



MAIN JUSTICE

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KING & SPALDING



Who's Accountable?

New Trends in the Fraud and Abuse Enforcement Process

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Rayburn House Office Building, Capitol Hill

This second forum of the three-part series will discuss the government's more recent theories of fraud and abuse enforcement in the context of the larger debate over the expansion of criminal liability, due process, and whether law enforcers are going beyond their mandates by seeking to regulate conduct of corporations.

There are essentially two types of law enforcement against individuals and companies accused of defrauding government health care programs.

1. Prosecuting individuals who defraud taxpayers by improperly charging Medicare and Medicaid for services that weren't rendered, or medical devices whose prices were inflated. Such criminal actions are generally against small shops guilty of clear fraud for individual gain.
2. Actions against highly regulated large pharmaceutical companies, hospitals and medical device manufacturers that are the backbone of the health care industry, and that are already spending millions of dollars attempting to comply with a complex web of laws. These companies are subject to shifting legal theories or vague or conflicting statutes, raising questions about proportionality of sanctions, prosecutor discretion and how to balance the procedural rights of defendants against the strong public interest in maintaining integrity of public health care programs.

The billions of dollars in fines and settlements the government obtains each year from major health care companies are increasingly viewed as a form of profit claw-back, because these actions aren't seeming to make progress toward the government's stated goal of improving companies' compliance with laws and ethics. After years of aggressive enforcement, the government announces larger and larger recoveries each year, and enforcement actions against major companies are growing, not abating.

What's more, billions of dollars in fines are negotiated every year in conference rooms, away from the scrutiny of judges, juries and the public, because companies cannot risk a day in court – even if they believe their arguments are likely to prevail. The government's leverage is great: It can exclude companies from government contracts – the so-called “death penalty,” – even if the conduct in question involved individual employees acting without the knowledge of manager or executives, and against express corporate policies.

Meanwhile, almost every major pharmaceutical company is operating under a Corporate Integrity Agreement (CIA), imposed by the Health and Human Services Inspector General in exchange for allowing them to continue to do business with federal health care programs.

CIA's impose a detailed list of actions companies must take at the direction of the Inspector General. Industry is increasingly viewing the agreements as a form of back-door regulation that agencies can't or won't impose through the regular and clear issuance of front-door compliance guidance.

Are these companies fundamentally dishonest – looking to cut corners for profits and viewing fines and legal fees as a cost of doing business – or is the real goal of government enforcement something other than fostering compliance with the laws?

Unclear laws, and the increasingly bold discretion of prosecutors to impose back-door regulation on companies through the law enforcement process, drains companies of funds that could be used for research and development or providing care to individuals, and diverts the focus of executives from running their companies to defending themselves from potentially ruinous allegations.

Topics of the October forum will include some or all of the following:

Are fines working? Billions of dollars in fines have been levied against pharmaceutical companies over allegations of fraud in marketing of drugs. But the cases keep coming. If the goal is not simply to rack up big penalties but to ensure compliance with the law and delivery of quality health care and drugs, what is the best way to get there?

Emphasis on individual liability. Regulators and law enforcement have increasingly aimed to hold individuals at companies liable for illegal conduct – even when they don't personally know about the alleged violations. Will individual liability change the corporate culture, or does it hobble companies with fear and uncertainty? To what extent should an individual in a large, complex organization be held liable for the actions of others far removed from his direct supervision and whom he may have never even met?

Debarment. Called the “nuclear option,” the government has the authority to exclude companies found to have committed fraud from participating in federal programs like Medicare and Medicaid. But because debarment – also known as exclusion – could destroy a company and wipe out jobs, the government has generally allowed subsidiaries to enter criminal guilty pleas, protecting the parent companies.

Off-label marketing. Pharmaceutical companies are not allowed to market drugs for uses not approved by the Food and Drug Administration. But because it is legal for a physician to prescribe a drug deemed medically appropriate, even without FDA approval, the question of whether pharmaceutical companies should be barred from communicating with doctors about off-label use has raised First Amendment questions. Industry also sees a lack of clarity between FDA, OIG and DOJ interpretations that create uncertainty about how to comply with the law.

The Affordable Care Act. The new health care law strengthens the HHS OIG's ability to impose civil and monetary penalties for fraud, and authorizes an additional \$350 million for prosecution and investigation. It also eliminates requirements that providers be found to have knowingly and intentionally committed fraud, making it easier to pursue enforcement actions but raising questions about accountability.

Pharmaceutical pricing. HHS OIG guidance in 2003 warned against so-called “marketing the spread” by pharmaceutical companies – the term refers to advertising the potential profit physicians can realize when they prescribe a drug that is reimbursed at a higher amount by the government than its wholesale price. The result over the last decade has been a raft of False Claims Act cases garnering billions in fines and penalties from pharmaceutical companies over pricing strategies.