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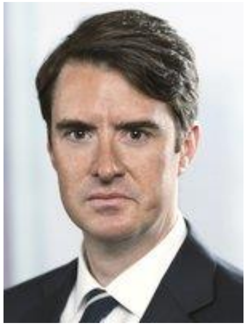
2019 Trends In DOJ Health Care Enforcement

By **Eóin Beirne, Jason Burrell and Nicole Henry**

(January 10, 2020, 5:33 PM EST) -- Criminal health care enforcement in 2019 was in many ways a continuation of 2018, with opioid-related enforcement the clear top priority for the U.S. Department of Justice, in addition to having a sustained focus on prosecuting individuals and data-driven identification of health care fraud.



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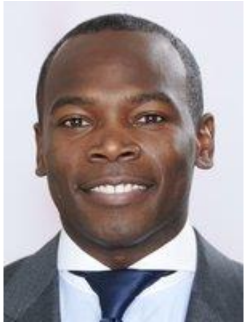

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This trend is reflected in statistics published by the U.S. Department of Health and Human Services' Office of Inspector General in its most recent semiannual report to Congress.[1] There, the OIG reported an uptick in both the number of criminal actions brought in 2019 (809 vs. 764 in 2018[2]) and a significant increase in the expected investigative recoveries ($5.04 billion in 2019 vs. $2.91 billion in 2018).

The DOJ issued several important guidance documents in 2019 that further its goal of increasing transparency into DOJ decision-making and creating some predictability for corporate owners, boards of directors or special committees addressing internal evidence of fraud.

A memo directing prosecutors on how to evaluate corporate compliance programs is intended to reinforce the DOJ’s hope that extending the Foreign Corrupt Practices Act corporate enforcement policy to all types of corporate criminal investigations will lead to corporations devoting substantial resources to compliance, which would lead them to self-report violations, cooperate with the government, and remediate in return for avoiding prosecution.[3]

The DOJ will undoubtedly continue to look for opportunities to publicly demonstrate its willingness to decline prosecutions when a corporation cooperates completely.

Opioids

Insys Therapeutics

The DOJ’s prosecution of the founder and a number of executives of Insys Therapeutics Inc. in federal court in Massachusetts was one of the most closely watched cases in 2019. All five defendants who went to trial were convicted in May, as discussed below.

In June, the DOJ announced a global resolution with the company, settling the criminal and civil investigations of the company's kickback scheme related to its high-dose fentanyl sublingual spray, Subsys.[4]

On the criminal side, the company entered into a five-year deferred prosecution agreement, agreed to pay a $2 million fine and agreed to forfeit $28 million, while the company's operating subsidiary pleaded guilty to five counts of mail fraud.

On the civil side, Insys agreed to pay $195 million to settle allegations of False Claims Act violations, an increase from the handshake deal to pay $150 million the parties had reached in 2018.[5] Within days of its settlement with the government, the company filed for bankruptcy protection.

The DOJ's resolution with the company came on the heels of the convictions of five former Insys executives, which marked the first successful criminal prosecution of top pharmaceutical executives for opioid-related conduct.[6] Insys founder John Kapoor, along with its former national director of sales, two former regional sales directors and a former vice president of managed markets, were all convicted of all counts.

Those counts included a Racketeer Influenced and Corrupt Organizations, or RICO, Act count, about which U.S. District Judge Allison Burroughs of the U.S. District Court for the District of Massachusetts had expressed some skepticism before trial regarding the government's legal theory.

After the convictions, Judge Burroughs vacated the honest services mail and wire fraud and the Controlled Substances Act RICO predicates, ruling that the jury could not have found the required intent given the evidence the government presented, but she also called the defendants' conduct reprehensible.

If the deterrent effect of the Insys prosecutions had not previously been apparent, it surely will be after the upcoming sentencing hearings at which the government will be seeking sentences in the range of five years for cooperating witnesses who pleaded guilty before trial to a range of six to fifteen years for those convicted.

In addition to company executives, prosecutions of individual providers who took kickbacks from Insys in return for writing prescriptions continued in 2019. For example, a New Jersey doctor was indicted for allegedly receiving bribes and kickbacks for prescribing more than 28 million micrograms of Subsys,[7] and a former physician assistant in New Hampshire was convicted and sentenced to 48 months for participating in the Insys scheme.[8]

Purdue Pharma

Continuing the opioid theme, Purdue Pharma LP, the besieged maker of OxyContin (oxycodone hydrochloride), filed for bankruptcy in September and its owners, the Sackler family, have attempted to fend off efforts to pierce the corporate veil by numerous aggrieved parties. The family is reported to have offered to pay $3 billion to resolve thousands of individual suits brought by state and local governments.

Thus far, a consortium of states led by the attorneys general of Massachusetts and New York has refused the offer citing the far higher amount of money the family is reported to have extracted from the company. No criminal charges have been brought against any Purdue executive or member of the Sackler family.

Other Opioid-Related Enforcement

In July, the DOJ announced the largest recovery by the United States in a case concerning an opioid drug.[9] Reckitt Benckiser Group PLC agreed to pay $1.4 billion to resolve its criminal and civil liability related to a federal investigation of the marketing of the opioid addiction treatment drug Suboxone (buprenorphine and naloxone). For many, Suboxone is a highly-valued street drug that is commonly diverted and misused.

In April, the U.S. Attorney's Office for the Southern District of New York brought what it called a "first of its kind" prosecution against one of the largest pharmaceutical distributors in the country and various executives for drug trafficking.[10] The DOJ charged Rochester Drug Co-Operative Inc. and two executives with violating federal narcotics laws by distributing opioids to pharmacy customers that it allegedly knew were being sold and used illicitly.

2019 Takedowns

The annual round up of individual wrongdoers dubbed by the DOJ as the health care fraud takedown was not one dramatically coordinated effort in 2019 but rather several geographic or thematic takedowns. The 11 regional takedowns occurred over the course of April, August and September 2019, and mostly targeted individuals for their roles in diverting opioids as well as in fraud schemes involving telemedicine and unnecessary laboratory testing.

In the 2018 takedown, the DOJ arrested, in one coordinated effort, over 600 individuals including doctors, nurses and other licensed medical professionals across 58 federal districts on a single day,[11] whereas the total number netted in 2019 was reported by the OIG as 482 individuals in separate mini-takedowns.

It is notable, given the DOJ's increased emphasis on and the higher number of individual prosecutions in 2019, that the total number of individuals charged in these takedowns was lower in 2019 compared to the previous year. This decrease perhaps reflects a greater focus on individualized prosecutions rather than the rounding up of groups of defendants as we have seen in prior years.

As part of the takedown in April, the DOJ announced charges against 24 defendants across 17 districts for their role in a $1.2 billion scheme known as Operation Brace Yourself.[12] The government alleged that durable medical equipment companies paid kickbacks and bribes to medical professionals working with telemedicine companies to obtain medically unnecessary orthotic braces. The physicians involved either did not see the patients or had only brief telephonic conversations with them.

The defendants, who included C-suite executives, telemedicine companies, owners of durable medical equipment companies and licensed medical professionals, allegedly lured elderly and disabled patients into the scheme via an international telemarketing network that they controlled. The international call center advertised braces to Medicare beneficiaries and convinced them to accept free or low-cost durable medical equipment braces regardless of medical necessity.

Similarly, the DOJ also pursued genetic testing fraud in 2019, resulting in indictments against 35 individuals across five federal districts for over $2.1 billion in fraudulent claims to Medicare.[13]

The alleged scheme involved genetic testing laboratories' payment of kickbacks and bribes to physicians in exchange for Medicare beneficiary referrals. The physicians who ordered the medically unnecessary genetic cancer testing for Medicare beneficiaries claimed to have treated patients via telemedicine, but they did not meet or see the patients or had only brief telephonic conversations with them. The testing ordered was often not provided to the patients' treating physicians or was not used in the course of treatment.

In the Northeast, the DOJ focused on pill mill clinics that involved more than $800 million in loss to the federal health care programs and the distribution of over 3.25 million opioid pills, for which the DOJ charged 48 people in total.[14] Similarly, in Texas, the DOJ charged 58 individuals for their distribution of 6.2 million opioid pills.[15]

In addition to the DOJ's continued focus on pill mills in rural parts of the country, another takedown in September resulted in charges against 53 individuals in the Midwest alleging $250 million in illegitimate billings,[16] and 34 individuals on the West Coast were charged in fraud schemes involving fraudulent billings for diagnostic testing that was not medically necessary.[17]

Kickbacks and Medical Necessity

As demonstrated by its pursuit of genetic testing and durable medical equipment fraud, as discussed above, the government continued in 2019 to aggressively target schemes involving kickbacks offered or paid to medical professionals as an incentive to order medically unnecessary items or services. Other matters are emblematic of this enforcement trend as well.

For example, in Texas, two physicians were sentenced to over 25 years for their roles in a scheme to defraud Medicare.[18] Evidence presented at trial established that a Houston physician falsely certified medical orders about patients' medical conditions and need for medical services, which his co-conspirator, an owner of a medical clinic, sold to home health agencies.

Co-conspirators at the home health agencies used the fraudulently certified orders to bill Medicare for medical services that were not medically necessary or not provided. The clinic's owner was sentenced to 30 years in prison for her role in the scheme.

Medical Devices

The DOJ also continued to target medical device companies' promotion of unsafe products. Medical device manufacturer ACell Inc. pleaded guilty to one misdemeanor count relating to its powder wound dressing product and agreed to pay $15 million to resolve criminal and civil liability.[19] Pursuant to the plea agreement, ACell admitted that after learning in 2012 that its powder wound dressing was contaminated and posed serious risk to patient health, it removed the device from the market.

However, ACell failed to report the product's market removal to the FDA and concealed the removal from doctors, hospitals and patients, some of which had already used the device. The settlement also resolves civil false claims act allegations that ACell sales representatives were misrepresenting clinical data, making inaccurate coding recommendations, and paying kickbacks to providers through speaker programs and other entertainment.

Factors Present When Cases Go Criminal

As discussed above, the DOJ continued to bring its bread-and-butter cases involving opioids, telemedicine, medical necessity, kickbacks and medical devices in 2019. We continue to note common trends among these cases, such as the DOJ's continued increased focus on prosecuting individuals and the typical factors present where the DOJ brings criminal charges, including when high-level executives or managers directed the misconduct, the conduct involves patient harm or the alleged conduct targeted vulnerable populations.

For example, in October, a Southern California doctor was found guilty for his role in a $12 million scheme to provide medically unnecessary procedures and upcode claims to Medicare, in addition to repackaging used and contaminated catheters for reuse on patients.[20]

In November, three defendants were found guilty of a $154 million health care fraud scheme involving hospice and home health. The defendants allegedly falsely told home health patients they had less than 6 months to live in order to secure their cooperation in certification for (unqualified) hospice benefits.

The DOJ noted the particularly disturbing conduct of the defendants, stating that defendants "preyed on the most vulnerable population — those in need of hospice and home health care — to line their pockets with millions of dollars and engage in lavish spending."[21]

Finally, the DOJ's largest health care fraud case ever charged ended last year in a 20-year prison sentence for defendant Philp Esformes. Esformes, a Florida owner of skilled nursing and assisted living facilities, was found guilty for his role in the $1.3 billion fraud scheme to provide services that were not medically necessary or were procured through the payment of kickbacks.[22]

Esformes' nursing homes housed elderly patients along with younger adults with mental illness and drug addiction — often resulting in harm to the individuals as Esformes "cycled patients through his facilities in poor condition where they received inadequate or unnecessary treatment."

DOJ Guidance

As part of the Department of Justice's Criminal Division's effort the past two years toward enhancing transparency, new policy updates announced by the division include guidance on how prosecutors will evaluate corporate compliance programs and assess corporate "inability to pay claims."[23]

Compliance Programs

With respect to corporate compliance programs, in April the DOJ issued updated guidance that emphasized the importance of implementing corporate compliance programs that are not only well-designed on paper but also effective and appropriately applied in the corporation's day-to-day operations.[24]

While only binding on the Criminal Division, the guidance document is intended to assist prosecutors across the entire agency in evaluating whether a corporation's compliance program was effective at the time of an alleged offense as well as at the time of resolution. The extensive summary of factors contained in the memo provides a road map for corporations to analyze their own compliance programs and tailor their policies to recommendations of the DOJ.

Having an effective compliance program at the time of the alleged offense can be a strong mitigating factor when a prosecutor is evaluating the wrongdoing under the Principles of Federal Prosecution of Business Organizations and determining the appropriate form of resolution, monetary penalty or compliance obligations as part of a negotiated resolution.[25]

Criminal Ability to Pay Analysis

A few months later, in October, Assistant Attorney General Brian Benczkowski issued a memorandum to federal prosecutors with guidance on how to assess a company's ability to pay a criminal fine.[26] The memo provides the framework the DOJ will use in criminal investigations to assess "legitimate inability to pay argument[s]" as well as the "facts and arguments that won't be given credence."

In sum, the guidance directs prosecutors to analyze the following four factors: (1) background on the company's current financial condition; (2) whether alternative sources of capital exist; (3) likely significant adverse collateral consequences if the criminal fine exceeds a company's ability to pay; and (4) whether the proposed fine will impair the company's ability to make restitution to victims.

Moreover, the memorandum requires that a corporation complete an accompanying two-page inability-to-pay questionnaire when making an inability to pay claim to the government.

For years, the DOJ's Civil Division has implemented an inability-to-pay process for resolving civil False Claims Act cases, yet this is the first time that the DOJ has issued guidance in the criminal context.

Although the Civil Division requests standard financial information that overlaps with the Criminal Division's form, the new criminal inability-to-pay provides an extensive list of financial information required by the Criminal Division. This financial form is not similarly standardized on the civil side, with different U.S. Attorneys' offices around the country employing slightly different forms.

What Will 2020 Bring?

We expect the increasingly effective data-driven investigative tools to allow DOJ to continue to identify and prosecute corporations and individuals for all manner of fraud that leads to increased health care costs. Opioid prosecutions will certainly continue, with perhaps additional charges brought against executives deemed responsible for causing or increasing the nation's addiction epidemic. The government also will continue to strictly scrutinize new technologies or novel ways of delivering medical care that are susceptible to fraud and will undoubtedly pursue creative new theories of prosecution.

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