Punishing Health Care Fraud — Is the GSK Settlement Sufficient?

Kevin Outterson, J.D., LL.M.
N Engl J Med 2012; 367:1082-1085September 20, 2012DOI: 10.1056/NEJMp1209249

Interview with Prof. Kevin Outterson on record-breaking settlements of pharmaceutical fraud cases and the need for further regulation. (14:05)

On July 2, 2012, the Department of Justice announced the largest settlement ever in a case of health care fraud in the United States. GlaxoSmithKline (GSK) agreed to plead guilty to three criminal counts and settle civil charges brought under various federal statutes; the company will pay a total of $3 billion to the federal government and participating states. Since 2009, the federal government has collected more than $11 billion in such settlements under the False Claims Act.

In the Federal District Court in Boston a few days later, GSK pleaded guilty to two criminal counts for sales of misbranded Paxil (paroxetine) and Wellbutrin (bupropion). These drugs are considered misbranded when they are promoted for indications for which they have not been approved by the Food and Drug Administration — the practice commonly known as off-label promotion. Providers cannot be reimbursed for misbranded drugs under federal and state rules. GSK also pleaded guilty to a third crime, failing to report safety data related to Avandia (rosiglitazone). Failing to report safety data violates the Food, Drug, and Cosmetic Act and leads to serious questions about whether clinicians are basing their decisions on the best evidence. GSK also settled related civil liabilities for these and other drugs.

Despite the size of the fine and civil settlements, it would be a mistake to assume that GSK was an outlier in the global pharmaceutical and medical-device industries. Indeed, many of the major companies have settled with the Department of Justice in recent years (see Table 1

TABLE 1

Largest Pharmaceutical-Company Settlements with the U.S. Government, 2009–Present.

). When the GSK settlement was announced, 25 major companies and 8 of the top 10 global pharmaceutical companies were under “corporate integrity agreements” (see Table 2)

TABLE 2

Corporate Integrity Agreements in Force with Pharmaceutical and Medical-Device Companies, as of July 2, 2012.).

Corporate integrity agreements, now a routine part of settlements for health care fraud, typically require enhanced compliance activities within the company for 5 years, including reports to the government from an independent monitor.

But questions remain about the efficacy of fines and corporate integrity agreements in deterring corporate misbehavior. The 2012 fines against Abbott Laboratories and GSK represent a modest percentage of those companies' revenue.1 Companies might well view such fines as merely a cost of doing business — a quite small percentage of their global revenue and often a manageable percentage of the revenue received from the particular product under scrutiny. If so, little has been done to change the system; the government merely recoups a portion of the financial fruit of firms' past misdeeds.

One partial solution would be to impose penalties on corporate executives rather than just the company as a whole. Boston whistleblower attorney Robert M. Thomas, Jr., embraces this approach: “GSK is a recidivist. How can a company commit a $1 billion crime and no individual is held responsible?”

The GSK corporate integrity agreement does include some provisions that attempt to change corporate culture. First, GSK must revise its compensation systems to “ensure that financial incentives do not inappropriately motivate” sales representatives; these changes include new restrictions on compensation for off-label promotion. GSK has now implemented a program to eliminate incentive-based compensation for sales representatives based on “territory/individual level sales goals,” which will alter the financial incentives for sales representatives who

meet with physicians. Second, GSK senior executives and other employees who are paid bonuses and other compensation may in the future be asked to repay those amounts if certain types of fraudulent behavior occur that violate the corporate integrity agreement. As has been noted in the financial press, this requirement does nothing to recoup several substantial recent bonuses given to senior management at such firms,[2] but it does make it more difficult to repeat the practice, at least at GSK. Third, in view of the serious questions about failure to report negative data related to Avandia's safety, GSK must commit itself to “research and publication practices” designed to make more clinical trial information available to clinicians and regulators. These commitments have several disturbing exceptions: GSK will “generally” seek publication for research results, and summaries of clinical trial data will be posted on a clinical study register “with rare exception.” These are but partial steps toward transparency.

These measures can certainly be improved. For one thing, though all these provisions seem advisable, they are imposed only under a corporate integrity agreement, as opposed to official regulations, and expire in 5 years. Legislative reformers should consider whether the entire industry should be regulated on a level playing field, as opposed to through piecemeal agreements. In addition, individuals must be held responsible in appropriate circumstances. Models might include federal tax law, under which directors and officers of nonprofit corporations cannot be indemnified against fines imposed on them as individuals for particularly egregious violations.[3] Key leaders can also be excluded from participation in federal health programs. The academic researchers involved in the controversy regarding the safety data for Avandia has thus far escaped sanctions as well.[4]

If the corporate fines are too small, the False Claims Act will need to be amended so that a higher percentage of the revenues derived from fraudulent activities is recouped. At the same time, federal law must insist on greater transparency for clinical trial results, so that negative safety data are not hidden from clinicians and regulators.

Finally, these types of fraud are hard to detect from the outside. Internal documents are often critical to these cases. Most of the time, these documents are provided by internal whistleblowers. In a recent survey, researchers identified several ways in which the whistleblower provisions of the False Claims Act could be strengthened to encourage whistleblowers to come forward and to protect them from retaliation.[5] Whistleblowers should be encouraged, not punished for their testimony.

Disclosure forms provided by the author are available with the full text of this article at NEJM.org.

This article was published on September 12, 2012, at NEJM.org.

SOURCE INFORMATION: From Boston University School of Law, Boston.