

Enforcement in Kickback Cases

Katherine A. Lauer, Partner
HCCA Scottsdale Regional Meeting
November 8, 2019

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Overview

- New Anti-kickback provisions of EKRA
- Trials – Criminal and Civil
- Criminal Division Policy Guidance
- Civil FCA Settlements
- Ongoing Enforcement Efforts/New Areas of Focus

New Anti-kickback Provisions of EKRA

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3

July 2018: Eliminating Kickbacks in Recovery Act (EKRA) Introduced

Amid National Opioid Crisis, Rubio & Klobuchar Introduce Bill to Eliminate Patient Brokering

JUL 20 2018

Washington, D.C. – U.S. Senators Marco Rubio (R-FL) and Amy Klobuchar (D-MN) yesterday introduced the Eliminating Kickbacks in Recovery Act, [legislation to prohibit patient brokering](#) by punishing unscrupulous actors that prey on patients seeking treatment in order to exploit the patient's insurance. In May, Rubio [introduced](#) legislation to help states, law enforcement, private insurers and patients identify potentially illicit treatment centers and sober homes to ensure those who need treatment are able to find legitimate facilities.

October 2018: Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act

POTUS Enacts Opioids Package with Rubio Provision to Eliminate Patient Brokering

OCT 24 2018

Miami, FL – Today, President Trump signed into law the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act, which includes several provisions championed by U.S. Senator Marco Rubio (R-FL) to prevent and treat opioid addiction, including [the Eliminating Kickbacks in Recovery Act](#). This provision will help stop payments to middlemen referring patients to illicit sober homes and treatment centers—[increasingly a problem in South Florida](#). The SUPPORT for Patients and Communities Act [passed](#) the Senate, 98-1, on October 3.

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5

18 U.S.C. § 220 - Illegal remunerations for referrals to recovery homes, clinical treatment facilities and laboratories

(a) Offense.--Except as provided in subsection (b), whoever, with respect to services covered by a health care benefit program, in or affecting interstate or foreign commerce, knowingly and willfully--

- (1)** solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind, in return for referring a patient or patronage to a recovery home, clinical treatment facility, or laboratory; or
- (2)** pays or offers any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind--
 - (A)** to induce a referral of an individual to a recovery home, clinical treatment facility, or laboratory; or
 - (B)** in exchange for an individual using the services of that recovery home, clinical treatment facility, or laboratory,

shall be fined not more than \$200,000, imprisoned not more than 10 years, or both, for each occurrence.

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6

Criminal Trials

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7

Department of Justice
Office of Public Affairs

FOR IMMEDIATE RELEASE

Friday, April 5, 2019

South Florida Health Care Facility Owner Convicted for Role in Largest Health Care Fraud Scheme Ever Charged by The Department of Justice, Involving \$1.3 Billion in Fraudulent Claims

A federal jury found a South Florida health care facility owner guilty today for his role in the largest health care fraud scheme ever charged by the Justice Department, involving over \$1.3 billion in fraudulent claims to Medicare and Medicaid for services that were not provided, were not medically necessary or were procured through the payment of kickbacks.

After an eight-week trial, Philip Esformes, 50, of Miami Beach, Florida, was convicted of one count of conspiracy to defraud the United States, two counts of receipt of kickbacks in connection with a federal health care program, four counts of payment of kickbacks in connection with a federal health care program, one count of conspiracy to commit money laundering, nine counts of money laundering, two counts of conspiracy to commit federal program bribery, and one count of obstruction of justice before U.S. District Judge Robert N. Scola Jr. of the Southern District of Florida. Sentencing has not yet been scheduled.

According to evidence presented at trial, from approximately January 1998 through July 2016, Esformes led an extensive health care fraud conspiracy involving a network of assisted living facilities and skilled nursing facilities that he owned. Esformes bribed physicians to admit patients into his facilities, and then cycled the patients through his facilities, where they often failed to receive appropriate medical services, or received medically unnecessary services, which were then billed to Medicare and Medicaid, the evidence showed. Several witnesses testified to the poor conditions in the facilities and the inadequate care patients received, which Esformes was able to conceal from authorities by bribing an employee of a Florida state regulator for advance notice of surprise inspections scheduled to take place at his facilities. The evidence further showed that Esformes used his criminal proceeds to make a series of extravagant purchases, including luxury automobiles and a \$360,000 watch. Esformes also used criminal proceeds to bribe the basketball coach at the University of Pennsylvania in exchange for his assistance in gaining admission for his son into the university. Altogether, the evidence established that Esformes personally benefited from the fraud and received in excess of \$37 million.

United States v. Texas, No. 19-10011 (5th Cir.)



U.S. Department of Justice
Civil Division, Appellate Staff
950 Pennsylvania Ave. NW, Rm. 7513
Washington, DC 20530

Tel: (202) 616-5374

March 25, 2019

RE: *Texas v. United States*, No. 19-10011 (5th Cir.)

Dear Mr. Cayce:

The Department of Justice has determined that the district court’s judgment should be affirmed. Because the United States is not urging that any portion of the district court’s judgment be reversed, the government intends to file a brief on the appellees’ schedule.

United States v. Texas, No. 19-10011 (5th Cir.)

III. The Individual Mandate Is Not Severable From The Guaranteed-Issue And Community-Rating Provisions, And The Rest Of The ACA Is Not Severable In Turn	36
A. The individual mandate is inseverable from the guaranteed-issue and community-rating provisions	37
B. The rest of the ACA’s provisions are inseverable	43

Department of Justice

U.S. Attorney's Office

Northern District of Texas

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FOR IMMEDIATE RELEASE

Wednesday, April 10, 2019

Seven Guilty in Forest Park Healthcare Fraud Trial

Following four days of deliberations, a federal jury returned guilty verdicts for seven individuals implicated in the Forest Park Medical Center bribery scheme Tuesday evening, announced U.S. Attorney Erin Nealy Cox.

Wilton McPherson "Mac" Burt, Jackson Jacob, Douglas Sung Won, Michael Bassem Rimlawi, Shawn Mark Henry, Mrugeshkumar Shah, and Iris Kathleen Forrest were all convicted of conspiracy to pay or receive healthcare bribes.

Ten other defendants had already pleaded guilty in the \$200 million scheme, designed to induce doctors to steer lucrative patients – particularly those with high-reimbursing, out-of-network private insurance – to the now defunct hospital.

Most of the kickbacks, which totaled more than \$40 million, were disguised as consulting fees or "marketing money" doled as a percentage of surgeries each doctor referred to Forest Park.

Instead of billing patients for out-of-network co-payments, instituted by insurers to de-incentivize the high costs associated with out-of-network treatment, Forest Park allegedly assured patients they would pay in-network prices. Because they knew insurers wouldn't tolerate such practices, they concealed the patient discounts and wrote off the difference as uncollected "bad debt."

Hospital manager Alan Beauchamp, who testified for the government, admitted that Forest Park "bought surgeries," and then "papered it up to make it look good."

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11

Department of Justice

U.S. Attorney's Office

District of Massachusetts

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FOR IMMEDIATE RELEASE

Thursday, May 2, 2019

Founder and Four Executives of Insys Therapeutics Convicted of Racketeering Conspiracy**First successful prosecution of top pharmaceutical executives for crimes related to the prescribing of opioids**

BOSTON – The founder and four former executives of Insys Therapeutics Inc. were convicted today by a federal jury in Boston in connection with bribing medical practitioners to prescribe Subsys, a highly-addictive sublingual fentanyl spray intended for cancer patients experiencing breakthrough pain, and for defrauding Medicare and private insurance carriers.

Insys founder and former Executive Chairman John N. Kapoor, 76, of Phoenix, Ariz.; Richard M. Simon, 48, of Seal Beach, Calif., the former National Director of Sales; Sunrise Lee, 38, of Bryant City, Mich., a former Regional Sales Director; Joseph A. Rowan, 45, of Panama City, Fla., a former Regional Sales Director; and Michael J. Gurry, 55, of Scottsdale, Ariz., the former Vice President of Managed Markets, were convicted by a federal jury of RICO conspiracy. Sentencing dates have not yet been set.

Prior to the start of the trial, two other high-level Insys executives pleaded guilty and testified during the trial: Michael Babich, of Scottsdale Ariz., the former CEO and President of the company, and Alec Burlakoff, of Charlotte, N.C., the former Vice President of Sales.

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12

Civil FCA Trials

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13

Civil FCA Trials

U.S. ex rel. Lutz v. BlueWave Healthcare Consultants, Inc., et al., Nos. 9:14-cv-230, 9:11-cv-1593 and 9:15-cv-2458 (D.S.C.)

- Two-week jury trial concluded in January 2018 resulting in judgments totaling more than \$114 million against three individuals who were found to have paid physicians illegal remuneration disguised as “process and handling fees” of between \$10 and \$17 for each patient they referred to two blood testing laboratories. The government also introduced evidence at trial that this kickback scheme resulted in physicians referring patients to the labs for medically unnecessary tests.
- Earlier in the case, the government obtained pre-judgment writs of attachment and garnishment against two of the individual defendants for property valued at \$16.7 million under the Federal Debt Collection Procedures Act after showing that defendants had transferred assets “with the effect of hindering, delaying or defrauding the United States,” 28 U.S.C. 3101(b). 225 F. Supp. 3d 460 (D.S.C. 2016).
- The 4th Circuit dismissed defendants’ appeals of the pre-judgment relief for lack of appellate jurisdiction, finding that the district court’s order denying defendants’ motion to quash the writs was non-final and not a collateral order because, among other things, the ruling was “completely enmeshed with the merits of the qui tam action.” 853 F.3d 131 (4th Cir. 2017).

Civil FCA Trials

U.S. ex rel. Cairns v. D.S. Medical, LLC, et al., No. 1:12 CV 00004 (E.D. MO)

- Two-week trial concluded in October 2017 resulting in \$5.5 million judgment against neurosurgeon Dr. Sonjay Fonn, his fiancée Ms. Deborah Seeger, and their professional corporations DS Medical and Midwest Neurosurgeons. The evidence showed that Dr. Fonn performed spinal fusion surgery using implants for which his fiancée received commissions, which were used to benefit Dr. Fonn in the form of lavish purchases such as a yacht and home improvements.

Criminal Division Policy Guidance

JM 9-47.120**FCPA Corporate Enforcement Policy**

- Makes permanent the FCPA “pilot program”
- Applies in all FCPA cases, principles applied in all Criminal Division cases
- Purpose
 - Incentivize and reward voluntary disclosures, cooperation, and remediation
 - Provide consistency and guidance to prosecutors on how to resolve corporate cases

JM 9-47.120**FCPA Corporate Enforcement Policy**

- Presumption of declination absent aggravating circumstances
 - Must disgorge illicit gain
 - Declinations are public
- If resolution is warranted, company will receive 50% off the bottom of the USSG fine range, except for recidivists
- Voluntary disclosure
- Full Cooperation
- Remediation
 - Requires “[i]mplementation of an effective compliance and ethics program, the criteria for which will be periodically updated and which may vary based on the size and resources of the company”

Criminal Division's Evaluation of Corporate Compliance Programs

U.S. Department of Justice
Criminal Division
Evaluation of Corporate Compliance Programs
(Updated April 2019)

This document is meant to assist prosecutors in making informed decisions as to whether, and to what extent, the corporation's compliance program was effective at the time of the offense, and is effective at the time of a charging decision or resolution, for purposes of determining the appropriate (1) form of any resolution or prosecution; (2) monetary penalty, if any; and (3) compliance obligations contained in any corporate criminal resolution (e.g., monitorship or reporting obligations).

Evaluation of Corporate Compliance Programs The 3 "Fundamental Questions" in JM 9-28.800 are the Framework

1. "Is the corporation's compliance program well designed?"
2. "Is the program being applied earnestly and in good faith?"
 - In other words, is the program being effectively implemented?
3. "Does the corporation's compliance program work" in practice?

Criminal Division's Evaluation of Corporate Compliance Programs - Anti-Kickback Statute Risk

- **Risk Assessment**
 - Risk Management Process
 - Risk-Tailored Resource Allocation
 - Updates and Revisions
- **Third-Party Management**
 - Risk Based and Integrated Processes
 - Appropriate Controls
 - Management of Relationships
 - Real Actions and Consequences

Civil FCA Settlements and Litigation

Civil FCA Settlements

- Give-Aways to Referral Sources
- Patient Inducements
- Hospital-Physician Arrangements
- Physician Ownership Arrangements

Give-Aways to Referral Sources

- ***U.S. ex rel. Bilotta v. Novartis Pharmaceuticals Corp. (Mar. 31, 2019 SDNY)*** – Granting partial summary judgment to the government and holding, among other things, that the government had “adduced sufficient particularized evidence of a company-wide kickback scheme” to induce physicians to prescribe the company’s cardiovascular drugs, including invitations to and honoraria for sham speaker programs involving lavish meals and drinks. Notably, the court ruled that the government does not need to prove a *quid pro quo* between physicians and Novartis to establish FCA liability at trial.
- ***U.S. et al. ex rel. Guzman v. Insys Therapeutics, Inc., et al. (C.D. Cal.)*** – In April 2018, the government filed its Complaint in Intervention in five *qui tam* actions alleging that Insys offered and paid kickbacks in the form of sham speaker fees, lavish meals and entertainment and jobs for prescribers’ friends and relatives, to induce physicians and nurse practitioners to prescribe its highly addictive opioid painkiller, Subsys – a sublingual form of fentanyl approved by FDA only for opioid-tolerant cancer patients – to patients who met none of the FDA-approved criteria. The government’s complaint identifies multiple Subsys prescribers and company sales representatives who either pleaded guilty or were convicted after trial for offering or accepting kickbacks. The complaint also alleges that Insys employees lied to Medicare Part D plans and other insurers about patients’ medical conditions in order to obtain authorization for Subsys prescriptions. consolidated civil actions are currently stayed; on May 2, federal jury in Boston convicted the founder and four former Insys executives.

Give-Aways to Referral Sources

- **Galena Biopharma, Inc. (D.N.J.)** – In September 2017, Galena paid \$7.55 million to settle allegations that it paid kickbacks to doctors to induce prescriptions of its sublingual fentanyl-based drug Abstral. The kickbacks included more than 85 free meals to doctors and staff from a single, high-prescribing practice; paying doctors \$5,000, and speakers \$6,000, plus expenses, to attend an “advisory board” that was partly planned, and attended, by Galena sales team members; paying approximately \$92,000 to a physician-owned pharmacy under a performance-based rebate agreement to induce the owners to prescribe Abstral; and paying doctors to refer patients to the company’s RELIEF patient registry study, which was nominally designed to collect data on patient experiences with Abstral, but acted as a means to induce the doctors to prescribe Abstral. Two Alabama physicians (Drs. Ruan and Couch) were convicted in S.D. Ala. in May 2017 for accepting kickbacks to prescribe Subsys and Astral.
- **Inform Diagnostics, Inc. f/k/a Miraca Life Sciences (M.D. Tenn.)** (announced Jan. 30, 2019) – Pathology laboratory paid \$63.5 million to settle three *qui tam* actions alleging AKS and Stark Law violations for providing subsidies for electronic health records (EHR) systems and free or discounted technology consulting services to physicians based on actual or anticipated referrals.
- **Covidien LP (ND Cal)** – In March 2019, Covidien agreed to pay \$17.5 million to settle two *qui tam* actions alleging provision of free or discounted customized practice development and market development support to California and Florida physicians to induce purchases of Covidien’s vein ablation products.

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25

Patient Inducements – Pharmaceutical Co-Pay Foundations

Since 2017, government settlements involving this conduct exceed \$850 Million.

- **United Therapeutics (Dec 2017) - \$210 Million** <https://www.justice.gov/opa/pr/drug-maker-united-therapeutics-agrees-pay-210-million-resolve-false-claims-act-liability>
- **Pfizer (May 2018) - \$23.85 Million** <https://www.justice.gov/opa/pr/drug-maker-pfizer-agrees-pay-2385-million-resolve-false-claims-act-liability-paying-kickbacks>
- **Actelion Pharmaceuticals (Dec 2018) – \$360 Million** <https://www.justice.gov/opa/pr/drug-maker-actelion-agrees-pay-360-million-resolve-false-claims-act-liability-paying>
- **Jazz Pharmaceuticals (April 2019) - \$57 Million**
- **Lundbeck LLC (April 2019) - \$52.6 Million**
- **Alexion Pharmaceuticals (April 2019) - \$13 Million** <https://www.justice.gov/opa/pr/three-pharmaceutical-companies-agree-pay-total-over-122-million-resolve-allegations-they-paid>
- **Astellas Pharma US (April 2019) - \$100 Million**
- **Amgen Inc. (April 2019) - \$24.75 Million** <https://www.justice.gov/opa/pr/two-pharmaceutical-companies-agree-pay-total-nearly-125-million-resolve-allegations-they-paid>
- **US World Meds LLC (April 2019) - \$17.5 Million** <https://www.justice.gov/opa/pr/pharmaceutical-company-agrees-pay-175-million-resolve-allegations-kickbacks-medicare-patients>

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Patient Inducements – Individual Physician Co-Pay Waivers

- ***Dr. Asad Qamar and Institute of Cardiovascular Excellence (M.D. Fla.)***. In 2016, Dr. Asad Qamar and his Florida practice, the Institute of Cardiovascular Excellence (ICE), paid \$2 million and released claims to an additional \$5.3 million in suspended Medicare funds to settle two intervened *qui tam* lawsuits alleging that he and his practice paid kickbacks to patients by waiving Medicare copayments irrespective of financial hardship, thereby inducing patients to undergo unnecessary and invasive stent placements and other cardiac procedures. This conduct made Dr. Qamar the highest paid Medicare cardiologist in the United States in 2012 and 2013. Dr. Qamar also agreed to a three-year exclusion period.

Hospital-Physician Arrangements

- ***Health Management Associates LLC (D.D.C)*** -- On September 25, 2018, HMA Agreed to Pay over \$260M for false billing and kickback allegations. Expansive investigation including eight *qui tam* actions that were filed in several districts and consolidated in the District of Columbia. Specifically regarding the kickbacks, the government alleged that two HMA Hospitals, in order to induce referrals, provided a local physician group with free office space and staff, free rent and upgrades for another physician, discounted rent, and direct payments to cover overhead and admin costs to others. There were criminal parallel proceedings and three year non-prosecution agreement.
- On April 30, 2019, Gary D. Newsome, former CEO of HMA, agreed to pay \$3.46 million to settle allegations, including that he caused HMA to pay remuneration in the form of bonuses to Emergency Department physicians in return for referrals.
- ***William Beaumont Hospital (E.D. Mich)*** -- On August 2, 2018, Beaumont agreed to pay \$84.5M. The government alleged that Beaumont provided physician compensation substantially in excess of fair market value and free or below market value office space and employees to eight physicians to secure referrals.

Hospital-Physician Arrangements

- **MedStar Health (D. Md.)** -- On March 21, 2019, Medstar Union Memorial and MedStar Franklin Square Medical Center agreed to pay \$35M to settle allegations that they paid remuneration under the guise of professional services agreements to a cardiology group in exchange for referrals of lucrative cardiology procedures. There was also a medical necessity aspect alleging unnecessary angioplasties and stents performed by a physician from the cardiology group.
- **US ex rel. Luke v. Gardena Hospital et al. (C.D. Cal.)** -- On December 18, 2018, Avanti Hospitals LLC and six of its owners agreed to pay \$8.1M to resolve kickback allegations. Specifically, the government alleged that Gardena Hospital – an Avanti subsidiary – and two other Avanti affiliates paid above-fair market value compensation to a high referring physician as a medical director to incentivize him to refer to Gardena Hospital.

Physician Ownership

U.S. v. Reliance Medical Systems, LLC, et al., No. CV 14-6979 DDP (C.D. Cal.)

- The government has sued Reliance, a spinal implant supplier, two of its physician-owned distributorships (PODs) and three non-physician owners for allegedly violating the AKS by giving spinal surgeons an ownership interest in PODs that supplied implants for use in the physicians' own surgeries, thereby allowing them to profit from their orders of Reliance products and inducing them perform spinal surgeries that were medically unnecessary or more intense than medically necessary.
- The government also alleges that the defendants conspired to conceal the surgeons' ownership interest in the PODs from hospitals where they performed surgeries.
- In January 2017, Dr. Aria Sabit, a former physician owner of a Reliance POD and a named defendant in the government's complaint, was sentenced to 235 months in prison, forfeited \$2.8 million and settled the government's civil claims against him after pleading guilty in E.D. Mich. to multiple counts of healthcare fraud. Among other things, Sabit admitted to his participation in the kickback scheme, and admitted that the financial incentives provided to him by his POD and his co-conspirators caused him to use more spinal implant devices than were medically necessary to treat his patients in order to generate more sales revenue for his POD, which resulted in serious bodily injury to his patients.

Physician Ownership

- U.S. ex rel. Bruno et al. v. Schaeffer, et al. (M.D. La.), 2018 WL 3041191 (June 18, 2018)*** – Physician-owned lab case. Relators have pursued this declined case and are proceeding with discovery--recently surviving a motion to dismiss. Relators allege that Defendants offered physicians ownership interests in labs called Physician Owned Labs (POL) which existed in name only, and they received payments from the labs in proportion to the number of urine specimens the physician sent to a lab for testing covered by private insurance. Interestingly, Relators also allege that the scheme incentivized the same doctors to send their urine specimens covered by Medicare and Medicaid to another lab. The Court held that it is reasonable to infer that the POL scheme will increase the chances the physicians will refer to the lab that bills to Medicare and Medicaid, even though they are not paid for those

Ongoing Enforcement Efforts/ New Areas of Focus

Ongoing Enforcement Efforts/New Areas of Focus

- Kickbacks and the Opioid Crisis
- Telemedicine/DME/Laboratories cases
- Electronic Health Records Programs and related kickbacks
- Continued Focus on Accountability of Individuals
- Liability of non-healthcare providers, such as equity firms
- New Safe Harbors

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