

The Unintended Consequences of Targeting Health Care Fraud

Contributed by William A. Sarraille, Sidley Austin LLP

At times during the health care debate, Democrats and Republicans only agreed on their zeal to proclaim how much they were committed to intensifying the Government's war on health care fraud. Lost in these moments of rare bipartisanship, however, were the uncounted, but real, costs of the Government's ever increasing focus on health care fraud enforcement.

The Drumbeat to Target Health Care Fraud

It was nearly impossible during the health care debate to find a member of Congress who failed to decry health care fraud and its costs. For many members of Congress (and others) health care fraud enforcement is something of a panacea. In their view, health care fraud enforcement will permit us to avoid what some observers would say is an inevitable day of reckoning, created by unsustainable budget deficits, that will necessitate painful health care program budget cuts. Senator Leahy (D-VT), for example, urged his colleagues to adopt a broad array of new anti-fraud measures because "[e]xperience shows that anti-fraud efforts give taxpayers a superb return on investment, with a payback of between six dollars and fourteen dollars for every dollar spent."¹

From the other side of the aisle, Senator Coburn (R-OK) urged his colleagues to "do the Willie Sutton thing" and "go for where the money is" by focusing on health care fraud.² For those of you who may not recall Sutton, he was a Depression era bank robber who, when asked why he robbed banks, said he did so "because that's where the money is." The remark left many within the health care industry with their tongues wagging, because industry believes that overly-aggressive law enforcement sometimes leads to demands for large settlements for conduct that is lawful.

In any event, Congress clearly delivered on its promise to increase the focus on health care fraud and abuse in passing health care reform. The laws passed by Congress include some of the most important and extensive changes in health care fraud and abuse control ever enacted. At the core of the new provisions is a commitment to additional funding each fiscal year for health care enforcement, beginning with \$105 million in 2011.³

To be clear and fair, the federal government has been enormously effective in its enforcement efforts. With a focus primarily on pharmaceutical companies and,

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increasingly, device companies, the Government has a long list of "wins" to which it can point. Two settlements this year, one involving Lilly and the other Pfizer, brought "recoveries" of more than 1 billion dollars and then, shortly thereafter, more than 2 billion dollars.⁴ Increasingly, we are seeing settlements between \$200 and \$400 million dollars.

Unintended Consequences and Uncounted Costs

But, despite the Government's accomplishments, the focus on enforcement has real and uncounted costs.

Lurking behind the increasing focus on law enforcement is the notion that we can avoid or, at least, significantly reduce the need to make tough choices to control health care costs by increasing health care fraud enforcement recoveries. With health care reform bringing the Government more and more responsibility for health care expenditures, the notion that we can meaningfully delay or avoid significant budget cuts in the not too distant future seems, frankly, a pipe dream. And if the focus on health care fraud and abuse keeps policy-makers and the public from addressing the difficult decisions that we must address, then that is a significant problem.

Regulating an industry as complex as health care through Government investigations and prosecutions is a remarkably inefficient and, ultimately, counter-productive exercise. All too often, the Government's law enforcement efforts pick at areas where regulation has been inadequate, unclear, or contradictory.

For example, a major area of concentration for law enforcement has been the issue of off-label promotion of drugs and devices. A complex set of statutory and regulatory provisions governs the off-label promotion of drug and device products.⁵ Under the Government's view of the law, a company may not promote a drug or device product for a particular use that has not been approved for that use by the Food and Drug Administration (FDA). This is true even though a physician may lawfully prescribe a product for a use that is not approved by the FDA and even though the federal and state governments routinely reimburse providers for unapproved or "off-label" uses under the Medicare, Medicaid, and other federal health care programs. Interestingly, the FDA's interpretation of the prohibition on off-label promotion is now the subject of a lawsuit brought by a manufacturer.

Regulation through Investigations and Prosecutions

In essence, many within health care complain that the Government is effectively regulating industry through investigations and prosecutions, instead of issuing regulations that clearly set out what is and is not permitted. Where regulations can only be issued with the benefit of notice and an opportunity for public comment and involve a careful consideration of the benefits and costs associated with a proposed regulatory standard, that kind of thoughtful process is nowhere present in the rough and tumble world of health care enforcement, where companies often cannot fight the Government, because the effects of losing a case, even if small, are too great to risk. There are a number of problems with this approach, and the public should be just as concerned about the unintended consequences of this policy as the health care industry is.

One issue is that, because it takes years to investigate and bring an investigation to completion, the only "regulation" that comes out of a law enforcement process is necessarily dated, coming years after the program or activity that gives rise to the case. This inevitably means that the Government is slower than it could and should be in specifically addressing conduct that it believes to be inappropriate. Rather than focus on an enforcement-oriented approach that operates on the "gotcha" principle, the Government would be more effective in achieving its policy goals if it would place a greater emphasis on issuing regulations and guidance in a timely fashion that is clear and consistent.

Indeed, regulatory agencies are noticeably chilled as soon as an issue becomes the subject of an investigation or prosecution. In candid moments, regulators concede that they are unlikely to regulate an area once it becomes the focus of a case, out of a concern that they may undermine the Government's enforcement position or that they may be criticized by their law enforcement colleagues and Congress if they express a different or more nuanced view.

Another problem is that investigations and prosecutions typically focus on individual companies, and not on the industry as a whole. Without a clear industry-wide regulatory standard, different companies respond differently to a settlement or other resolution of a case. The less risk tolerant a company is the more likely it is to change its conduct in response to law enforcement action taken against another company. Conversely, more risk tolerant companies cling to more aggressive programs in the absence of clear regulatory guidance, even in the face of a government investigation or case against a competitor. This means that the focus on law enforcement has a differential impact on companies that are more or less willing to take risk. Paradoxically, then, the emphasis on law enforcement "solutions" to perceived abuses actually is sometimes less effective than clear regulation in altering conduct the Government contends is problematic.

Government officials sometimes respond to this critique by saying, rather ominously, "just wait, we'll get to those other companies in time." But that is an unsatisfying answer, both because the Government's resources, though enormous, are not unlimited and because, even if the Government "gets" to all other companies that are engaged in similar conduct, more risk tolerant companies will act differently than less risk adverse companies in the interim, potentially distorting the marketplace.

Further, although there is little data available to quantify this cost, ambiguous standards coupled with the threat of criminal prosecutions or large civil settlements force even the most compliant company to devote enormous resources into compliance programs and systems that drive up the cost of health care. Clear regulatory standards consistently articulated would permit the health care industry to achieve a higher level of compliance and at a markedly lower level of cost, allowing significant savings to be passed on to payors, like the Government, and consumers.

So, the next time you hear a politician talk about how we can meaningfully control health care costs by intensifying health care enforcement efforts, remember the uncounted costs. If it were only that easy to solve spiraling health care costs, we would have controlled those costs long ago. The drum beat for intensified health care enforcement is a siren's song.

William A. Sarraille is a partner in Sidley's Washington, D.C. office. He concentrates on a variety of healthcare matters, including the defense of False Claims Act cases, Medicare and Medicaid reimbursement, coverage and coding, pharmaceutical price reporting, issues related to the marketing and promotion of pharmaceuticals and medical devices, internal investigations, clinical research issues, healthcare acquisitions and due diligence, compliance program audits, legislative matters, the Foreign Corrupt Practices Act, international compliance and healthcare contracting, and the representation of witnesses and companies before Congressional Committees.

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¹ Statement of Senator Patrick Leahy on the Motion to Proceed to H.R. 3590, the "Patient Protection and Affordable Care Act" (Nov. 21, 2009), *available at* http://leahy.senate.gov/press/press_releases/release/?id=62ef39d7-76f2-4621-b7b8-f1d959433ef3 (last accessed Apr. 21, 2010).

² Discussion on Cost Containment at Bipartisan Meeting on Health Care Reform (Feb. 25, 2010), *available at* <http://www.whitehouse.gov/the-press-office/discussion-cost-containment-bipartisan-meeting-health-care-reform> (last accessed Apr. 21, 2010).

³ Patient Protection and Affordable Care Act, H.R. 3590, Pub. L. No. 111-149, § 6402(i) (enacted March 23, 2010); Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, § 1303(a) (enacted March 30, 2010).

⁴ See U.S. Department of Justice, Justice Department Announces Largest Health Care Fraud Settlement in its History: Pfizer to Pay \$2.3 Billion for Fraudulent Marketing (Sept. 2, 2009), *available at* <http://www.justice.gov/usao/ma/Press%20Office%20-%20Press%20Release%20Files/Sept2009/Pfizer.html> (last accessed Apr. 21, 2010) and U.S. Department of Justice, Eli Lilly and Company Agrees to Pay \$1.415 Billion to Resolve Allegations of Off-label Promotion of Zyprexa (Jan. 15, 2009), *available at* <http://www.justice.gov/opa/pr/2009/January/09-civ-038.html> (last accessed Apr. 21, 2010).

⁵ See, e.g., 21 U.S.C. §§ 331(a), 352(a) and (f)(1), 355(a) and 21 C.F.R. § 201.128.