2d 105, 108 (9th Cir. 1989) (holding that a judge's admonition to the jury that the jury could convict defendant for receipt of kickbacks in exchange for referral of Medicare payments, "unless it found payment 'wholly and not incidentally attributable to delivery of goods or services,'" was accurate); United States v. Borrasi, 639 F.3d 774, 782 (7th Cir. 2011) (ruling that the portion of payments received by the defendant that compensated him for his past referrals or induced future referrals for health care services paid for by Medicare violated the Anti-Kickback Statute: "Nothing in the Medicare fraud statute implies that only the primary motivation of remuneration is to be considered in assessing [the defendant's] conduct. We join our sister circuits in holding that if part of the payment compensated past referrals or induced future referrals, that portion of the payment violates [the Anti-Kickback Statute]"); United States v. Davis, 132 F.3d 1092, 1094 (5th Cir. 1998) (affirming trial court's decision to deny a requested instruction that the jury may find the defendant guilty of conspiracy only if it finds that the defendant's cash payments to a particular physician "were 'for no other purpose' than 'inducing the referral of Medicare patients'").

38. 760 F.2d 68, 72 (3d Cir. 1985).

who served as President of Cardio-Med., Inc. (Cardio-Med), a company that provided diagnostic services.[39] When a physician ordered a diagnostic service from Cardio-Med for a Medicare beneficiary, Cardio-Med would bill Medicare for the service and, after receiving reimbursement, would forward a portion of the reimbursement, referred to as a "consulting fee," to the ordering physician.[40] The Defendant testified that if he did not pay the physicians their "consulting fees," the physicians would not order diagnostic services from Cardio-Med.[41]

At trial, the judge instructed the jury that if *one* purpose of the "consulting fees" paid to the physicians was to induce their ordering of services from Cardio-Med, the Anti-Kickback Statute had been violated.[42] Defendant argued that the jury charge was erroneous; that is, the Statute was violated only when the *only* purpose behind the fees was to improperly induce patient referrals.[43] The Third Circuit upheld the trial court's instruction, ruling that the Anti-Kickback Statute was violated when *one* purpose of the fees was to induce the use of Cardio-Med's services, even if the payments were also intended to compensate the physicians for other consulting services.[44]

In addition to interpretive case law, the Office of Inspector General (OIG) has promulgated a number of safe harbor regulations.[45] These regulations carve out shelters for arrangements that do not violate the Anti-Kickback Statute even though the arrangements may, on their face, appear to be capable of inducing referrals in violation of the Statute.[46] Arrangements sheltered under the safe harbor regulations include, but are not limited to, certain equipment rental payments, personal services payments, management payments, sale of practice payments, warranty payments, practitioner recruitment payments, payments to group purchasing organizations, obstetrical malpractice insurance subsidies, non-monetary remuneration necessary for electronic health records, and non-monetary remuneration necessary for electronic prescribing.[47] Common among sheltered payments is the requirement that the payment

39. *Id.* at 69–70.
40. *Id.*
41. *Id.* at 70.
42. *Id.* at 71.
43. *Id.*
44. *Id.* at 72.
45. 42 C.F.R. § 1001.952(a)-(bb) (2017).
46. *See* Jeffrey Schwartz, *Elaborating on Sham Transactions as Evidence of Violations of the Anti-Kickback Statute*, 13 WASH. U. J.L. & POL'Y 357, 367–68 (2003) (discussing the safe harbor regulations).
47. 42 C.F.R. § 1001.952(a)–(bb).

be consistent with fair market value in an arms-length transaction and not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under a federal health care program.[48]

The Department of Justice (DOJ) actively enforces the Anti-Kickback Statute. As a recent example, the DOJ announced in August 2018 that Reliant Rehabilitation Holdings (Reliant), a provider of rehabilitation services in north Texas, agreed to pay $6.1 million to resolve allegations that Reliant paid illegal remuneration to nursing homes and doctors in connection with care provided to Medicare and Medicaid patients.[49] United States Attorneys for the Northern District of Texas argued that Reliant offered nursing homes illegal remuneration, including nurse-practitioner services at free or below-market-value rates, "in order to induce or reward nursing homes for contracting with Reliant to provide rehabilitation therapy for their residents."[50]

Even more recently, the DOJ announced in November 2018 the conviction of fifty-six-year-old Sophia Eggleston, a patient recruiter from Detroit, Michigan, on two counts of receiving kickbacks in violation of the Anti-Kickback Statute.[51] After a three-day trial in the Eastern District of Michigan, a federal jury found that Eggleston participated in an illegal kickback scheme between 2009 and 2012 pursuant to which she "solicited and received kickbacks in exchange for referring Medicare beneficiaries to serve as patients at a home health agency owned by Eggleston's co-

48. *Id.* § 1001.952(b)(5) (including within the space rental safe harbor a requirement that the aggregate space rental charge be "consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs."); *id.* § 1001.952(d)(5) (including within the personal services and management contracts safe harbor a requirement that the "aggregate compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs.").

49. Press Release, U.S. Dep't of Justice, Office of Pub. Affairs, Reliant to Pay $6.1 Million to Settle False Claims Act Allegations That It Paid Kickbacks to Nursing Homes for Rehabilitation Therapy Business (Aug. 23, 2018), https://www.justice.gov/opa/pr/reliant-pay-61-million-settle-false-claims-act-allegations-it-paid-kickbacks-nursing-homes [https://perma.cc/8TYB-ASTU] [hereinafter Reliant Press Release] (announcing the settlement); *see also* Order of Dismissal, United States ex rel. Prose v. Reliant Rehab., No. 3:16-cv-0707 (N.D. Tex. Aug. 23, 2018).

50. Reliant Press Release, *supra* note 49.

51. Press Release, U.S. Dep't of Justice, Office of Pub. Affairs, Patient Recruiter Convicted in $1.1 Million Kickback Scheme (Nov. 5, 2018), https://www.justice.gov/opa/pr/patient-recruiter-convicted-11-million-kickback-scheme [https://perma.cc/P9UT-MENM].

conspirators."[52] The scheme resulted in the submission of approximately $1.1 million in claims to Medicare for home health services purportedly provided to the referred Medicare beneficiaries.[53]

### *B. Application to the Opioid Context*

#### 1. Physician Receipt of Remuneration from Pharmaceutical Companies in Return for Opioid Prescriptions

A number of physicians have been convicted of violating the Anti-Kickback Statute for receiving remuneration from pharmaceutical companies in return for the prescription of opioids manufactured by those companies. In March 2018, for example, Judge John McConnell of the United States District Court for the District of Rhode Island sentenced sixty-three-year-old Dr. Jerrold Rosenberg, a Brown University faculty member, to fifty-one months in prison and $754,736 in restitution for receiving $188,000 in sham speaker fees from Insys Therapeutics, Inc. (Insys) between 2012 and 2015.[54]

As background, Insys manufactures and markets Subsys, a highly addictive, fentanyl-based, sublingual spray drug approved by the Food and Drug Administration (FDA) for opioid-tolerant, adult cancer patients who experience break-through cancer pain.[55] Due to concerns regarding life-threatening respiratory depression and death, the FDA has contraindicated Subsys for use in opioid non-tolerant, non-cancer patients, including patients who experience post-operative pain as well as headaches, back pain, and joint pain.[56]

Dr. Rosenberg, a Subsys prescriber, admitted that he received the speaker fees from Insys even when he did not make any type of presentation on Insys's behalf and when presentation sign-in sheets were forged to include the names of health care practitioners with prescriptive authority who did not attend the (nonexistent) presentations.[57] Although

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52. *Id.*

53. *Id.*

54. Janelle Lawrence & Jef Feeley, *Ivy League Doctor Gets 4 Years in Prison for Insys Opioid Kickbacks*, BLOOMBERG (Mar. 9, 2018, 1:24 PM), https://www.bloomberg.com/news/articles/2018-03-09/ivy-league-doctor-gets-4-years-prison-for-insys-opioid-kickbacks [https://perma.cc/9XLV-ZNXL].

55. Second Amended Complaint for Violations of the False Claims Act & State False Claims Acts at 6, ¶¶ 25–26, Filed Under Seal, United States ex rel. Guzman v. INSYS Therapeutic Inc., No. 2:13-cv-05861 (C.D. Cal. June 13, 2016) [hereinafter Guzman Second Amended Complaint].

56. *Id.* at 27, ¶ 140.

57. Benjamin Weiser & Katie Thomas, *5 Doctors Are Charged with Taking Kickbacks for Fentanyl Prescriptions*, N.Y. TIMES (Mar. 16, 2018), https://www.nytimes.com/2018/

the pharmaceutical industry has long paid influential doctors to give presentations to peer prescribers as part of drug marketing campaigns,[58] Dr. Rosenberg admitted that the sham speaker fees paid by Insys played a role in his decision to prescribe Subsys, including his decision to prescribe Subsys for ineligible patients; that is, opioid non-tolerant patients whose pain was not caused by cancer.[59] Perhaps worse than his acceptance of sham speaker fees in return for his writing of Subsys prescriptions, federal prosecutors also showed that Dr. Rosenberg "ignored and bullied patients who resisted staying on the powerful pain-killing spray."[60] During sentencing, Judge McConnell told Dr. Rosenberg: "You in effect sold your medical license to a pharmaceutical company"[61] and reminded the disgraced physician that "[g]reed has no role in that sacred relationship that exists between a doctor and a patient."[62] As discussed above, the Anti-Kickback Statute is premised on a number of concerns, including corruption of medical decision making.[63] Dr. Rosenberg's receipt of remuneration from Insys corrupted his medical decision making, even to the point where he bullied addicted patients—including those who requested assistance with stopping Subsys—into staying on Subsys.

Dr. Rosenberg is not the only physician who received remuneration from Insys in return for writing Subsys prescriptions for federal health care program patients. In February 2018, Judge Arthur Tarnow of the United States District Court for the Eastern District of Michigan sentenced fifty-nine-year-old Dr. Gavin Awerbuch to thirty-two months in prison and $4.1 million in restitution and fines after finding that, among other improprieties, Dr. Awerbuch received from Insys $138,435 in sham

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03/16/nyregion/fentanyl-subsys-drug-kickbacks.html [https://perma.cc/TBR8-HEHQ].

58. Katie Thomas, *Using Doctors with Troubled Pasts to Market a Painkiller*, N.Y. TIMES (Nov. 27, 2014), https://www.nytimes.com/2014/11/28/business/drug-maker-gave-large-payments-to-doctors-with-troubled-track-records.html [https://perma.cc/P5FT-ZVN7] ("The drug industry has long paid influential doctors to speak to peers as a way of building word-of-mouth marketing."); Charlotte Hu, *Opioid Overdose Deaths Are Highest in Places Where Pharma Spends the Most on Marketing, A New Study Finds*, BUS. INSIDER (Nov. 13, 2018, 10:07 AM), https://www.businessinsider.com/relationship-between-opioid-deaths-and-pharma-marketing-spending-2018-11 [https://perma.cc/M8HY-WG9V] ("In 2016, the pharmaceutical industry doled out nearly $10 million to US physicians for opioid-related marketing. That includes speaking and consulting fees . . . .").

59. Nate Raymond, *Doctor in Insys Opioid Kickback Scheme Gets Four Years in Prison*, REUTERS (Mar. 9, 2018, 5:03 AM), https://www.reuters.com/article/us-insys-opioids/doctor-in-insys-opioid-kickback-scheme-gets-four-years-in-prison-idUSKCN1GL1DP [https://perma.cc/K3L3-3JUQ].

60. Lawrence & Feeley, *supra* note 54.

61. *Id.*

62. Raymond, *supra* note 59.

63. *See supra* note 33 and accompanying text.

speaker fees in return for prescribing Subsys, including for patients who had no legitimate medical need for the drug.[64] In the six-month period prior to Dr. Awerbuch making his first (alleged) speech in October 2012 on Insys's behalf, Dr. Awerbuch wrote, on average, fewer than thirteen prescriptions for Subsys each month. In the six months after his first (alleged) speech on Insys's behalf, Dr. Awerbuch wrote, on average, approximately 118 prescriptions for Subsys each month.[65] Dr. Awerbuch was the highest prescriber of Subsys to Medicare beneficiaries nationally, writing more than twenty percent of all Subsys prescriptions for Medicare beneficiaries between 2009 and 2015.[66] The cost to Medicare of the 1,283 Medicare beneficiary prescriptions written by Dr. Awerbuch reached nearly $7 million.[67]

Drs. Rosenberg and Awerbuch are not the only physicians who have violated the Anti-Kickback Statute in the context of opioid prescriptions. In February 2017, an Alabama jury found that Drs. John Patrick Couch and Xiulu Ruan received remuneration from Insys and other pharmaceutical manufacturers in return for writing opioid prescriptions in violation of the Anti-Kickback Statute.[68] As background, Drs. Couch and Ruan owned and operated a practice in Mobile, Alabama, called Physician's Pain Specialists of Alabama (PPSA).[69] Between 2012 and 2015, Dr. Couch received at least $100,000 in sham speaking fees and Dr. Ruan received at least $170,000 in sham speaking fees from Insys.[70] An Insys Sales Representative named Natalie Perhacs admitted in her own guilty plea (in which she admitted that she paid remuneration to Drs. Couch and Ruan in violation of the Anti-Kickback Statute) that she

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64. Steve Friess, *Doctor Tied to Insys Opioid Kickback Probe Gets Prison Term*, REUTERS (Feb. 26, 2018, 4:50 PM), https://www.reuters.com/article/us-insys-opioids/doctor-tied-to-insys-opioid-kickback-probe-gets-prison-term-idUSKCN1GA2WE [https://perma.cc/68GH-Z6U7].

65. United States' Complaint in Intervention at 17, ¶ 63, U.S. v. Insys Therapeutics, Inc., No. 14-cv-3488 (C.D. Cal. Apr. 13, 2018) [hereinafter U.S. Complaint in Intervention].

66. Catherine Shaffer, *Founder of Opioid Company Arrested on Racketeering and Fraud Charges*, MICH. RADIO NEWS (Oct. 27, 2017), http://www.michiganradio.org/post/founder-opioid-company-arrested-racketeering-and-fraud-charges [https://perma.cc/79WB-LHDP] ("Awerbuch wrote more than twenty percent of Subsys prescriptions for Medicare beneficiaries nationwide between 2009 and 2014. Awerbuch pled guilty to health care fraud and distribution of controlled substances in 2016.").

67. Guzman Second Amended Complaint, *supra* note 55, at 24, ¶ 123.

68. Press Release, U.S. Dep't of Justice, U.S. Attorney's Office, S. Dist. of Ala., Dr. Couch and Dr. Ruan Sentenced to 240 and 252 Months in Federal Prison for Running Massive Pill Mill (May 26, 2017), https://www.justice.gov/usao-sdal/pr/dr-couch-and-dr-ruan-sentenced-240-and-252-months-federal-prison-running-massive-pill [https://perma.cc/DZ9F-YPKU] [hereinafter Couch and Ruan Press Release].

69. *Id.*

70. *Id.*

scheduled approximately one speaker program per week for Drs. Couch and Ruan but that, for the majority of such programs, the physicians either: (1) spoke to the same prescribers over and over again about Subsys; (2) spoke to non-prescribing PPSA staff about Subsys; or (3) did not speak about Subsys at all,[71] thus negating any substantive justification for the speaker programs and, therefore, the speaker payments. During the year 2014, Drs. Couch and Ruan were writing opioid prescriptions as fast as one prescription every four minutes.[72] The total cost to the government of these prescriptions was $15.5 million.[73]

At the conclusion of their seven-week trial, the jury found the Alabama-based physicians guilty of several federal criminal offenses, including receiving remuneration from Insys in return for prescribing Subsys in violation of the Anti-Kickback Statute.[74] Some of the patients for whom Drs. Couch and Ruan prescribed Subsys included non-cancer patients who experienced traditional neck, back, and joint pain; that is, patients for whom the FDA expressly contraindicated Subsys. In May 2017, Senior Judge Callie Virginia Smith Granade of the United States District Court for the Southern District of Alabama sentenced Drs. Couch and Ruan to twenty and twenty-one years in prison, respectively.[75]

### 2. Non-Physician Receipt of Remuneration from Pharmaceutical Companies in Return for Opioid Prescriptions

The above section described three cases involving four physicians who admitted they received, or who were found by a jury to have received, remuneration in the form of sham speaker fees in return for opioid prescriptions in violation of the Anti-Kickback Statute. Other non-physician prescribers, including nurse practitioners and physician assistants, also have accepted remuneration from pharmaceutical companies in return from prescribing opioids manufactured by those companies in violation of the Anti-Kickback Statute.

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71. *See* United States' Complaint in Intervention, *supra* note 64, at 14–15, ¶ 49.

72. J.B. Biunno, *Mobile Pain Doctors Found Guilty of Running Pill Mill*, NEWS5 WKRG (Feb. 23, 2018, 10:45 AM), https://www.wkrg.com/news/local-news/breaking-mobile-pain-doctors-found-guilty-of-running-pill-mill/867786039 [https://perma.cc/NLY9-8K3K] ("In the first indictment filed against the doctors, investigators gathered evidence that Couch and Ruan wrote 66,892 prescriptions combined in 2014, deliberately 'over-prescribing controlled substances to increase revenue.' It amounted to writing a prescription once every four minutes.").

73. Jill Riepenhoff, *Case Study: Drs. John P. Couch and Xiulu Ruan*, ABC7 WWSB (Feb. 26, 2018, 3:46 PM), http://www.mysuncoast.com/story/37546844/case-study-drs-john-p-couch-and-xiulu-ruan/ [https://perma.cc/Z6ZZ-DZ3Z] (last updated Oct. 17, 2018, 7:01 PM).

74. Couch and Ruan Press Release, *supra* note 68.

75. *Id.*

For example, Heather Alfonso, a Connecticut-licensed nurse practitioner who worked at the Comprehensive Pain and Headache Treatment Center in Derby, Connecticut, pled guilty in June 2015 to receiving kickbacks from Insys in return for prescribing Subsys.[76] Prosecutors showed that between January 2013 and March 2015, Ms. Alfonso received approximately $83,000 in speaker fees from Insys for participating in more than seventy "dinner programs."[77] Frequently, the only attendee at these "dinner programs" was an Insys sales representative or a friend or co-worker of Ms. Alfonso who had no prescriptive authority,[78] thus negating any substantive justification for the program. Ms. Alfonso, who was one of the top-ten highest prescribers of Subsys in the U.S., admitted that the speaker fees she accepted influenced her prescription of the highly-addictive drug, including for non-cancer patients who had chronic pain not associated with cancer:[79] "If I was going to choose between one drug or another, I would choose the Subsys because that's what I was getting paid for."[80] Judge Michael Shea of the United States District Court for the District of Connecticut has delayed Ms. Alfonso's sentencing numerous times due to her cooperation with federal and state investigators in other health care fraud cases.[81]

The Government has investigated other non-physician opioid prescribers, including physician assistants, for their receipt of remuneration from pharmaceutical manufacturers in violation of the Anti-Kickback Statute. In March 2017, for example, physician assistant Christopher Clough was indicted for accepting remuneration from Insys in return for prescribing Subsys.[82] Mr. Clough treated pain patients in

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76. Press Release, U.S. Dep't of Justice, U.S. Attorney's Office, Dist. of Conn., APRN Admits Receiving Kickbacks from Drug Company for Prescribing Pain Medication (June 23, 2015), https://www.justice.gov/usao-ct/pr/aprn-admits-receiving-kickbacks-drug-company-prescribing-pain-medication [https://perma.cc/AM93-DRKU] [hereinafter Alfonso Press Release]; Katie Thomas, *Nurse Pleads Guilty to Taking Kickbacks from Drug Maker*, N.Y. TIMES (June 25, 2015), https://www.nytimes.com/2015/06/26/business/nurse-pleads-guilty-to-taking-kickbacks-from-drug-maker.html [https://perma.cc/3F2K-G2TP].

77. Alfonso Press Release, *supra* note 76.

78. *Id.*

79. Lisa Chedekel, *Case Against Derby Nurse Involves Potent Painkiller*, HARTFORD COURANT (June 24, 2015, 6:17 PM), https://www.courant.com/health/hc-nurse-indicted-drug-kickbacks-folo-20150624-story.html [https://perma.cc/JYE9-AXWJ].

80. Janelle Lawrence, *Opioid Nurse Sold Out Patients for $82,000 in Insys Kickbacks*, BLOOMBERG (Feb. 12, 2019, 6:00 AM), https://www.bloomberg.com/news/articles/2019-02-12/opioid-nurse-sold-out-patients-for-82-000-in-insys-kickbacks [https://perma.cc/BMR4-49E2].

81. *Id.*; Lisa Chedekel, *Derby Nurse's Sentencing Delayed Six Months*, NEW HAVEN REG. (Jan. 24, 2017, 11:38 AM), https://www.nhregister.com/connecticut/article/Derby-nurse-s-sentencing-delayed-six-months-11313986.php [https://perma.cc/3C7D-WNAP].

82. Press Release, U.S. Dep't of Justice, U.S. Attorney's Office, Dist. of N.H., Former Physician

Somersworth, New Hampshire and is alleged to have received approximately $40,000 in speaker fees from Insys.[83] As with the other Subsys prescribers discussed above, Mr. Clough likely gave no presentations to peer prescribers at all and/or sign-in sheets were forged to include the names of prescriber attendees who did not attend the (likely non-existent) presentations.[84]

3. Prescriber Receipt of Remuneration from Pharmacists in Return for Opioid Prescriptions Filled at Related Pharmacies

In addition to prescribers who have received remuneration from pharmaceutical companies in return for prescriptions of opioids manufactured by those same companies, prescribers also have received remuneration from pharmacists in return for opioid prescriptions that were filled at related pharmacies. For example, Dr. Carl Dennis Fowler, a sixty-one-year-old physician who practiced family medicine in West Bloomfield, Michigan, was convicted in March 2014 of receiving remuneration in violation of the Anti-Kickback Statute.[85] As background, Michigan pharmacist Babubhai Patel (Patel) owned and operated twenty-six pharmacies (the Patel Pharmacies) in the greater Detroit area.[86] Dr. Fowler wrote numerous prescriptions for expensive drugs, without regard to whether the drugs were medically necessary, that could be filled at one of the Patel Pharmacies, as well as prescriptions for OxyContin and oxycodone, which were later resold on the street market.[87] A jury found that Dr. Fowler received from Patel bribes and kickbacks in return for Dr. Fowler's prescription of expensive drugs, including opioids, that were filled at one of the Patel Pharmacies and that were billed to Medicare and Medicaid.[88]

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Assistant Charged in Healthcare Kickback Scheme (Mar. 24, 2017), https://www.justice.gov/usao-nh/pr/former-physician-assistant-charged-healthcare-kickback-scheme [https://perma.cc/4F9X-4DYW].

83. *Id.*

84. *Id.*

85. 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 [https://perma.cc/RX88-PQR7].

86. *Id.*

87. *Id.*

88. *Id.*

### 4. Physician Receipt of Remuneration from Laboratories in Return for Drug Test Orders

The sections above described cases involving prescribers who received remuneration in return for writing opioid prescriptions for government program patients. Other cases implicating the Anti-Kickback Statute involve physicians who receive remuneration in return for referring government program patients to particular laboratories for opioid and other drug testing services. In June 2017, for example, Judge Kim R. Gibson of the United States District Court for the Western District of Pennsylvania sentenced Dr. John H. Johnson, a Pennsylvania-licensed physician who owned and operated a number of pain management clinics, to eighty-four months in prison and $2.3 million in restitution upon Dr. Johnson's conviction of violations of the Anti-Kickback Statute among other laws.[89]

As background, Dr. Johnson had entered into a joint venture with William Hughes, the owner of Universal Oral Fluids Lab (UOFL), pursuant to which Dr. Johnson referred all of his patients, including his Medicare and Medicaid patients, to UOFL for drug testing and related services.[90] After UOFL billed third-party payors, including Medicare and Medicaid, UOFL kicked back to Dr. Johnson an amount for each referred patient whose laboratory tests exceeded a certain dollar threshold, typically $100 to $150.[91] The evidence presented at trial showed that Dr. Johnson received these kickbacks "solely in exchange for the referrals Dr. Johnson provided to UOFL, and not in exchange for the performance of any other services."[92] The evidence also showed that UOFL received approximately $3,443,528 from Medicare and $1,147,768 from Pennsylvania Medicaid based on Dr. Johnson's referrals alone and that Dr. Johnson received more than $2,300,000 in kickbacks from UOFL between May 2011 and November 2013.[93] As discussed above, the Anti-Kickback Statute is premised on a number of concerns, including patient steering, overutilization of health care services, and increased costs to federal health care programs.[94] The joint venture between Dr. Johnson and UOFL

89. Press Release, U.S. Dep't of Justice, U.S. Attorney's Office, W. Dist. of Pa., Physician Sentenced to 7 Years in Prison for Accepting Kickbacks and Failing to Remit Employment Taxes (June 30, 2017), https://www.justice.gov/usao-wdpa/pr/physician-sentenced-7-years-prison-accepting-kickbacks-and-failing-remit-employment [https://perma.cc/WDG5-VA98].

90. *Id.*

91. *Id.*

92. *Id.*

93. *Id.*

94. *See supra* note 33 and accompanying text.

clearly raises concerns regarding patient steering to UOFL (versus other laboratories), overutilization of drug testing services, and increased costs to Medicare and Pennsylvania Medicaid.

Another similar, drug-testing-referral scheme involved two pain management physicians, Drs. Malik and Sherlekar, who owned practices in Maryland and New Jersey.[95] A jury found that Dr. Malik accepted remuneration from Accu-Reference, a New Jersey-based clinical laboratory, in return for referring urine toxicology specimens to Accu-Reference for opioid and other forms of drug testing.[96] In particular, the Government introduced evidence showing that, between April 2011 and July 2012, Drs. Malik and Sherlekar referred between 700 and 1,300 patient samples to Accu-Reference per month, resulting in billing claims to Medicare and private insurers of approximately $4.4 million in exchange for $1.4 million in kickbacks.[97] Drs. Malik and Sherlekar each received $240,000 of the kicked-back amounts while their former practice CEO and CFO, who received the offer of remuneration from Accu-Reference and brought the offer to Drs. Malik and Sherlekar, received the remainder of the remuneration.[98] On September 11, 2018, Dr. Malik was sentenced to eight years in prison.[99]

5. Offer or Payment of Remuneration

In addition to prohibiting the solicitation or receipt of remuneration in return for federal health care program business, the Anti-Kickback Statute also prohibits the offer or payment of such remuneration.[100] Several individuals have pled guilty to offering or paying remuneration to individuals with prescriptive authority in violation of the Anti-Kickback Statute. For example, Jeffrey Pearlman, an Insys district sales manager responsible for Insys sales in New Jersey, New York, Connecticut, and Rhode Island, pled guilty to one count of conspiracy to violate the Anti-

95. Press Release, U.S. Dep't of Justice, U.S. Attorney's Office, Dist. of Md., Pain Management Physician Sentenced to 8 Years in Federal Prison for Central Role in Million Dollar Kickback Scheme and Fraudulent Billing Scheme (Sept. 11, 2018), https://www.justice.gov/usao-md/pr/pain-management-physician-sentenced-8-years-federal-prison-central-role-million-dollar [https://perma.cc/5ZYB-5K3X].

96. *Id.*

97. *Id.*

98. *Id.*

99. *Id.* Dr. Sherlekar committed suicide shortly after he was indicted and, as a result, was neither tried nor sentenced. *Id.*

100. 42 U.S.C. §§ 1320a–7b(b)(2) (2012).

Kickback Statute in August 2018.[101] In his plea agreement, Pearlman admitted to conspiring to induce physicians, physician assistants, and nurse practitioners to prescribe Subsys by paying them speaker fees "that ranged from $1,000 to several thousand dollars."[102] As in the other speaker fee cases discussed above, the speaker fees paid by Pearlman were, in theory, to help Insys educate opioid prescribers about Subsys.[103] In reality, the presentations were non-educational gatherings held at expensive restaurants attended by friends and co-workers, most of whom did not have prescriptive authority,[104] thus negating the substantive justification for the speaker programs and, thus, the speaker fees. One such dinner occurred at a restaurant in New Haven, Connecticut, where Pearlman paid a Connecticut-licensed physician a speaker fee even though the physician did not make any type of educational presentation, and even though no other health care professionals with prescriptive authority were present to learn from the (non-existent) presentation.[105] Pearlman's sentencing was originally scheduled for October 31, 2018, although it appears to have been delayed.[106]

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101. Press Release, U.S. Dep't of Justice, U.S. Attorney's Office, Dist. of Conn., Drug Company Manager Admits Role in Kickback Scheme Related to Fentanyl Spray Prescriptions (Aug. 8, 2018), https://www.justice.gov/usao-ct/pr/drug-company-manager-admits-role-kickback-scheme-related-fentanyl-spray-prescriptions [https://perma.cc/W3R7-Z844].

102. *Id.*

103. *Id.*

104. *Id.*

105. *Id.*

106. *Id.* As of this writing, other Insys employees are being investigated and/or tried for the improper offer or payment of illegal remuneration to Subsys prescribers. *See, e.g.*, Janelle Lawrence, *Insys Founder's Protege Was 'Fall Guy' When Opioid Plan Faltered*, BLOOMBERG (last updated Feb. 15, 2019, 5:40 PM), https://www.bloomberg.com/news/articles/2019-02-15/insys-founder-s-protege-was-fall-guy-when-opioid-plan-faltered [https://perma.cc/93Y4-55MQ] (reporting that Michael Babich, Insys' Chief Executive Officer, recently pled guilty to conspiracy of violating the Anti-Kickback Statute for paying remuneration to prescribers to induce their prescription of Subsys); Chris Dolmetsch, *New York Doctor Pleads Guilty to Taking Kickbacks From Insys*, BLOOMBERG L. NEWS (Feb. 14, 2019, 1:53 PM), https://www.bloomberglaw.com/document/XF7UL0A0000000?bna_news_filter=health-law-and-business&jcsearch=BNA%252000000168ed4ad633adfdff5e49b30000#jcite (reporting that Alexandru Burducea, a New York physician who specialized in pain management, pled guilty on February 14, 2019, to conspiracy to violate the Anti-Kickback statute by accepting remuneration from Insys in exchange for prescribing Subsys); Janelle Lawrence, *How the 'Worst' Launch in Pharma History Spurred Opioid Surge*, BLOOMBERG (last updated Feb. 13, 2019, 11:54 AM), https://www.bloomberg.com/news/articles/2019-02-13/how-the-worst-launch-in-pharma-history-spurred-opioid-surge [https://perma.cc/69TA-XB5R] (discussing the ongoing racketeering trial of Insys founder John Kapoor); Janelle Lawrence, *Opioid Rap Video Adding to John Kapoor's Woes at Insys Trial*, BLOOMBERG (last updated Feb. 14, 2019, 9:23 AM), https://www.bloomberg.com/news/articles/2019-02-13/opioid-rap-video-adding-to-john-kapoor-s-woes-at-insys-trial [https://perma.cc/35S8-ND8V] (reporting on the racketeering trial of Insys founder John Kapoor, including prosecutors' admission into evidence of an Insys rap video designed to influence physicians to prescribe higher doses of Subsys).

Several opioid manufacturers also have settled allegations of violations of the Anti-Kickback Statute's offer or payment prohibitions. For example, in September 2017, the DOJ announced that Galena Biopharma, Inc. (Galena) would pay more than $7.55 million to resolve allegations that it violated the federal False Claims Act by violating the Anti-Kickback Statute; that is, by paying remuneration to physicians to induce the physicians to prescribe Galena's fentanyl-based drug, Abstral.[107] In particular, the Government alleged that Galena offered and paid both in-kind and cash remuneration to physicians to induce their prescriptions, including: (1) "providing more than 85 free meals to physicians and staff from a single, high-prescribing, [medical] practice"; (2) paying physicians and speakers between $5,000 and $6,000 to attend a questionable "advisory board" meeting that was planned and attended only by Galena sales team members; (3) "paying approximately $92,000 to a physician-owned pharmacy under a performance-based rebate agreement to induce the pharmacy owners[,]" none other than Alabama-based Drs. Couch and Ruan, to prescribe Abstral; and (4) paying physicians to refer patients to the company's patient registry study that ostensibly was designed to collect data on patient experiences with Abstral but in reality served as a means to induce physicians to prescribe Abstral.[108] In the press release announcing the settlement, William E. Fitzpatrick, the Acting United States Attorney for the District of New Jersey stated, "The conduct alleged by the government and resolved by today's settlement was egregious because it incentivized doctors to over-prescribe highly addictive opioids."[109]

Other opioid manufacturers also have initiated settlement discussions regarding allegations of violations of the offer or pay prohibitions within the Anti-Kickback Statute. On August 8, 2018, the media (perhaps presumptuously) reported that Insys would pay at least $150 million to settle DOJ allegations that it violated the offer or pay prohibitions within the Anti-Kickback Statute including in connection with payments made to many of the recipients discussed earlier in this Article.[110] The media

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107. Press Release, U.S. Dep't of Justice, Office of Pub. Affairs, Galena Biopharma Inc. to Pay More Than $7.55 Million to Resolve Alleged False Claims Related to Opioid Drug (Sept. 8, 2018), https://www.justice.gov/opa/pr/galena-biopharma-inc-pay-more-755-million-resolve-alleged-false-claims-related-opioid-drug [https://perma.cc/QD9G-2YMG].

108. *Id.*

109. *Id.*

110. *See, e.g.*, Nate Raymond & Andy Thibault, *Insys to Pay $150 Million to Settle U.S. Opioid Kickback Probe*, REUTERS (Aug. 8, 2018, 7:09 AM), https://www.reuters.com/article/us-insys-opioids/insys-to-pay-150-million-to-settle-u-s-opioid-kickback-probe-idUSKBN1KT1G5 [https://perma.cc/4RPZ-4E2T] (announcing the settlement).

further reported on that same date that Insys would pay the $150 million over five years and would potentially make up to $75 million in additional payments.[111] The media quoted Insys CEO Saeed Motahari as stating, "This [settlement] is a very important step for our company to move forward and continue our transformative efforts to foster a compliant and ethical culture."[112] On February 5, 2019, a status report filed with the United States District Court for the Central District of California referenced a "settlement-in-principle" that was allegedly reached by and between the federal and state government plaintiffs and Insys on August 9 [not 8], 2018; however, that filing also stated that "discussions regarding these settlement issues . . . are currently ongoing and remain incomplete. Among other things, the parties continue to discuss and attempt to resolve various criminal, civil, and administrative issues towards the finalization of the settlement-in-principle reached by them in August 2018."[113]

The Insys settlement discussions have their roots in five separate qui tam cases, including the first qui tam case that was filed under seal by relator Maria Guzman in August 2013.[114] In April 2018, the U.S. Government intervened in the five (now consolidated) cases,[115] which were partially unsealed in May 2018.[116] Guzman's complaint alleges that Insys sales representatives paid Subsys prescribers speaker fees[117] and other cash amounts as high as $100,000[118] as well as in-kind remuneration including stock options,[119] sexual favors,[120] escort services,[121] strip

111. *Id.*

112. *Id.*

113. United States of America's Status Report at 3–4, United States ex rel. Guzmam v. Insys Therapeutics, No. 2:13-cv-5861-JLS (AJWx) (C.D. Cal. Feb. 5, 2019).

114. Complaint, United States ex. rel. Guzman v. Insys Therapeutics, Inc., No. 2:13-cv-5861-JLS (AJWx) (C.D. Cal. Aug. 12, 2013) [hereinafter Guzman First Complaint]; Guzman Second Amended Complaint, *supra* note 55. *See generally* Michael Filoromo & Matthew LaGarde, *Insight: Leveraging the False Claims Act to Combat Opioid Misuse*, BLOOMBERG L. (Aug. 2, 2018, 9:01 AM), https://www.bloomberglaw.com/document/XCMEEI70000000?bna_news_filter=health-law-and-business&jcsearch=BNA%252000000164f57fdb1faff7fd7f517c0002#jcite [https://perma.cc/394U-F2HX] (noting that relator Maria Guzman filed the first of the five underlying qui tam actions and that all five actions were ultimately consolidated and transferred to the United States District Court for the Central District of California).

115. U.S. Complaint in Intervention, *supra* note 65.

116. Order Unsealing Cases, United States v. Insys Therapeutics, Inc., No. 2:13-cv-5861 JLS (AJWx) (C.D. Cal., May 11, 2018).

117. Guzman Second Amended Complaint, *supra* note 55, at 14–17, ¶¶ 66–84.

118. *Id.* at 12, ¶ 58.

119. *Id.*

120. *Id.* at 8, ¶ 38.

121. *Id.* at 11, ¶ 53.

dances,[122] trips to shooting ranges,[123] lunches for physician office staff,[124] coolers of filet mignon steaks,[125] and the hiring of prescribers' significant others[126] in return for the prescription of Subsys.

The factual allegations set forth in the consolidated qui tam actions against Insys are bold and specific. For example, one of the lawsuits quotes a text message written by an Insys employee stating, "Don't worry about [the physicians'] speaking abilities. They do not need to be good speakers. They need to write a lot of Subsys."[127] Statements like these provide strong evidence that the purpose of the Insys speaker programs was not to educate peer prescribers but, instead, to exchange remuneration for selected speakers' writing of Subsys prescriptions.

By further example, the same lawsuit quotes a text message sent by an Insys employee to a particular physician who not only practiced medicine but also owned a restaurant. The text message to the physician stated, "'I can commit to 100k to you via speaker programs or meals towards your restaurant. We don't need the food, just charge our card and give [us] an itemized receipt. Just need your support on [S]ubsys.'"[128] When the Insys employee stated that Insys does not need the food provided by the physician's restaurant, the Insys employee is eliminating the only legitimate reason for Insys's payment to the restaurant. Then, when the Insys employee stated that Insys "[j]ust need[s] your support on [S]ubsys,"[129] the employee is essentially admitting that the purpose of the payment is to induce Subsys prescriptions.

The same lawsuit also quotes a text message written by an Insys employee to a potential prescribing physician stating that the employee wants to know if the physician's girlfriend would like a full-time job working for the employee.[130] The text message further states, "I could also use a few Subsys prescriptions. We have not seen anything, I want to have some fun!!! Can't do it [without] [S]ubsys scripts coming in at least once a day. Have [your girlfriend] call me next week."[131] This text message is strong evidence that the Insys employee is willing to hire the physician's

122. *Id.* at 18, ¶ 86.
123. *Id.* at 19, ¶ 92.
124. *Id.*
125. *Id.* at 25–26, ¶ 131.
126. *Id.* at 12, ¶ 58.
127. *Id.* at 15, ¶ 70.
128. *Id.* at 16, ¶ 75.
129. *Id.*
130. *Id.* at 22, ¶ 116.
131. *Id.*

girlfriend in exchange for the physician writing at least one Subsys prescription per day. Stated another way, the hiring of the girlfriend appears to be in-kind remuneration offered in return for Subsys prescriptions.

On November 6, 2018, the media reported that Insys was looking to sell its opioid-related assets, including Subsys.[132] It is likely that the company's allegedly looming $150 million settlement payment, its inability to further trade remuneration for Subsys prescriptions, and the negative press associated with Insys's role in the still-strong opioid crisis, impacted this decision.

## III. THE FEDERAL CIVIL FALSE CLAIMS ACT

### *A. Background*

In addition to the Anti-Kickback Statute, the federal government has other tools designed to combat opioid fraud and abuse, including the federal civil False Claims Act (FCA). The FCA creates civil liability for any person who: (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 [that is] material to a false or fraudulent claim"; (3) knowingly uses a false statement to decrease an obligation to pay money to the government; and (4) conspires with respect to the preceding conduct, among other illegal conduct.[133] 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 (*e.g.*, up-coding a health care service to receive a higher level of reimbursement), claims for unnecessary health care services, claims for health care services performed by health care providers excluded from participating in federal health care programs, and the submission of false information about a health care service provided or a charge for such service.[134] Knowing conduct includes conduct involving

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132. Maria Armental, *Insys Looks to Sell Opioid-Related Assets, Including Subsys*, WALL ST. J. (Nov. 6, 2018, 12:30 AM), https://www.wsj.com/articles/insys-looks-to-sell-opioid-related-assets-including-subsys-1541482212 [https://perma.cc/47WF-GZEG].

133. 31 U.S.C. § 3729(a)(1)(A), (B), (C), and (G) (2012); *id*. § 3729(b)(2) (defining claim).

134. *See generally* Magellan Health Services, Inc., *Fraud, Waste and Abuse Training for Medicare and Medicaid Providers PowerPoint, at PowerPoint Slides 13–14*, https://www.magellanprovider.com/MHS/MGL/about/handbooks/supplements/fwa_training.pdf [https://perma.cc/8K2B-8HUR] (last visited Mar. 18, 2019) (listing illustrative examples of FCA

actual knowledge of a falsehood as well as conduct involving deliberate ignorance or reckless disregard of the truth.[135]

Per the terms of the FCA, individuals who violate the law are "liable to the federal government for a civil penalty of not less than $5,000 and not more than $10,000, as thereafter may be adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 [(FCPIIA)], plus three times the amount of damages" (called "treble damages").[136] For penalties assessed after January 29, 2018, the most recent FCPIIA adjustment has increased the civil penalty range from not less than $11,181 to not more than $22,363.[137] Because the FCA is a civil statute, the burden of proof for an FCA violation is the preponderance of the evidence standard.[138]

Claims that violate the FCA may be classified as factually false or legally false. Factually false claims include claims or supporting documentation that are false on their face, such as claims that knowingly contain improper codes, claims for (nonexistent) care provided to fictitious patients, and claims supported by falsified medical record or other documentation.[139] Legally false claims are different than factually false claims in that they may, at first glance, appear to be facially, technically accurate in the sense that a provider may have seen a patient in the office for a twenty-five-minute visit and the accompanying claim may state that a twenty-five-minute office visit occurred.[140] However, because the provider failed to meet an applicable statute or regulation in connection with the office visit, the claim for the visit is classified as legally false.[141]

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violations).

135. 31 U.S.C. § 3729(b)(1) (2012).

136. *Id*. § 3729(a)(1) (setting forth these statutory amounts).

137. Civil Monetary Penalties Inflation Adjustment, Final Rule, 83 Fed. Reg. 3944-01, 3945 (Jan. 29, 2018) (to be codified at 28 C.F.R. pt. 85), https://www.federalregister.gov/documents/2018/01/29/2018-01464/civil-monetary-penalties-inflation-adjustment [https://perma.cc/PW6A-NTBX] (setting forth new amounts that apply for violations after certain dates in 2017 and 2018).

138. 31 U.S.C. § 3731(d) (2012) ("In any action brought under Section 3730, the United States shall be required to prove all essential elements of the cause of action, including damages, by a preponderance of the evidence.").

139. *See* Burke v. Record Press, Inc., 951 F. Supp. 2d 26, 30 (D.D.C. 2013) ("'A claim can be "factually false if it invoices for services that were not rendered" or incorrectly describes goods or services provided.'"); 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.'").

140. *Burke*, 951 F. Supp. 2d at 30.

141. *Id.* (quoting United States v. DRC, Inc., 856 F. Supp. 2d 159, 167 (D.D.C. 2012)) ("'A claim may be "legally false" if it represents falsely that the party submitting the claim has complied with an applicable federal statute or regulation, or with a contractual term.'").

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.[142] An express false certification occurs 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 or invoice.[143] In the absence of an explicitly false certification, some courts in certain situations imply compliance with federal laws as part of the claimant's submission of a reimbursement claim.[144] Stated another way, 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 for payment.[145]

In its 2016 decision in *Universal Health Services, Inc. v. United States ex rel. Escobar*, the Supreme Court of the United States resolved a circuit split regarding the viability of implied false certification claims, holding that such claims are permissible under the FCA.[146] The Court stated that "misrepresentations by omission can give rise to liability,"[147] reasoning that "half-truths—representations that state the truth only so far as it goes, while omitting critical qualifying information can be actionable."[148] The Court also held that, "when a defendant submits a claim, it impliedly certifies compliance with all conditions of payment."[149] However, the Court also inserted a materiality requirement; that is, a "misrepresentation

142. *See, e.g.*, Benjamin Dacin, *Legal Materiality and the Implied Certification Theory of the False Claims Act: Why Courts Have Rejected the Traditional Standards of Materiality in Favor of a Precondition to Payment Requirement*, 17 MICH. ST. U. J. MED. & L. 31, 34 (2012) (distinguishing between factually false and legally false claims); 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) (providing guidance regarding the types of misrepresentations that should suffice for FCA liability under the implied false certification theory of liability; noting that, while the implied false certification theory survived *Universal Health Services, Inc. v. United States ex rel. Escobar*, without more definitive guidance the lower courts will be left to sort out confusing, highly fact-specific cases); Joseph R. Berger, *Recent Rulings on Implied Certification under the False Claims Act: Limitations on a Common-Law Theory*, 16 J. HEALTH CARE FRAUD 2, 2–10 (2010) (summarizing district and appellate court decisions involving the implied false certification theory of liability under the FCA); Scott Oswald et al., *Health Care Law Expands False Claims Act Liability under Anti-Kickback Statute*, 26 NO. 3 WESTLAW J. GOV'T CONTRACT 2, 9 (2012) (explaining how the Affordable Care Act rendered moot the former reliance on the implied false certification theory of liability in order to bring a False Claims Act case based on a violation of the Anti-Kickback Statute).

143. Krause, *supra* note 142, at 1817.

144. *Id.*

145. *Id.*

146. 136 S. Ct. 1989, 1999 (2016).

147. *Id.*

148. *Id.* at 2000.

149. *Id.* at 1995.

about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment decision in order to be actionable . . . ."[150] The Court clarified that materiality would not be found where "noncompliance is minor or insubstantial."[151] Instead, materiality is determined by "'the effect on the likely or actual behavior of the recipient of the alleged misrepresentation.'"[152] Compliance with the Anti-Kickback Statute, discussed in Part I of this Article, has been found to be a material condition of payment by the Medicare program.[153] Indeed, President Obama's Affordable Care Act amended the Anti-Kickback Statute in 2010 to state that, "a claim that includes items or services resulting from a violation of [the Anti-Kickback Statute] constitutes a false or fraudulent claim for purposes of [the False Claims Act]."[154]

All pharmaceutical companies, including opioid manufacturers, must certify compliance with a number of statutes and regulations, including requirements set forth in the federal Food, Drug, and Cosmetic Act (FDCA) and the FDCA's implementing regulations.[155] Among other prohibitions, the FDCA forbids false or misleadingly-labeled products as well as products with labels that do not bear "adequate directions for use."[156] The FDCA's implementing regulations clarify that directions are inadequate if they are deficient with respect to the "conditions, purposes, or uses" for which the drug is intended, the quantity of dose, or the frequency of administration.[157] The FDCA is also violated when a drug is

150. *Id.* at 1996, 2002 ("What matters is . . . whether the defendant knowingly violated a requirement that the defendant knows is material to the Government's payment decision. A misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment decision in order to be actionable under the False Claims Act.").

151. *Id.* at 2003.

152. Universal Health Servs. v. United States ex rel. Escobar, 136 S. Ct. 1989, 2002 (2016) (quoting 26 RICHARD A. LORD, WILLISTON ON CONTRACTS § 69:12 (4th ed. 2003)).

153. U.S. Complaint in Intervention, *supra* note 71, at 35, ¶ 10–11.

154. 42 U.S.C. § 1320a-7b(g) (2012). *See also* United States ex rel. Hutcheson v. Blackstone Med. Inc., 647 F.3d 377, 395 (1st Cir. 2011) ("If kickbacks affected the transaction underlying a claim . . . the claim failed to meet a condition of payment . . . . We find . . . that the kickbacks were capable of influencing Medicare's decision as to whether to pay the hospital and physician claims.").

155. 21 U.S.C. §§ 301–399f (2012 & Supp. 2017) (codifying the FDCA); 21 C.F.R. §§ 201.1–201.328 (2017) (codifying the FDCA's implementing regulations).

156. 21 U.S.C. § 331(a) (2012 & Supp. 2017) (prohibiting the introduction into interstate commerce of misbranded drugs); *id.* § 352(a) (stating that a drug or device is deemed to be misbranded if its label is false or misleading); *id.* § 352(f) (requiring adequate directions for use); 21 C.F.R. § 201.5 (2017) (defining adequate directions for use; providing reasons directions may be inadequate for use).

157. 21 C.F.R. § 201.5 (2017) ("Adequate directions for use means directions under which the layman can use a drug safely and for the purposes for which it is intended. Directions for use may be inadequate because, among other reasons, of omission, in whole or in part, or incorrect specification of . . . [s]tatements of all conditions, purposes, or uses for which such drug is intended, including

marketed "off label"; that is, for a use or at a dosage other than those approved by the Food and Drug Administration (FDA).[158]

In addition, pharmaceutical manufacturers must certify compliance with regulations governing risk evaluation and mitigation strategies (REMS).[159] As background, the FDA has authority to require a REMS in situations in which the FDA determines that safety measures (beyond labeling) are needed to ensure that a drug's benefits outweigh its risks.[160] REMS include medication guides, communication plans, and lists of recommendations and goals to assure the safe use of a drug.[161] The FDA explains that, "REMS focus on preventing, monitoring and/or managing a specific serious risk by informing, educating and/or reinforcing actions to reduce the frequency and/or severity of the event."[162]

Under the FCA's qui tam[163] provisions, a private person known as a relator (or whistleblower) who has knowledge of past or present fraud committed against the federal government is permitted to bring a suit in the government's name and on the government's behalf.[164] If the government proceeds with the action brought by the private person, the private person can receive "at least fifteen percent but not more than twenty-five percent of the proceeds of the action or settlement of the claim, depending upon the extent to which the person substantially contributed to the prosecution of the action, as well as reasonable attorney's fees, costs, and expenses."[165] "If the government does not proceed with [the action], the [private] person shall receive an amount . . . . not less than 25 percent

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conditions, purposes, or uses for which it is prescribed, recommended, or suggested in its oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drug is commonly used . . . ."); *id.* (including omissions or incorrect specifications relating to "[q]uantity of dose" and "[f]requency of administration or application" within the concept of inadequate directions for use).

158. *See* United States v. Caronia, 576 F. Supp. 2d 385, 389 (E.D.N.Y. 2008) (defining "off-label" uses as those that are "non-FDA approved").

159. 21 U.S.C. § 355-1(e) (2012 & Supp. 2017) (providing regulations governing REMS, including their content, communication plan).

160. The Food and Drug Administration Amendments Act, Pub. L. No. 110–85, § 901, 121 Stat. 823 (2007).

161. U.S. Food & Drug Admin., *Risk Evaluation and Mitigation Strategies (REMS)* (last updated Feb. 2, 2018) https://www.fda.gov/Drugs/DrugSafety/REMS/default.htm [https://perma.cc/ZXG5-V7Q7].

162. *Id.*

163. The term qui tam is derived from the Latin phrase "*qui tam pro domino rege quam pro se ipso in hac parte sequitur*," meaning "he who sues in this matter for the king as well as for himself." *See* Pamela H. Bucy, *Federalism and False Claims*, 28 CARDOZO L. REV. 1599, 1600 (2007) (translating and discussing the term); J. Randy Beck, *The False Claims Act and the English Eradication of Qui Tam Legislation*, 78 N.C. L. REV. 539, 550 (2000) (same).

164. 31 U.S.C. § 3730(b) (2012) (allowing a private person to bring a civil action for violations of 31 U.S.C. § 3729).

165. *Id.* § 3730(d)(1).

and not more than 30 percent of the proceeds of the action or settlement, plus reasonable attorney's fees and costs."[166]

A wide range of business competitors, disgruntled former employees, over-billed patients, and other individuals have brought qui tam actions under the FCA against pharmaceutical companies and other health industry participants.[167] Unless the action is brought by the Attorney General or the person bringing the action is the original source of the information, a court has the authority to dismiss a qui tam action if "substantially the same allegations or transactions as alleged in the action or claim were [already] publicly disclosed": (1) in a "hearing in which the Government or its agent is a party;" (2) in a "federal report, hearing, audit, or investigation;" or (3) "from the news media."[168]

Using the FCA's qui tam provisions, relators have successfully alleged that drug manufacturers have violated the FDA's off-label marketing prohibitions and REMS provisions in a number of non-opioid cases, resulting in substantial settlements. In July 2017, for example, the DOJ announced that New Jersey-based Celgene Corporation had agreed to pay $280 million to settle fraud charges involving the company's illegal promotion of two cancer drugs for uses not approved by the FDA.[169] The settlement resolved allegations that Celgene promoted its cancer drugs Thalomid and Revlimid "for uses that were not approved by the FDA and not covered by federal health care programs."[170] "The allegations included the use of false and misleading statements about the [two cancer] drugs," as well as the payment of remuneration "to physicians to induce them to prescribe the two drugs."[171] In the press release announcing the settlement, Acting United States Attorney Sandra R. Brown stated, "Patients deserve to know their doctors are prescribing drugs that are likely to provide effective treatment, rather than drugs marketed aggressively by pharmaceutical companies."[172]

A few months later, in September 2017, the DOJ announced that

166. *Id.* § 3730(d)(2).

167. *See* Krause, *supra* note 142, at 1816.

168. 31 U.S.C. § 3730(e)(4) (2012) (barring certain qui tam actions, including those in which the allegations or transactions have already been publicly disclosed).

169. Press Release, U.S. Dep't of Justice, U.S. Attorney's Office, Cent. Dist. of Cal., Celgene Agrees to Pay $280 Million to Resolve Fraud Allegations Related to Promotion of Cancer Drugs for Uses Not Approved by FDA (July 24, 2017), https://www.justice.gov/usao-cdca/pr/celgene-agrees-pay-280-million-resolve-fraud-allegations-related-promotion-cancer-drugs [https://perma.cc/LZ6A-CJ7L].

170. *Id.*

171. *Id.*

172. *Id.*

Aegerion Pharmaceuticals agreed to pay $35 million to the federal government to resolve allegations that it violated the FCA by causing false claims to be submitted to Medicare and Medicaid with respect to its prescription drug Juxtapid.[173] The allegations in the FCA portion of the settlement, totaling $28.8 million, related to Aegerion's promotion of Juxtapid for patients without a diagnosis of, or consistent with, homozygous familial hypercholesterolemia (HoFH), which is a rare, inherited disorder that prevents the removal of LDL-C (known as "bad cholesterol") from the blood, causing abnormally high levels of circulating LDL-C.[174] The allegations in the FCA portion of the settlement also related to Aegerion's: (1) false and misleading statements to physicians that Juxtapid was appropriate for use in patients with high cholesterol generally, not just patients with HoFH; and (2) "alteration or falsification of statements of medical necessity and prior authorizations that were submitted to federal health care programs."[175]

Aegerion also pled guilty, agreeing to pay a criminal fine and forfeiture of $7.2 million, as a result of its violations of the FDA's REMS provisions.[176] As background, the FDA required a REMS as part of Juxtapid's approval.[177] "The specific purpose of the Juxtapid REMS was to educate prescribers about the risks of liver toxicity and to restrict access to Juxtapid only to those patients with a clinical or laboratory diagnosis consistent with HoFH."[178] Aegerion allegedly filed a misleading REMS assessment report and, later, failed to comply with REMS requirements, such as distributing Juxtapid only for the treatment of HoFH (not high cholesterol generally) without adequate directions for such use.[179] Aegerion's settlement resolves a qui tam action initially filed by Michele Clarke, Tricia Mullins, and Kristi Winger Szudlo, former Aegerion employees, who received $4.7 million for their qui tam work.[180] Both the Celegene and Aegerion settlements show that compliance with the FDCA and its implementing regulations, including its "off label" marketing

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173. Press Release, U.S. Dep't of Justice, Office of Pub. Affairs, Drug Maker Aegerion Agrees to Plead Guilty; Will Pay More Than $35 Million to Resolve Criminal Charges and Civil False Claims Allegations (Sept. 22, 2017), https://www.justice.gov/opa/pr/drug-maker-aegerion-agrees-plead-guilty-will-pay-more-35-million-resolve-criminal-charges-and [https://perma.cc/LMV3-NNEG].

174. *Id.*

175. *Id.*

176. *Id.*

177. *Id.*

178. *Id.*

179. *Id.*

180. *See* Complaint, United States et al. v. Aegerion Pharm., Inc., et al., No. 13-cv-11785 (D. Mass. July 26, 2013).

prohibitions and its REMS requirements, can result in violations of the FCA.[181]

### *B. Application to the Opioid Context*

#### 1. Cases Involving Factually False Claims

Although the legally false certification theory of FCA liability has received significant attention in part due to the Supreme Court's 2016 opinion in *United States ex rel. Escobar*, health industry participants that prescribe or dispense opioids have the potential to violate more traditional (and academically more straightforward) provisions within the FCA, including those that prohibit factually false claims. For example, the DOJ announced in June 2017 that "Rhine Drug Company and Andrew 'Carter' Clements, Jr. agreed to pay a total of $2.175 million to resolve allegations that they violated the [FCA]."[182] In particular, the Government alleged that Rhine Drug Company and Clements violated the FCA by submitting claims to Medicare for drugs that Rhine Drug Company had actually not dispensed to patients.[183]

The press release announcing the settlement quoted Acting United States Attorney James Durham as stating, "'Pharmacists are supposed to bill only for what they dispense and they're to keep accurate records of the prescription drugs they let walk out of their pharmacies.'"[184] The press release also quoted Derrick L. Jackson, Special Agent in Charge of the federal Department of Health and Human Services-Office of Inspector General (HHS-OIG) Office in Atlanta, as stating, "Billing Medicare for prescription drugs that were never dispensed to patients is a serious allegation."[185] The only good news about the factually false claims made in the Rhine Drug Company case is that they do not contribute to the patient injury (*i.e.*, addiction) side of the opioid crisis. That is, the

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181. *See generally* Michael Filoromo & Matthew LaGarde, *Insight: Leveraging the False Claims Act to Combat Opioid Misuse*, BLOOMBERG L. NEWS (Aug. 2, 2018, 9:01 AM), https://news.bloomberglaw.com/health-law-and-business/insight-leveraging-the-false-claims-act-to-combat-opioid-misuse [https://perma.cc/H6Z2-UZ2H] (discussing the application of the FCA to the submission of false opioid claims).

182. Press Release, U.S. Dep't of Justice, U.S. Attorney's Office, S. Dist. of Ga., Dodge County Pharmacy and Pharmacist to Pay Over $2 million to Resolve False Claims Act and Controlled Substances Act Violations (June 13, 2017), https://www.justice.gov/usao-sdga/pr/dodge-county-pharmacy-and-pharmacist-agree-pay-over-2-million-resolve-false-claims-act [https://perma.cc/8MR6-HVJ4].

183. *Id.*

184. *Id.*

185. *Id.*

factually false bills certainly increased costs to federal health care programs; however, no live patients received any opioids as a result of the illegal conduct.[186]

In a second example of a case involving factually false claims, the DOJ announced in January 2018 that Matthew Anderson, a chiropractor who worked in Lenior City, Tennessee, agreed to pay $1.45 million plus interest to resolve FCA violations for his part in contributing to the Tennessee opioid crisis.[187] As background, Anderson and his management company managed four pain clinics in Tennessee, including "Cookeville Center for Pain Management, Spinal Pain Solutions in Harriman, Preferred Pain Center of Grundy County, and McMinnville Pain Relief Center."[188] The Government alleged that Anderson and his management company, among other illegal conduct, instructed employees at all four clinics to up-code office visits by assigning an inaccurate billing code to increase Medicare reimbursement.[189] The press release announcing the settlement quoted Derrick L. Jackson, Special Agent in Charge of the HHS-OIG office in Atlanta, as stating, "The opioid epidemic has had a crushing effect on patients and families across middle Tennessee . . . Pill mills like these billed medically unnecessary services to Medicare and TennCare and contributed to problems of opioid abuse and addiction."[190]

In a third example of a case involving factually false claims, the qui tam relators (and now the Government in intervention) in the consolidated cases against Insys allege that Insys's Internal Reimbursement Center (IRC) prepared false documentation that would accompany claims to federal health care programs. In particular, the qui tam relators allege that the IRC, which assisted prescribers with completing Subsys prior authorization forms, would include in those prior authorization forms cancer diagnoses when the patients to whom the forms related did not have cancer or had a distant cancer diagnosis unrelated to their current pain.[191] In addition, the qui tam relators allege that, in cases in which a prescriber had included the patient's true (but non-reimbursable) diagnosis on a Subsys prior authorization form (*e.g.*, chronic pain or back pain), Insys would later change that diagnosis to a false (but reimbursable) diagnosis

186. *Id.*

187. 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/opa/pr/tennessee-chiropractor-pays-more-145-million-resolve-false-claims-act-allegations [https://perma.cc/62ZW-75UK].

188. *Id.*

189. *Id.*

190. *Id.*

191. *See* Guzman Second Amended Complaint, *supra* note 55, at 45–46, ¶¶ 228–35.

(*e.g.*, cancer).[192]

Unlike prescribers and dispensers, pharmaceutical manufacturers do not actually submit claims to federal health care programs. However, pharmaceutical manufacturers can "cause" a false claim to be submitted (or "cause" a false, material prior authorization form to be submitted) in cases in which the manufacturer changes a patient's diagnosis from a non-reimbursable diagnosis to a reimbursable diagnosis on a prior authorization form that is submitted to a payor. These types of false statements, or records, are illegal under the FCA because the FCA creates liability not just for those who submit 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.[193]

2. Cases Involving Legally False Claims

In addition to cases involving factually false claims, several health industry participants have settled FCA allegations predicated on violations of material statutes and regulations including, but not limited to, provisions within the Controlled Substances Act (CSA). These cases are known as legally false claims cases. For example, PharMerica Corporation agreed to pay the Government $31.5 million in May 2015 "to resolve a lawsuit alleging that PharMerica 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.[194] As background, "PharMerica is a long-term care pharmacy that dispenses medications to residents of long-term care facilities, including nursing homes and skilled nursing facilities."[195] Many of the prescriptions filled by PharMerica, including oxycodone and fentanyl, were for controlled substances listed in Schedule II under the CSA.[196] In terms of the CSA allegations, the Government alleged that PharMerica pharmacies located across the nation frequently dispensed oxycodone, fentanyl, and other

192. *Id.* at 53, ¶ 272.

193. 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).

194. 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 [https://perma.cc/3KLJ-XJBN] [hereinafter PharMerica Press Release].

195. *Id.*

196. *Id.*

Schedule II controlled drugs without a CSA-required physician prescription.[197] Instead, nursing home staff would order opioids and other controlled drugs for residents and PharMerica pharmacists would dispense the staff-ordered drugs without a physician's prescription.[198] PharMerica agreed to pay $8 million to resolve the Government's CSA allegations.[199]

In terms of the FCA allegations, the Government alleged that PharMerica knowingly submitted false claims to Medicare Part D—the part of Medicare that provides a prescription drug benefit—for the same improperly dispensed Schedule II drugs.[200] PharMerica agreed to pay $23.5 million to resolve the Government's FCA allegations.[201] The FCA allegations were initially raised by relator Jennifer Denk, a pharmacist formerly employed by PharMerica, under the FCA's qui tam provisions.[202] Ms. Denk received $4.3 million for her qui tam work on the case.[203]

The consolidated qui tam actions against Insys contain numerous other legally false claims allegations. For example, the qui tam relators (and now the Government in intervention) allege that Insys violated the FCA by violating the Anti-Kickback Statute by offering or paying remuneration to prescribers in return for writing Subsys prescriptions.[204] As discussed in Part I, President Obama's Affordable Care Act amended the Anti-Kickback Statute in 2010 to state that, "a claim that includes items or services resulting from a violation of [the Anti-Kickback Statute] constitutes a false or fraudulent claim for purposes of [the False Claims Act]."[205] By further example, the qui tam relators (and now the Government in intervention) allege that Insys violated the FCA by marketing and promoting Subsys for off-label uses.[206] In particular, the plaintiffs argue that Insys' promotional activities influenced prescribers to

197. *Id.*

198. *Id.*

199. *Id.*

200. *Id.*

201. *Id.*

202. Complaint, United States ex rel. Denk v. PharMerica Corp., No. 2:09-cv-720 (E.D. Wis. July 23, 2009).

203. *See* PharMerica Press Release, *supra* note 194.

204. *See* Guzman Second Amended Complaint, *supra* note 55, at 52, ¶ 268.

205. 42 U.S.C. § 1320a-7b(g) (2012). *See also* United States ex rel. Hutcheson v. Blackstone Med. Inc., 647 F.3d 377, 394–95 (1st Cir. 2011) ("If kickbacks affected the transaction underlying a claim . . . the claim failed to meet a condition of payment . . . . We find . . . that the kickbacks were capable of influencing Medicare's decision as to whether to pay the hospital and physician claims.").

206. *See* Guzman Second Amended Complaint, *supra* note 55, at 34–42 (referencing cases in which Insys instructed its sales representatives regarding off-label uses of Subsys and targeted physicians who were neither oncologists nor pain specialists when the FDA had approved Subsys only for cancer-related pain).

prescribe Subsys for non-cancer-pain uses not covered by federal health care programs, which "caused" the claims ultimately submitted by those prescribers to be false in violation of the FCA.[207]

3. Qui Tam Actions Barred in Cases Involving Prior Public Disclosure

Remember that, unless a qui tam action is brought by the Attorney General or the person bringing the action is an original source of information, a court has the authority under the FCA to dismiss a qui tam action if "substantially the same allegations or transactions as alleged in the action or claim" have already been publicly disclosed by the news media, through a hearing in which the Government is a party, or in a federal report, hearing, audit, or investigation.[208] These dismissal provisions may soon be applied to a qui tam opioid case. In *United States ex rel Manchester v. Purdue Pharma et al*., relator Robert Manchester filed a qui tam action against a number of defendants, including Purdue Pharma, McKesson Corporation, Cardinal Health, and AmerisourceBergen Corporation.[209] In his complaint, Manchester alleged that Purdue failed to tell the FDA about an abuse-deterrent formulation of OxyContin.[210] On August 22, 2018, the United States filed a motion arguing that the case should be dismissed, reasoning that Manchester based his allegations against the defendants "only on publicly available information."[211] In its motion, the United States specified that both news media and federal reports raised the issue of alleged marketing to overprescribing physicians before Manchester filed his action, making Manchester's case worthy of dismissal under the terms of the FCA.[212]

207. *Id.* at 56–57, ¶¶ 280–81.

208. 31 U.S.C. § 3730(e)(4) (2012) (barring certain qui tam actions, including those in which the allegations or transactions have already been publicly disclosed).

209. Third Amended Complaint and Demand for Trial by Jury, United States ex rel. Robert E. Manchester et al. v. Purdue Pharma L.P. et al., Case No. 1:16-cv-10947-MLW (D. Mass. Aug. 23, 2018).

210. *Id.*

211. Memorandum of Law in Support of the United States' Motion to Dismiss Relator's Complaint, United States ex rel. Manchester et al. v. Purdue Pharma L.P. et al., Case No. 1:16-cv-10947-MLW (D. Mass. Aug. 22, 2018).

212. *See* Daniel Seiden, *DOJ Believes Opioid Case Will Fail Against Big Pharma Firms*, BLOOMBERG L. (Aug. 24, 2018, 2:21 PM), https://www.bloomberglaw.com/document/XA44D4PG000000?bna_news_filter=federal-contracting&jcsearch=BNA%2520000001656c0bdc20a16d7f6fa8250002#jcite [https://perma.cc/BU3R-D4JD] (discussing the public's prior knowledge of the allegations made in the Manchester qui tam action).

## IV. CONCLUSIONS AND NEW INITIATIVES

This Article has identified and discussed several opioid cases that involve the federal Anti-Kickback Statute and the federal civil False Claims Act. What effect have these two statutes had on the opioid crisis as a whole? Starting with the Anti-Kickback Statute, the federal Government clearly is using this legal tool in an attempt to cut off opioid over-prescribing and/or testing over-referring induced by remuneration. The prescribing physicians, nurse practitioners, and physician assistants discussed in Part I of this Article had been receiving millions of dollars of remuneration in return for their frequent opioid prescriptions, referrals of patients for drug testing services, and referrals of patients for opioid addiction treatment services. Remember Dr. Johnson, who had entered into a joint venture with William Hughes, the owner of Universal Oral Fluids Lab (UOFL), pursuant to which Dr. Johnson referred all of his patients, including his Medicare and Medicaid patients, to UOFL for drug testing and related services?[213] In that case, UOFL received approximately $3,443,528 from Medicare and $1,147,768 from Pennsylvania Medicaid based on Dr. Johnson's referrals alone.[214] In addition, Dr. Johnson received more than $2,300,000 in kickbacks from UOFL between May 2011 and November 2013.[215] And, this is just one opioid case involving one referring physician and one referred-to entity. From this perspective, the Anti-Kickback Statute can be seen as an effective tool for combating opioid-related health care fraud, abuse, and waste and for protecting patients in cases in which a prescriber's medical judgment has been compromised by illegal remuneration.

That said, note how many of these cases discussed in Part I of this Article involved the opioid Subsys, manufactured by Insys. In terms of the prescription portion of the opioid crisis, which is just one portion of the overall opioid crisis,[216] Subsys is an exceptionally "small [opioid] fish."[217] In particular, fewer than 0.02% of the 52 million opioid patients

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213. Press Release, U.S. Dep't of Justice, U.S. Attorney's Office, W. Dist. of Pa., Physician Sentenced to 7 Years in Prison for Accepting Kickbacks and Failing to Remit Employment Taxes (June 30, 2017), https://www.justice.gov/usao-wdpa/pr/physician-sentenced-7-years-prison-accepting-kickbacks-and-failing-remit-employment [https://perma.cc/MU87-9N4J].

214. *Id.*

215. *Id.*

216. *See generally* Oliva, *supra* note 8 (arguing that the prescription portion of the opioid crisis is just one small part of the overall opioid crisis, which also includes illicit drugs).

217. Jill Riepenhoff, *Some Get Rich as Opioid Addicts Suffer*, DAILY INDEP. (Mar. 2, 2018), https://www.dailyindependent.com/news/some-get-rich-as-opioid-addicts-suffer/article_712e2234-1dbc-11e8-8332-d7d5b1157a0b.html [https://perma.cc/U7MB-ZGVQ?type=image].

were prescribed Subsys in the year 2015, which many view as the peak of opioid prescribing in the United States.[218] Stepping back even further, Insys is not even among the top fifty pharmaceutical companies in terms of payments to opioid prescribers, and most of Insys's top payees are, to this day, still practicing medicine or nursing and are still serving as physician assistants.[219] Although Insys certainly ranks high in terms of its aggressive opioid marketing practices and its bold remuneration schemes, which explains why they are an easy governmental target, the Government's take-down of key Insys payors and top Subsys prescribers is relatively insignificant when viewed from the perspective of the entire opioid manufacturing industry.

The Anti-Kickback Statute thus may be viewed as an effective tool for purposes of dealing with individual bad actors, like Drs. Couch and Ruan, whose opioid prescriptions were fueled by remuneration and greed. However, the Anti-Kickback Statute is also a relatively small tool in terms of combating the overall opioid crisis. Remember that although the opioid crisis is frequently framed as a prescription drug epidemic primarily attributable to the over-prescription of opioids, illicit (non-prescription) drugs also play a very large role in the crisis[220] and opioid prescribing has been on the decline since 2016.[221] Also remember that Congress enacted the Anti-Kickback Statute based on the concern that health care kickbacks can lead to corruption of medical decision making; patient steering; overutilization of health care items, services, and supplies; increased costs to federal health care programs; and unfair competition.[222] The Anti-Kickback Statute was simply not designed to address, and does not address, the many other behavioral, sociocultural, socioeconomic, and criminal justice factors that are believed to contribute to the opioid crisis.[223]

For example, in terms of behavioral factors that contribute to the opioid crisis, some physicians overprescribe opioids even though they do

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218. *Id.*

219. *Id.*

220. *See generally* Oliva, *supra* note 8 (making this argument).

221. *See, e.g.*, Pat Anson, *Significant Decline in U.S. Opioid Prescribing*, PAIN NEWS NETWORK (Apr. 15, 2016), https://www.painnewsnetwork.org/stories/2016/4/15/significant-decline-in-us-opioid-prescribing [https://perma.cc/5KVZ-BKDK] (referencing a report finding that the opioid crisis is "increasingly being fueled by illegal opioids such as heroin and illicit fentanyl, not by prescription pain medication intended for patients" and that hydrocodone prescription is on the decline).

222. *Roadmap for New Physicians*, *supra* note 33.

223. *See, e.g.*, Nat'l Inst. of Health, *Executive Summary - Contributions of Social and Behavioral Research in Addressing the Opioid Crisis* (Mar. 6, 2018) [hereinafter NIH Study], https://www.nih.gov/heal-initiative/executive-summary-contributions-social-behavioral-research-addressing-opioid-crisis [https://perma.cc/EZR5-H2DB].

not receive remuneration for those prescriptions. That is, some physicians simply overprescribe—either because they were taught to prescribe in that manner or because they developed their own over-prescribing behaviors.[224] By further example, in terms of sociocultural and socioeconomic factors that contribute to the opioid crisis, one line of research views opioid addiction as a symptom of an economic and social despair that is both: (1) markedly higher among those without a college degree; and (2) one result of a long process that has eroded working-class life in the United States and that has led to an increase in pain-related complaints.[225] A second line of research shows that the criminal justice system is ill-equipped to address the opioid crisis, and that criminalization of illicit drug use has the unintended effect of increasing stigma and decreasing access to treatments by individuals with opioid use disorder.[226] In summary, the opioid crisis has multiple contributing factors, most of which cannot be addressed by the Anti-Kickback Statute.

In terms of the behavior that the Anti-Kickback Statute (and the False Claims Act) are designed to address, it must be noted that these statutes are limited in their application to federal (versus private) health care program business. The Anti-Kickback Statute thus does not apply to a patient recruiter who offers or pays remuneration in return for private health insurance business, or a prescriber who solicits or receives remuneration in return for writing opioid prescriptions or referring patients for drug testing or addiction treatment services that are reimbursed by private health insurance. The same is true of a prescriber who submits a false claim to a private insurer or who makes a false statement that is material to a claim submitted to a private insurer. That said, other federal laws,[227] including the new Eliminating Kickbacks in Recovery Act of 2018,[228] as well as many state laws[229] do apply in the context of private health insurance.

What about the effectiveness of the False Claims Act in terms of

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224. *See, e.g.*, Marty Makary, *How Doctors Can Stop the Opioid Crisis at Its Source: Quit Overprescribing*, USA TODAY, (Aug. 4, 2017, 3:15 AM), https://www.usatoday.com/story/opinion/2017/08/04/doctors-stop-opioid-crisis-quit-overprescribing-marty-makary-column/504860001/ [https://perma.cc/2STX-WKS8] (quoting a physician who stated that, for most of his surgical career, he gave out opioids "like candy").

225. *See* NIH Study, *supra* note 223, at 5.

226. *Id.*

227. *See* 18 U.S.C. § 1347(a) (2012); *see also* Support for Patients and Communities Act, Pub. L. No. 115-271, §§ 8121–8122, 132 Stat. 3894 (2018) (two federal health care fraud and abuse laws that apply in the context of private health insurance).

228. *See infra* notes 235–42 and accompanying text.

229. *See, e.g.*, Peter E. Kalb, *Health Care Fraud and Abuse*, 282 JAMA 1163 (Sept. 22, 1999) (discussing state health care fraud and abuse laws).

combating the opioid crisis? As discussed in Part II of this Article, some factually false claims, including claims for services never provided, certainly can increase unnecessary costs to federal health care programs. However, these factually false claims do not contribute to the patient injury (or addiction) side of the opioid crisis because opioids were never dispensed to any live patients. Other factually false statements, including diagnoses that are falsified to ensure reimbursement, can contribute to the patient injury side of the opioid crisis, however. For example, when a non-cancer patient receives an opioid approved by the FDA only for patients with cancer-related pain due to a falsified diagnostic statement, the patient may be unnecessarily exposed to a highly addictive drug and life-threatening respiratory depression as a result.

Because the False Claims Act targets so many different types of conduct, including factually false and legally false claims, as well as expressly false and impliedly false certifications, the False Claims Act is viewed as an important tool in terms of combating the opioid crisis.[230] One follow-up issue, though, is whether the Government has sufficient resources to investigate all of the behavior that potentially violates the False Claims Act in the context of opioids. On one hand, the DOJ announced in February 2018 the creation of its Prescription Interdiction & Litigation (PIL) Task Force, specifically designed to fight the prescription opioid crisis.[231] According to the DOJ's press release on the topic, the PIL Task Force will "aggressively deploy and coordinate all available criminal and civil law enforcement tools to reverse the tide of opioid overdoses in the United States, with a particular focus on opioid manufacturers and distributors."[232] The press release specifically announces that the DOJ will use the False Claims Act in its fight against the opioid crisis:

> The PIL Task Force will use criminal and civil actions to ensure that distributors and pharmacies are obeying [DEA] rules designed to prevent diversion and improper prescribing. It will use the False Claims Act and

230. *See, e.g.*, 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/ [https://perma.cc/Q5BS-EP7U] (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.").

231. Press Release, U.S. Dep't of Justice, Office of Pub. Affairs, Attorney General Sessions Announces New Prescription Interdiction & Litigation Task Force (Feb. 27, 2018), https://www.justice.gov/opa/pr/attorney-general-sessions-announces-new-prescription-interdiction-litigation-task-force [https://perma.cc/UQM2-UWKW].

232. *Id.*

> other tools to crack down on pain-management clinics, drug testing facilities, and physicians that make opioid prescriptions.[233]

Whether governmental funding is sufficient to support the important activities of the PIL Task Force remains to be seen, although recent reports suggest that the enforcement of the FCA in opioid cases continues to increase.[234]

The federal government has other new initiatives relevant to opioid fraud and abuse, and the implementation and enforcement of these new initiatives remains to be seen as well. On October 24, 2018, President Trump signed into law the SUPPORT for Patients and Communities Act (SUPPORT Act), a comprehensive piece of legislation designed to combat the opioid crisis.[235] The SUPPORT Act appropriates millions of dollars from the Treasury and the federal Supplementary Medical Insurance Trust Fund to support a variety of federal agencies in the creation and/or execution of new research studies, reports, demonstration projects, programs, guidelines, and enforcement efforts designed to combat the opioid crisis.[236] One part of the SUPPORT Act establishes the Eliminating Kickbacks in Recovery Act of 2018 (EKRA).[237] EKRA builds on the prohibitions set forth in the federal Anti-Kickback Statute by making illegal the knowing and willful solicitation or receipt, or offer or payment, of remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for the referral of a patient or patronage to a recovery home, clinical treatment facility, or laboratory or to induce a referral of an individual to a recovery home, clinical treatment facility, or laboratory.[238] 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 promotes sustained recovery from substance use disorders.[239] EKRA further defines clinical treatment

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233. *Id.*

234. *See* James Swann, *Fraudulent Opioid Prescribers Can Expect More Federal Charges*, BLOOMBERG L. NEWS (Feb. 4, 2019), https://www.bna.com/fraudulent-opioid-prescribers-n57982095984/ [https://perma.cc/7UQ4-4SHX] (reporting that "'[t]otal FCA filings in cases involving opioid fraud among prescribers, drug companies, and addiction treatment centers also increased in [fiscal year] 2018 compared to previous years'", and that "'[p]roviders prescribing and distributing opioids are on notice that their actions will be watched closely, and it's essential that they remain up to date on current laws, monitor prescribing practices, and report any diversion promptly'").

235. *See* Support for Patients and Communities Act, Pub. L. No. 115-271, § 7031, 132 Stat. 3894 (2018).

236. *Id.*

237. Eliminating Kickbacks in Recovery Act of 2018, Pub. L. No. 115-271, §§ 8121–8122 (2018).

238. *Id.*

239. *Id.*

facility 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.[240]

Although some behaviors prohibited by EKRA are technically already prohibited by the federal Anti-Kickback Statute, EKRA applies to remuneration exchanged for both public *and* private health care program business.[241] As such, EKRA builds on the federal Anti-Kickback Statute by prohibiting the exchange of remuneration for referrals for private-health-insurance-reimbursed recovery home services, clinical treatment services, and laboratory services. (EKRA, like the Anti-Kickback Statute, would not apply to the referral of these services when paid for by cash or credit card.) In a recent press release, the DOJ explained why EKRA was needed: "[P]atients in substance abuse treatment facilities are not usually typical Medicare beneficiaries, but are often people on private insurance or even people in their early [twenties] still on their parents' insurance. 'These patients are really treated as cash registers . . . .'"[242] EKRA establishes criminal penalties of not more than $200,000, imprisonment of not more than ten years, or both, for each violation of EKRA.[243] EKRA further provides that it does not supersede or preempt other applicable federal or state laws, including the federal Anti-Kickback Statute.[244]

In addition to the PIL Task Force and EKRA, the Centers for Medicare and Medicaid Services (CMS) also recently created a mega anti-fraud program, called the Unified Program Integrity Contractor (UPIC), in an attempt to improve health care fraud and abuse economies of scale and address state-specific fraud and abuse issues.[245] In particular, UPIC will be responsible for health care fraud and abuse data mining, investigations, law enforcement referrals, claims auditing, provider education, and other fraud and abuse prevention activities.[246] CMS designed UPIC with the goal of bridging and improving health care fraud and abuse communications between and among the federal Medicare Program and

240. *Id.*

241. *Id.*

242. Matt Phifer, *Justice Dept. Aims to Thwart Substance Abuse Treatment Fraud*, BLOOMBERG L. (Nov. 5, 2018, 10:54 AM), https://news.bloomberglaw.com/health-law-and-business/justice-dept-aims-to-thwart-substance-abuse-treatment-fraud [https://perma.cc/GP2E-FSMQ].

243. Eliminating Kickbacks in Recovery Act of 2018 §§ 8121–8122.

244. *Id.*

245. James Swann, *Medicare Herds Four Anti-Fraud Programs Under One Roof*, BLOOMBERG L. (Nov. 8, 2018, 5:30 AM), https://news.bloomberglaw.com/health-law-and-business/medicare-herds-four-anti-fraud-programs-under-one-roof [https://perma.cc/46ZN-539X].

246. *Id.*

state Medicaid Programs.[247] According to CMS, UPIC will be capable of detecting health care providers who, for example, commit Medicare fraud and abuse and then relocate to a new state and attempt to repeat the fraudulent activity in connection with the new state's Medicaid Program.[248]

Between the new PIL Task Force, EKRA, and UPIC, the federal government's health care fraud and abuse detection, investigation, and enforcement efforts appear to be at an all-time high. Hopefully, these new initiatives will assist in the detection and prevention of opioid fraud and abuse as well.

247. *Id.*
248. *Id.*