

## Commentary

### **Time to Rein in the False Claims Act**

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The federal False Claims Act (FCA) has long been recognized as a full employment act for plaintiffs' lawyers. The game is to encourage fired employees to pose as "whistleblowers," reporting to the federal government on their former employees' alleged wrongdoing.

They file suit in the name of the United States as "private attorneys general," and then demand a 30 percent cut of whatever the employer pays in settlement to make the case go away. In the process, the good names of reputable companies and executives get smeared, with little opportunity to rebut the often baseless charges.

This is not to say that whistleblower claims are never meritorious or that companies never submit false claims to the federal government. But truly fraudulent conduct would eventually be exposed even if we significantly reduced the current incentives for whistleblowers to come forward.

What the current set of incentives does is encourage "whistleblowers" to report not only genuine wrongdoing but also every policy disagreement, and even wholly praiseworthy conduct by those who have crossed swords with the whistleblower. Such an irrational set of incentives creates enormous unwarranted costs and deprives consumers of optimal services in such fields as health care.

The absurdity of this FCA process has reached new heights with the case of Peter Rost, a former drug executive at Pharmacia and Pfizer who was fired last year. While at Pharmacia, he played a leading role in the marketing of Genotropin, a synthetic human growth hormone.

His lawyers now claim - in a suit pending in Boston - that Pharmacia improperly promoted the sale of Genotropin and that this promotion somehow defrauded the federal government.

Although Pharmacia never sought any payment from the federal government in connection with the sale of Genotropin, Rost's lawyers claim that Pharmacia violated the FCA by inducing others (e.g., doctors) to present the federal Medicaid program with "false" claims for payment.

The suit does not assert that the doctors failed to administer Genotropin to their patients, mind you; rather, it asserts that the doctors' claims for reimbursement were "false" because they administered Genotropin for a use that has not been approved by the Food and Drug Administration (i.e., an "off-label" use).

There is a major problem with this theory: there is nothing "false" about making a claim for reimbursement for a drug administered by a doctor for an off-label use. Indeed, a significant percentage of all drug prescriptions are for off-label uses, and in many fields doctors would be guilty of malpractice

if they did not prescribe drugs for such uses.

My organization, the **Washington Legal Foundation**, recently won litigation against FDA that upheld the First Amendment right of manufacturers to disseminate truthful off-label information about their products.

Moreover, even if a quack doctor decides to seek federal reimbursement for an off-label use that is so far outside the mainstream that it is not properly reimbursable, a manufacturer cannot be said to have "caused" the reimbursement claim to be presented simply because it is aware that such claims are being made.

To date, no evidence has been produced suggesting either that any false claims were made regarding the sale of Genotropin, or that Pharmacia or Pfizer (which acquired Pharmacia in 2003) ever induced doctors to make such claims.

The federal government has decided to take a pass on the suit Rost filed in the government's name. Undeterred, his attorneys continue to litigate the case. If they can force a settlement, they stand to recover substantial fees. They now face a motion to dismiss because, the evidence suggests, Pfizer fully informed the federal government regarding Genotropin marketing practices before the suit was filed - meaning that Rost was not blowing the whistle on anybody.

So now the case is being tried in the press, and the name of a respected pharmaceutical executive is being dragged into the process. In an effort to demonstrate that Pharmacia executives were encouraging doctors to prescribe Genotropin for off-label uses, Rost's lawyers appear to have encouraged widespread dissemination of internal Pharmacia documents to Business Week and other news media.

One such memo, dutifully reported by Business Week last month, indicates that a Florida doctor in 2000 wrote to Pharmacia's then-CEO, Fred Hassan, encouraging Pharmacia to enter into a "strategic alliance" with him to market Genotropin for an off-label use.

Hassan wrote "follow up" on the memo and passed it along to other executives. Based on that cryptic note, it's insinuated that Hassan in some fashion may have encouraged efforts to market Genotropin improperly.

Hassan is now head of Schering Plough, another pharmaceutical company not involved in the marketing of Genotropin. A confidentiality agreement with Pfizer prevents him from commenting directly. But executives who worked with Hassan at Pharmacia state that it is absurd to suggest that he did more than glance at and pass along the letter from 2000 or any of the numerous letters sent to him by doctors who prescribed Pharmacia's products.

And they point out that it is in fact a demonstration of Hassan's good practice as a top executive to insist that all external correspondence get a follow-up and acknowledgment.

So this is what the FCA has come to. It is a law with significant unintended consequences, providing plaintiffs' lawyers with a large incentive to pursue litigation at all costs in hopes of snaring a massive contingency fee award. It requires companies to incur huge expenses to defend against often baseless charges - expenses that inevitably get passed on to consumers in the form of higher prices. It encourages efforts to pull in as many managers in an organization as possible, despite the toll this can take on the reputations of innocent people. Its bounty provision gives employees a huge financial incentive to pursue those claims, even when the employees have not suffered any injury.

Companies are often forced to settle insubstantial claims to avoid incurring even further litigation expenses and to avoid the negative publicity that arises every time the baseless charges are repeated.

It is time for the courts to put a stop to such abuse. When Congress adopted the FCA, its intent was to prevent criminals from defrauding the federal government, not to permit spurious use of the courts and the press in hopes of financial gain. The financial incentives to bring baseless suits can be significantly reduced with little danger that whistleblowers would be deterred from coming forward to report genuine wrongdoing.

*(Richard Samp is chief counsel of the Washington Legal Foundation. He served as lead counsel for WLF in Washington Legal Foundation v. Friedman, a federal suit that established the First Amendment right to disseminate truthful information about off-label uses of FDA-approved products.)*

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