COMMENTARY

THE AMERICAN JOURNAL of MEDICINE®

Health Care Fraud: The Leading Violation of the False Claims Act

It is a sign of the times when the lion's share of the schemes intent on defrauding the federal government are in the health care arena.[1] Data reported by the Department of Justice (DOJ) reveal that 80% of the $11.4 billion recovered over the last 4 years under the False Claims Act (31 U.S.C. §§ 3729 – 3733) involved "health care fraud matters."[1] What has been dubbed "An American Sickness" of the "Medical-Industrial Complex" appears to be alive and well long after the 1980s, during which the corporatization of health care was glamorized.[2] This stark reality makes it all too plain why a single-payer health care system, a staple of much of the industrialized world, is unlikely to materialize in the United States any time soon.[2] Herein we discuss the knowing misuse of taxpayer funds in violation of the False Claims Act, review a sampling of fraudulent health care schemes, and explore ongoing legal concerns as to the prosecution thereof.

The False Claims Act (FCA), a federal statute first enacted in 1863, remains the bulwark against perpetrators of fraud against the US government. Thrice amended, the FCA leads the way in redressing the misappropriation of taxpayer assets. In the context of health care, the FCA is squarely focused on the illegal submission of claims for payment to Medicaid, Medicare, or TRICARE that one knows, or should know, are false or fraudulent. In so doing, the FCA provides a remedy for civil damages when a party 1) makes a false statement or engages in a fraudulent course of conduct that is done with 2) knowledge that was 3) material and 4) caused the government to pay out money or forfeit money it was due. The FCA also establishes a remedy of actual damages according to which health care providers will be required to pay 3 times the amount of reimbursement for each claim that is found to be false. When applicable, criminal charges (18 U.S.C. § 287) can also be brought to bear. Criminal penalties for submitting false health care claims may include imprisonment and the imposition of criminal fines.

In a striking illustration of the reach of the FCA, the DOJ recovered a total of $2 billion from the Reckitt Benckiser Group (Parsippany, NJ; a global consumer goods conglomerate) and Indivior Solutions (North Chesterfield, Va; a specialty pharmaceutical business) for their shared criminal and civil liability in the fraudulent marketing of the opioid addiction treatment drug Suboxone (Buprenorphine).[3] Concurrently, the former chief executive officer of Indivior was sentenced to 6 months in federal prison. As alleged by the DOJ, the 2 companies promoted the sale and use of Suboxone to physicians who were writing prescriptions "for uses that lacked a legitimate medical purpose and to state Medicaid agencies using false and misleading safety claims that Suboxone Film was less susceptible to accidental pediatric exposure than Suboxone Tablets." Further allegations pertained to Indivior's alleged effort to delay the entry of generic competition so as to control the market price of Suboxone. This latter intervention is alleged to have entailed an improper submission of a petition to the US Food and Drug Administration (FDA) claiming that the Suboxone Tablet had been discontinued "due to safety concerns" about pediatric exposure.

In a case involving the Medicaid Drug Rebate Program (42 CFR § 447.509), Mylan N.V. (Canonsburg, Pa) agreed to pay a total of $465 million to resolve allegations of underpayment of rebates to Medicaid for the sale of its EpiPen product (a branded epinephrine auto-injector drug).[4] As per the DOJ, Mylan N.V. knowingly and improperly misclassified its single-source EpiPen product as a generic drug so as to avoid the payment of rebates to Medicaid "even though EpiPen had no FDA-approved therapeutic equivalents and even though Mylan marketed and priced EpiPen as a brand name drug." In so doing, Mylan N.V was allegedly skirting the Medicaid Drug Rebate program, the very purpose of which is to ensure that state Medicaid programs are not "susceptible to price gouging by manufacturers of drugs that were available from only a single source" that is, brand name drugs.

In yet another brazen violation of the FCA, a co-owner of numerous compounding pharmacies and pharmaceutical

Funding: None.

Conflicts of Interest: The authors declare no conflicts of interest.

Authorship: Both authors had access to the data and contributed to writing the manuscript.

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https://doi.org/10.1016/j.amjmed.2021.12.014

distributors who is alleged to have defrauded TRICARE was sentenced to serve 18 years in prison and pay over $344 million in restitution.[5] Between 2012 and 2016, it is alleged that the principals involved orchestrated a scheme to defraud TRICARE and other health care benefit programs by distributing compounded medications that were not medically necessary. In one such case, TRICARE was charged at least 2000% more for drugs than they charged cash-paying customers. The costs incurred by TRICARE for compounded drugs rose from $5 million in 2004 to $1.75 billion in fiscal year 2015. The principals involved also solicited recruiters to procure prescriptions for high-margin compounded medications and paid those recruiters commissions on claims reimbursed by TRICARE. They also solicited (and at times paid kickbacks to) practitioners to authorize prescriptions for high-margin compounded medications.

While the FCA has proven to be a potent tool, a contentious debate swirls around the question of whether the FCA has given prosecutors too much power and should thus be reformed. Some have argued that overenforcement and overcriminalization follow under the act when the government alleges that the health care administered is inefficient, too costly, or unnecessary. This reality has been further exacerbated by the fact that the settlement pressure on those accused is so high as to lead to relatively few trials to test the limits of the government's power.[6] Opponents of the status quo have recommended, among other things, changes to the intent requirement of the statute, alterations to the way damages are calculated, a raising of the standard of proof, and a safe harbor for good faith reliance on erroneous information.[6] There also have been critiques of the willingness of the DOJ to accept settlements in health care fraud cases without the admission of wrongdoing from the defendants.[7] This practice is striking, in part, because in many other contexts, the DOJ encourages prosecutors not to accept criminal pleas wherein the accused maintains his or her innocence.[7] The overriding concern is that the current prosecutorial approach fuels a narrative that paying FCA penalties is merely a cost of doing business rather than a grave breach of the public trust.

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