

HHS EXPANDED USE OF FRAUD LAW'S “CORPORATE DEATH SENTENCE” IS LEGALLY SUSPECT

by

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Every year the Department of Justice (“DOJ”), with great fanfare, announces its recoveries under the False Claims Act (“FCA”). In December 2002, DOJ issued a press release to trumpet that it has recovered more than \$10 billion under the FCA since the Act was substantially amended in 1986. DOJ stated that in 2002 alone, the government recovered \$1.2 billion with \$980 million stemming from health-related FCA cases.

The amazing fact that remains undisclosed is that substantially all of DOJ’s civil fraud recoveries have stemmed from settlements and not judgments awarded after trial. For example, HCA has settled for more than \$1.7 billion without any trial to test the government’s case. Similar settlements were negotiated with Fresenius (\$375 million) and SmithKline (\$325 million). More recently DOJ has set its sights upon the pharmaceutical industry with TAP Pharmaceutical Products settling for \$560 million in September 2001, Bayer for \$257 million in December 2002, and Pfizer for \$49 million in October 2002.

For those not privy to the inner-workings of DOJ or the HHS Office of Inspector General (“OIG”), or who have not participated in settlement negotiations, it may be a mystery as to why large publicly-traded companies settle highly suspect allegations for hundreds of millions of dollars without ever forcing the government to prove its case. The answer is simple: the government asserts that it will exclude these companies from participation in Medicare and Medicaid, and other government insurance programs, if they are unwilling to pay an exorbitant amount of money. Exclusion for many healthcare providers would be catastrophic since Medicare and Medicaid are frequently a primary source of revenue. As a result, even those FCA defendants possessing substantial litigation resources, or who are confident that they have not violated the

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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 dare pursue.

Besides bureaucratic ambition, there are other reasons DOJ prosecutors and the OIG use the exclusion authority to transform weak fraud cases into multi-million dollar recoveries. Under the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), for example, these agencies can retain a substantial portion of their recoveries to expand their bureaucracies, staff, and power.

Because of the dramatic, leverage enhancing effect threatening exclusion can have during settlement negotiations, and because of the OIG’s direct financial interest in augmenting fraud recoveries under HIPAA, the OIG, in 1998, by regulatory fiat, vastly expanded its own authority to exclude healthcare entities. Historically, the OIG had applied its exclusion authority only against “direct” providers of healthcare, that is, those individuals and entities that bill Medicare and Medicaid for items and services and receive payment. In an abrupt regulatory shift in 1998, the OIG unilaterally determined that it may also exercise its exclusion authority over “indirect” providers, such as research-based pharmaceutical and biotechnology companies. As is set forth below, the OIG’s interpretation is legally dubious, potentially subverts the administration of justice, and may adversely impact patient care.

The OIG’s Exclusion Authority. The Social Security Act authorizes the Secretary of HHS (and through a delegation of authority, the OIG) to “exclude ... individuals and entities from *participation*” in Federal health care programs, such as Medicare and Medicaid. 42 U.S.C. § 1320a-7. Such exclusion *must* be imposed following certain types of criminal conduct (such as a conviction for the submission of a single false healthcare claim) and *may* be imposed when a provider engages in less serious infractions. The statutory term “participation” is a term of art in the Social Security Act, referring to individuals and entities that have entered into an agreement with the Centers for Medicare and Medicaid Services to bill and receive program payment for services furnished to beneficiaries.

Consistent with the meaning of the term “participation,” the OIG, in 1992, stated that it would only apply its exclusion authority against participating providers (*i.e.*, entities that receive payment directly from the program, such as hospitals, skilled nursing facilities, clinical laboratories, and physicians, and employees and agents of those entities). 57 Fed. Reg. 3298. As a result of the OIG’s power to exclude direct healthcare providers and Congress’ 1986 amendments to the FCA, DOJ’s and the OIG’s FCA settlements against direct providers skyrocketed between 1990 and 1997. For example, in fiscal year 1987, DOJ recovered only \$1.5 million in health-related cases. In fiscal year 1997, by contrast, it received \$657 million. From 1994 to 1997 alone, the government recovered more than \$1 billion in health-related civil fraud recoveries.

As a result of these settlements, the OIG learned that the threat of exclusion was a powerful weapon in settlement negotiations. The consequences of exclusion for a direct provider can be devastating. For example, exclusion of a hospital, clinical laboratory, skilled nursing facility, or HMO will choke off its primary source of revenue for a significant period, even if it is later vindicated. For this reason, exclusion is known as the “corporate death sentence” because most providers could not survive exclusion and would be compelled to shut down. Faced with even the threat of exclusion, which can be applied based on a single transgression by a single employee, most companies quickly yield to prosecutors’ offers of civil settlements or plea bargains.

However, during this time period (through 1996), the OIG also stated that it would not exercise its authority to exclude indirect providers, such as research-based pharmaceutical and biotechnology companies, that do not directly receive Medicare or Medicaid payment. Not surprisingly, since the OIG did not assert exclusion authority as to indirect providers, there were no significant health-related FCA recoveries against these providers during this time period.

DOJ and OIG’s Shifting Financial Interest in HIPAA. In 1996, an event totally unrelated to the exclusion law occurred that caused the OIG to reconsider — and substantially broaden — its interpretation of the exclusion law, which resulted in its application to indirect providers. Specifically, Congress passed HIPAA, which established a national Health Care Fraud and Abuse Program under the joint direction of the Attorney

General and the Secretary of HHS, acting through the OIG. Under this Program, DOJ and the OIG can use their civil and criminal fraud recoveries to expand their budgets, staff and authority. For example, HIPAA requires that an amount equaling recoveries from healthcare investigations — including criminal fines, forfeitures, civil settlements and judgments, and administrative penalties, but excluding restitution and compensation to the victim agency — be deposited in the Medicare Trust Fund. HIPAA then appropriates monies from the Medicare Trust Fund in amounts that the Secretary of HHS and the Attorney General jointly certify as necessary to finance anti-fraud activities. See *The Department of Health and Human Services and the Department of Justice Health Care Fraud and Abuse Control Program Annual Report for FY 2001* (Apr. 2002) (describing the process). During fiscal year 2001, DOJ and the OIG certified \$181 million for appropriation to the Account. These resources supplement the direct appropriations to HHS and DOJ that are devoted to health care fraud enforcement, though they provide the sole source of funding for Medicare and Medicaid enforcement by the OIG, which received \$130 million in 2001.

Given this change in law, the OIG promptly determined to reconsider its position regarding whether it should exercise its exclusion authority against indirect providers. Specifically, the OIG set its sight on expanding the scope of its exclusion authority so that it could now ensnare indirect providers within its FCA dragnet and expand its cut of the settlements. Accordingly, even though the OIG had consistently taken the position that its exclusion authority should not extend to indirect providers, in 1997, the OIG abruptly shifted course and found that it was not merely “authorized,” but also was “obligated,” to exclude indirect providers under certain circumstances. 62 Fed. Reg. 47182. Specifically, under the guise of making “technical and conforming” changes to its regulations, the OIG stated that limiting the exclusion authority to participating providers may inappropriately limit the law’s effect.

Because reimbursement would be denied to direct providers who purchased items or supplies from excluded indirect providers, commentators found the OIG’s proposal was unfair and unfeasible. They argued that such exclusion would penalize innocent direct providers who would now bear the brunt of enforcing the exclusion by being denied reimbursement and potentially being subject to FCA prosecution by billing for services from excluded entities. 63 Fed. Reg. 46676. Further, commentators pointed out that this construction could ultimately harm patient care because vulnerable Medicare and Medicaid beneficiaries could be denied needed healthcare services or supplies to treat life-threatening conditions. In response, the OIG stated that it would “entertain a request for waiver of an exclusion, such as, for example, if a convicted pharmaceutical company manufactures the only drug deemed effective to treat a particular disease,” as long as a waiver is requested by a State agency. *Id.* at 46,680. However, telegraphing its true intent and ensuring that its perceived cure to the patient harm concern would be futile, the OIG mandated that its decision to “deny or rescind a request for a waiver” would “not [be] subject to judicial review.” 42 C.F.R. § 1001.1801.

Thus, although lacking in statutory authority, the OIG, by a regulatory sweep of its pen, arrogated to itself a long desired mechanism to apply its enforcement activity against some major players in the healthcare industry (*e.g.* pharmaceutical and biotechnology companies and medical equipment manufacturers), since it was no longer hampered by the inability to apply its ultimate weapon — exclusion. With exclusion as a possible sanction, the OIG can now leverage up weak fraud cases into multi-million dollar recoveries, as its recent FCA settlements reflect. However, in its zeal for this authority, the OIG overlooked one thing — its statutory authority. By promulgating this regulation without statutory authority, the OIG exhibited a willingness to use legally questionable means to achieve its financial goals and expand its bureaucratic authority.

The OIG’s Interpretation Undermines the Administration of Justice and Adversely Impacts Patient Care. Besides being of questionable legality, the OIG’s interpretation undermines the administration of justice. No one doubts that the government should have powerful enforcement tools to punish culpable parties and protect Medicare program beneficiaries, and it does. Volume eighteen of the United States Code is replete with criminal statutes to police and deter unlawful conduct. The civil FCA provides that wrongdoers pay the government treble damages and civil penalties of up to \$11,000 for each false claim. These statutes deter inappropriate conduct and ensure that the government receives appropriate restitution.

The threat of exclusion, however, is frequently not invoked to redress governmental harm or protect program beneficiaries, but to satisfy DOJ’s and the OIG’s budgetary goals. In this sense, prosecutors often are

unfairly using their power to threaten the very existence of entire health care companies through exclusion to coerce exorbitant settlements or guilty pleas without having to test their cases in court.

The unfairness and injustice of the government's approach is most pronounced when the government threatens providers with exclusion when the provider's acts, even under the government's rendition of the facts, involve a single claim, an isolated practice, or a small part of the company's overall operations. Under these circumstances, the government states that it will exclude the provider from Medicare and Medicaid for *any* violation of *any* scope, however aberrational, unless the provider surrenders an exorbitant amount of money. Under these circumstances, companies are effectively denied due process rights to defend at trial because either it must capitulate to the government's outrageous, extortionate demands or risk its existence by betting that it will ultimately prevail at trial. An enforcement system should not require a company to literally bet its life to present a defense.

The OIG's crass use of the exclusion law to fund its operations would not be as problematic if it did not result in patient harm, but it does. Under the OIG's regulations, an indirect provider, such as a pharmaceutical manufacturer, can be excluded based upon a single, isolated act, and thousands of patients can thereby be denied access to potential life-saving and life-enhancing products. Although the OIG provides that redress is possible by a request for a waiver of exclusion, there is no reasonable assurance that the request will ever receive meaningful review because the OIG has refused parties access to court to review its denial of a waiver.

Potential Remedies to Redress the OIG's Overreaching. There are several possible fixes that can be made to redress the OIG's unlawful interpretation of its exclusion authority. The first, and best, fix would be for the OIG to recognize — as historically it did recognize before its financial interest impeded its judgment — that at bottom the exclusion authority is a restriction on the receipt of program payment and, by law, only applies to those that receive program payment. Under this established interpretation of the Social Security Act, the exclusion law would not apply to entities such as research-based pharmaceutical and biotechnology companies that do not receive program payment. Of course, the government can continue to invoke the full range of other criminal, civil, and administrative remedies against these entities.

Even if the OIG does not repeal its unlawful interpretation, there are other potential fixes that can be narrowly tailored to address concerns about the OIG's abusive use of the exclusion authority to extort unfair settlements that are wholly disproportionate to any wrong committed against the government and concerns about potential harm to patient care. First, to ensure that the scope of exclusion is no broader than necessary to protect program beneficiaries, the exclusion authority should be limited to the particular products or individuals involved in the alleged misconduct. 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. This corrective ensures the fair administration of justice because DOJ and the OIG would have to negotiate a settlement based upon the alleged misconduct without having the added leverage of imposing a corporate death sentence if the company does not capitulate to the government's demands.

Second, to address potential patient harm stemming from the denial of care or disruption in the provision of care, the Secretary of HHS should be required to certify, prior to a provider being excluded, that the exclusion would not have an adverse impact on patient access to healthcare. Additionally, unlike the OIG's existing waiver of the exclusion provision mentioned previously, the Secretary's certification should be subject to administrative and judicial review. This requirement would ensure that actual patient care is not harmed as DOJ and the OIG attempt to set new recovery records to bolster their budgets.

Conclusion. In his famous dissent in an FCA Supreme Court case, *United States ex rel. Marcus v. Hess*, Justice Jackson wrote that if government prosecutors could obtain a financial interest by instituting a legal action, "the time might come when the scandals of law-enforcement would exceed the scandals of its violation." 317 U.S. 537, 560 (1943).

Unfortunately, that time may have arrived when OIG conjured up its application of the exclusion law to indirect providers. If HHS is unwilling to rein in OIG's overreaching, it may fall to Congress to act by repealing the OIG's unlawful interpretation of the exclusion law or, at a minimum, reform the law to ensure that it is applied fairly and does not result in harm to patient care.