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DOJ and OIG Launch Wave of Aggressive Prosecutions Targeting Entities and Individuals for Illegal Health Care Marketing Practices

In the last few months, the United States Department of Justice (DOJ) and the Office of Inspector General (OIG) have obtained over half a billion dollars in settlements and multiple criminal convictions arising from enforcement actions related to health care marketing practices. Specifically, the government has recently announced enforcement actions against multiple pharmaceutical companies, a laboratory, and individual health care providers for alleged violations of federal fraud and abuse laws, including the Anti-Kickback Statute (AKS) and the False Claims Act (FCA). Signaling that these victories are only the beginning, DOJ has also announced a series of criminal prosecutions of employees of these entities and policy initiatives that demonstrate the government's increased scrutiny of health care marketing practices.

The AKS is a criminal statute that prohibits knowingly and willfully offering, paying, soliciting, or receiving any remuneration to induce or reward the referral or generation of business reimbursed by a federal health care program (for example, Medicare or Medicaid). "Remuneration" is broadly defined under the AKS to include the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind. Violation of the AKS is a felony, subject to a maximum fine of $25,000 for each criminal act, up to five years of imprisonment, and exclusion from federal health care programs. All parties to an illegal arrangement under the AKS may be subject to AKS liability, which in part explains how DOJ was able to target parties on both sides of suspect arrangements in certain of the following cases. Additionally, violations of the AKS can subject parties to civil liability under the Civil Monetary Penalties Law (CMP) and the FCA. FCA liability carries monumental financial exposure, with the government entitled to treble damages as well as civil monetary penalties of up to $11,000 per false claim.

WARNER CHILCOTT

On October 29, 2015, DOJ announced that the U.S. subsidiary of pharmaceutical manufacturer Warner Chilcott had agreed to plead guilty to felony health care fraud as part of a $125 million civil and criminal settlement arising from Warner Chilcott's illegal marketing practices.

According to DOJ, Warner Chilcott allegedly paid kickbacks to physicians to induce them to prescribe its drugs, submitted inaccurate or misleading prior authorization requests to federal health care programs on behalf of beneficiaries to increase coverage of its drugs, and directed representatives to make unsubstantiated marketing claims about the efficacy of certain Warner Chilcott drugs. The kickbacks Warner Chilcott allegedly paid to physicians included illegal remuneration disguised as payments for medical education events and speaker programs.

In conjunction with the resolution of its case against Warner Chilcott, DOJ announced a series of criminal cases against Warner Chilcott employees related to the company's misconduct, including the indictment of a former Warner Chilcott president. DOJ's prosecution of individual Warner Chilcott employees indicates that DOJ is already acting in accordance with a recent memorandum issued by Deputy Attorney General Sally Yates that directs federal prosecutors to more thoroughly pursue individuals for corporate misconduct. DOJ further noted that a Massachusetts physician had been charged with accepting kickbacks in exchange for prescribing certain Warner Chilcott drugs in a case that appears similar to DOJ's Connecticut prosecution discussed below.

NOVARTIS

Novartis Pharmaceuticals Corp. recently entered into a $370 million settlement with DOJ to resolve a fraud and abuse case that had been scheduled for trial in early November. In 2013, DOJ alleged that Novartis had violated the AKS and FCA by paying kickbacks in the form of referrals, discounts, and rebates to specialty pharmacies to induce them to prescribe certain Novartis drugs. DOJ further alleged that, by inducing those pharmacies to prescribe certain Novartis drugs in violation of the AKS, Novartis caused those specialty pharmacies to violate the FCA by submitting false claims to Medicare and Medicaid. Two of the specialty pharmacies involved entered into related settlements with DOJ and certain states for $75 million in total.

Settlement of the Novartis case comes after the government issued a Special Advisory Bulletin in 2014 related to the AKS and coupons issued by pharmaceutical companies (previously discussed by Robinson+Cole here). It is also the second notable fraud and abuse settlement in recent years involving Novartis after the pharmaceutical manufacturer agreed to a $422.5 million settlement and Corporate Integrity Agreement (2010 CIA) with DOJ in 2010 related to illegal marketing of its drugs. Because the fraud and abuse allegations that gave rise to the most recent settlement occurred while the 2010 CIA was still in effect, Novartis entered into a related agreement to extend the 2010 CIA for an additional five years commencing as of November 18, 2015. In a separate case still pending, DOJ has also alleged that Novartis paid illegal remuneration to physicians in the form of payments for educational programs and that, as a result, federal health care programs paid out false claims tied to improper marketing practices that steered patients to Novartis drugs.

MILLENNIUM

DOJ's increased attention to AKS cases is confirmed by its recent $256 million settlement with Millennium Health (Millennium), a laboratory company in California that specializes in drug testing. The Millennium settlement, announced October 19, 2015, resolved allegations of violations of the AKS and the FCA. DOJ prosecuted Millennium for similarly abusive marketing practices that resulted in excessive and unnecessary services reimbursed by federal health care programs. DOJ alleged that Millennium employed a number of coercive marketing practices with physicians to drive referrals of medically unnecessary tests—such as the use of standing orders for patients instead of individual determinations based on medical necessity—and made unsupported threats of third-party legal actions against physicians who failed to order full test panels. DOJ also alleged that Millennium provided kickbacks to referring physicians in the form of free drug testing cups in exchange for exclusively referring tests to Millennium. As a result of Millennium's practices, Medicare paid millions of dollars for tests ordered by physicians at the behest of Millennium that were not reasonable or necessary.

CONNECTICUT

DOJ recently obtained a criminal conviction in Connecticut that serves as a warning to individual health care providers about liability arising from pharmaceutical marketing practices. Following a federal investigation, an advanced practice registered nurse pleaded guilty to violating the AKS by overprescribing a particular painkiller in exchange for $83,000 in payments from the drug's manufacturer, which payments DOJ considered to be kickbacks.

In this case, the nurse—who was employed by a private pain clinic in Connecticut—admitted to

accepting payments from the manufacturer of the painkiller Subsys. Subsys is approved for treatment of cancer patients, but the nurse admitted to increasingly prescribing it for a number of noncancer patients, which led to her become a leading nationwide Subsys prescriber. At the same time, she received payments from the manufacturer for over 70 "speaking engagements" that the government alleged were ostensibly presentations by the nurse on the benefits of Subsys but in reality consisted of private dinners arranged and paid for by the manufacturer. DOJ maintained that the correlation between the payments and the increased prescriptions demonstrated the criminal nature of the arrangement. As part of her guilty plea, the government stated that the nurse "admitted that the money she was paid influenced her prescribing of Subsys" and that the sham speaker program was orchestrated by representatives of the drug's manufacturer for the purpose of funneling kickbacks to her. The allegations related to the sham speaker programs in this case mirror the allegations brought by DOJ in cases against Novartis and Warner Chilcott mentioned above.

GOVERNMENT POLICY INITIATIVES

In early November, DOJ announced that it had retained a full-time compliance expert who will consult with DOJ's Fraud Section attorneys in connection with the prosecution of business entities, with methods including assessment of internal compliance policies and remedial actions taken by such business entities to detect and prevent future wrongdoing. DOJ settlements of corporate misconduct usually mandate heightened monitoring of compliance efforts for a certain period of time after the date of the settlement and provide for additional penalties in the event a business entity fails to comply with the requirements of the settlement. DOJ's hiring of a full-time compliance expert indicates that its Fraud Section is increasing its scrutiny of repeat offenders and may lead to higher penalties for noncompliance with settlement agreements.

Additionally, the OIG recently published its 2016 Work Plan, which states that OIG's investigative priorities for the coming year include reviewing pharmaceutical reimbursement practices under Medicare Part D and continuing to work with DOJ prosecutors on health care fraud cases similar to those discussed above.

PRACTICE POINTS

Health care organizations and providers would be well advised to scrutinize any remuneration potentially tied to product or patient referrals. It is readily apparent that an express quid pro quo arrangement is illegal, but exposure can also arise from a series of small, less direct, types of remuneration that imperceptibly aggregate over time into an eye-catching amount (such as the $83,000 in the Connecticut prosecution). Employers and providers are also reminded that government investigators have access to prescription and payment data (for example, under state-controlled substance reporting laws or the Physician Payments Sunshine Act) that can be correlated against that series of benefits to support fraud and abuse allegations. Additionally, providers may want to carefully analyze any payments offered by or received from health care drug or device manufacturers tied to educational programs or presentations regarding health care drugs or devices reimbursed under federal health care programs.

The range of government targets in these investigations, as well as the breadth of potential liability under the AKS and the FCA, indicate that the government is taking a multifaceted approach to combating health care fraud. These recent enforcement actions demonstrate not only the significant consequences of AKS violations, and the perils associated with certain health care marketing practices, but also the renewed vigor with which the government is investigating and prosecuting potential violations throughout the country. As the government implements reforms aimed at further reducing health care costs nationwide, the number of federal and state fraud and abuse cases will likely increase exponentially. Health care providers and organizations are therefore encouraged to take meaningful steps to ensure their compliance policies and procedures are up-to-date and that providers are sufficiently trained regarding suspect arrangements under fraud and abuse laws.

Members of Robinson+Cole's Health Law Group and Government Investigations Group routinely advise clients on drafting compliance programs aimed at educating health care providers on how to avoid high-

risk arrangements concerning prescription drug marketing and are available to assist with any issues that may arise. The Government Investigations Group also has extensive experience conducting internal investigations and representing organizations facing government inquiries into potential fraud or abuse misconduct.

If you have any questions, please contact one of the following Robinson+Cole lawyers:

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