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HEALTH CARE LAW

Recent False Claims Act prosecutions fall flat

Did previous large settlements in FCA cases result from rampant abuse or government leverage?

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THE FEDERAL False Claims Act (FCA) is the government's primary weapon to enforce its fraud and abuse laws. It empowers the federal government and private citizens (known as relators) to file actions against those alleged to have knowingly submitted false or fraudulent claims to the government. The government, under the statute, can obtain treble damages and civil penalties of up to $11,000 per claim; relators can obtain up to 30% of the government's recovery. 31 U.S.C. 3729-3733.

In 1986, Congress liberalized the FCA to make it easier for both the government and relators to file actions to enforce the statute. According to a Senate Judiciary Committee report, these amendments were animated in part to cure an alleged "resource mismatch" that existed between large corporations (and the large legal teams they could marshal) and the federal government (with its limited supply of troops). S. Rep. No. 99-345, at 8 (1986), reprinted in 1986 U.S.C.C.A.N. 5266, 5273.

Congress' 1986 amendments have resulted in an avalanche of FCA actions and recoveries. For example, by the end of 2003, the U.S. Department of Justice (DOJ) announced that it had recovered more than $12 billion under the FCA since the 1986 amendments. DOJ also stated that in that year it recovered $2.1 billion, with $1.7 billion stemming from health industry FCA cases. See generally http://oig.hhs.gov/fraud/cia/index.html (listing entities under a corporate integrity agreement); see also OIG Supplemental Compliance Program Guidance for Hospitals, 70 Fed. Reg. 4858 (2005).

As a result of these settlements, health care entities have been radically transformed. As a condition of entering into FCA settlements, the government agrees to waive its ability to exclude health care providers from participation in Medicare in exchange for companies' entering into detailed corporate integrity agreements (CIAs). As a result of these CIAs and related regulatory pronouncements, most companies in the health care industry—hospitals, long-term care facilities, research-based pharmaceutical and biotechnology companies, clinical laboratories and even physician practices—have comprehensive compliance programs.

Also, as a result of these settlements, the Department of Health and Human Services Office of Inspector General (OIG) has grown dramatically to police these compliance departments. As DOJ consummated FCA settlements, the OIG lobbied Congress to increase its budget, using the settlement figures as proof that fraud is rampant. As a result, the OIG's budget has grown substantially. This trend is likely to continue because the marginal cost of hiring an additional employee or expanding an office is far less than the projected additional recovery that will result from incurring the cost.

However, as the costs of health care continue to rise, and some are denied care, a question has arisen as to whether it is prudent to divert dollars away from patient care to manage and administer large compliance departments. Moreover, in light of a recent string of losses the government has suffered in prosecuting health care fraud, some have questioned the premise underlying the massive growth of the new compliance industry—that is, that health care fraud by large corporations is rampant. These individuals assert that Congress was simply wrong to believe that there was a "resource mismatch" that resulted in too little law enforcement. Instead, they say, there's a leverage mismatch that results in overenforcement of the fraud and abuse laws.

Too much enforcement?

The issue of whether there is too much or too little enforcement frequently starts with a discussion regarding what precisely has caused the dramatic spike in FCA recoveries since 1986. The conventional wisdom is that the government recoveries themselves are proof of systemic wrongdoing. The argument is that the amended FCA provided a needed tool to unleash DOJ and relators to bring the wrongdoers to justice.

Some defense lawyers, however, have pointed to a different catalyst for the recoveries. Specifically, they assert that the government's recoveries typically reflect not the strength of the government's case but the leverage it possesses based upon its ability to exclude companies from participation in Medicare if they are defeated at trial. Exclusion for many health care providers would be catastrophic since Medicare is frequently a primary source of revenue. As a result, even those FCA defendants possessing substantial litigation resources, or which are confident that they have not violated the act, face terrible consequences in the event that—for whatever reason—they should lose at trial. Settlement becomes not only an attractive alternative, but for most FCA defendants it is the only alternative they can pursue.

Recent evidence from cases the government has lost provides some support for this

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defense view. This is because the best barometer of the strength of the government's case is not the size of its settlements with large corporations—again, these settlements likely reflect the government's leverage given its power to exclude those companies—but whether the government's case succeeds at trial. While corporations typically will not litigate these cases to trial, brave individuals sometimes will because they may not care whether the government ultimately excludes them from participation in Medicare. Recent evidence from these trials demonstrates that while defendant corporations were willing to pay astronomical amounts to resolve the claims, the government could not successfully prosecute a single individual.

One example of this is the government's recent case against hospital operator HCA Inc. There the company ultimately settled a number of FCA claims for more than $1.7 billion without any trial to test the government's case. Yet the government's only successful criminal convictions of two executives—which resulted after two months of trial—were reversed. *U.S. v. Whiteside*, 285 F.3d 1345, 1352-53 (11th Cir. 2002). The 11th U.S. Circuit Court of Appeals concluded that the Medicare regulations in dispute were open to more than one reasonable interpretation and that since the executives' interpretation was reasonable, they could not be convicted under the law. At the end of the day, there were no convictions of executives and no one went to jail.

Another example is the government's prosecution of TAP Pharmaceutical Products Inc. The company paid more than $875 million to settle charges of fraudulent drug pricing and marketing. However, later, when the government prosecuted 11 of TAP's sales executives and managers, they, after a three-month trial, were acquitted of paying kickbacks and defrauding the government to promote the sale of the company products. The judge further threw out the guilty plea of the lone defendant who accepted a plea bargain prior to the trial of the 11 defendants. *U.S. v. MacKenzie*, No. 01-CR-10350 (D. Mass. Sept. 14, 2004).

Further, this trend may continue. Recently, after a four-month trial and testimony by more than 40 witnesses, a district court declared a mistrial in the government's controversial case against a Tenet Healthcare Corp. hospital and its former chief executive officer when the jury was unable to reach a verdict regarding whether the defendants paid kickbacks to area physicians in return for patient referrals. *U.S. v. Weinbaum*, No. 03CR1587-MJL (S.D. Calif.) (mistrial declared Feb. 17, 2005).

Legislative reforms

Cases like HCA and TAP illustrate a question worth serious study: Are the government's recoveries proportionate to the level of wrongdoing or are they simply a manifestation of the government's superior leverage? If it is truly the latter, then in the age of scarce health care resources, those resources are better expended on direct patient care rather than funding a cadre of bureaucrats—both those within companies and those at the OIG.

Indeed, if the government's current losing streak persists and if evidence continues to mount that settlements do not reflect corporate wrongdoing but instead governmental power, Congress might consider various reforms to ensure that allegations of fraud can be fought on a level playing field so that true transgressors of the law may be appropriately punished. Reforms that might be considered include:

Threat of Medicare exclusion forced settlements, they say.

■ *Amendments to the FCA.* Congress first considered amending the FCA in 1998 because of perceived overenforcement of the FCA against health care entities. The legislation, known as the Health Care Claims Guidance Act, was narrowly tailored and designed to make it more difficult for DOJ to assert that minor, technical regulatory breaches constituted FCA violations. For example, Congress proposed amending the statute to require DOJ to prove a violation by "clear and convincing evidence" rather than a "preponderance of the evidence" and to bar DOJ from obtaining a judgment when the amount of alleged damages was immaterial relative to a health care provider's annual claims.

To head off passage of this legislation, DOJ issued the "Holder Guidelines" to DOJ attorneys regarding their use of the FCA. See Memorandum from Eric H. Holder Jr., deputy attorney general (June 3, 1998). Current evidence may tend to demonstrate that the guidelines have not deterred DOJ lawyers from inappropriately threatening FCA liability to leverage weak cases. Consequently, Congress might again consider legislation to amend the FCA to ensure that it is not abused.

■ *Amendments to the exclusion law.* Additionally, Congress might consider amending the exclusion law to ensure that it is not used to leverage a weak case into a substantial settlement. First, to ensure that the scope of exclusion is no broader than necessary to protect program beneficiaries, the exclusion authority could be limited to the particular products or individuals involved in the alleged misconduct rather than be directed against the company as a whole. Such a limitation would prevent the OIG from threatening the exclusion of an entire company based upon the actions of a few individuals or conduct related to a single product line.

Second, to address potential patient harm stemming from the denial of care or disruption in the provision of care, the exclusion law could be amended so that the secretary of health and human services would be required to certify, prior to a provider being excluded, that the exclusion would not have an adverse impact on patient access to health care, and this certification should be subject to administrative and judicial review.

These reforms could dramatically level the playing field in FCA litigation against health care entities. They could guarantee that FCA cases are directed against true misconduct and that exclusion would be tailored against culpable individuals and conduct rather than the company as a whole. These reforms ultimately could ensure that amounts paid reflected the company's misconduct and not merely the government's power. NLJ