

## SPECIAL REPORT

## Whistle-Blowers' Experiences in Fraud Litigation against Pharmaceutical Companies

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Prosecution and prevention of health care fraud and abuse are essential to reducing U.S. health care spending.<sup>1-3</sup> A number of recent high-profile cases have uncovered suspect business practices and led to substantial recoveries; in September 2009, for example, Pfizer paid \$2.3 billion to settle allegations that it marketed its drugs illegally to physicians, leading to unnecessary payments by the government.<sup>4</sup>

Currently, 90% of health care fraud cases are “qui tam” actions in which whistle-blowers with direct knowledge of the alleged fraud initiate the litigation on behalf of the government.<sup>5</sup> Qui tam derives from the Latin phrase *qui tam pro domino rege quam pro se ipso in hac parte sequitur*, meaning “who as well for the king as for himself sues in this matter.” If a qui tam action leads to a financial recovery, the whistle-blower stands to collect a portion of the award. From 1996 through 2005, qui tam actions led to more than \$9 billion in recoveries.<sup>6</sup> Although such actions are touted as cost-effective<sup>7</sup> and may deter inappropriate behavior,<sup>8</sup> little is known about how well the qui tam process works.

From their vantage point at the center of the process, whistle-blowers have valuable insights. Popular portrayals of whistle-blowers vary widely: some anecdotes paint them as heroes struggling against corporate greed, emphasizing the hardships and retaliation they must endure; other accounts question their motives and the “excessive” rewards they receive.<sup>9-14</sup>

The goal of this study is to shed light on the motivations and experiences of whistle-blowers in cases of major health care fraud. We conducted interviews with whistle-blowers who were key informants in recent prosecutions brought against pharmaceutical manufacturers. Enforcement actions against pharmaceutical manufacturers have become the most lucrative type of health care

fraud litigation on the basis of recovery amounts (average and gross).<sup>6,15,16</sup>

### STUDY METHODS

Officials in the Civil Division of the U.S. Department of Justice helped us identify 17 federal qui tam cases against pharmaceutical manufacturers settled between January 2001 and March 2009 (Table 1). Using the unsealed complaints and settlement agreements, as well as direct approaches to attorneys involved in the litigation, we identified 42 whistle-blowers involved in these cases. We conducted individual, semistructured interviews with 26 (62%) of them. The interviews had a median duration of 40 minutes (interquartile range, 31 to 49) and addressed the whistle-blowers' motivations and experiences. We analyzed the interview transcripts using the constant comparative method of qualitative analysis.<sup>17,18</sup> A detailed description of the study methods is provided in the Supplementary Appendix, available with the full text of this article at NEJM.org.

### OVERVIEW OF THE QUI TAM LITIGATION PROCESS

The federal False Claims Act (FCA) prohibits the submission of false claims or statements to the government. Violators face fines of \$5,500 to \$11,000 per claim, plus treble damages. Whistle-blowers (referred to as relators) can initiate cases by filing a sealed complaint in federal court, nearly always with the help of a personal attorney. In our sample, 22 (85%) were employees of the defendant company (insiders), including 9 at the executive or midmanagerial level and 13 lower-level employees.

The Justice Department then investigates the allegations, often in conjunction with other in-

**Table 1. Whistle-Blower–Initiated Federal Pharmaceutical Fraud Cases Settled between January 2001 and March 2009.**

Company and Year	Settlement (millions of \$)	Drug	Summary of Alleged Improper Conduct
TAP, 2001	875	Lupron	Inflated government reimbursement for prescription of its drug by reporting average wholesale price as significantly higher than the average sales price
Warner-Lambert, 2003	49	Lipitor and others	Violated best-price rules by offering rebates to private insurers*; gave kickbacks to private insurers for favoring drug on formularies
AstraZeneca, 2003	335	Zoladex	Inflated government reimbursement for prescription of its drug by reporting average wholesale price as significantly higher than the average sales price
Bayer, 2003	257	Cipro and Adalat CC	Sold relabeled drugs to private payers at discounted prices and then concealed this information to avoid obligation to pay such rebates to the government
Warner-Lambert, 2004	430	Neurontin	Aggressively marketed drug for off-label indications; gave kickbacks to high-prescribing physicians; made false statements about safety
Schering-Plough, 2004	346	Claritin	Offered underpriced and free goods and services to private sector that it did not offer to government programs
GlaxoSmithKline, 2005	150	Zofran and Kytril	Inflated government reimbursement for prescription of its drug by reporting average wholesale price as significantly higher than the average sales price
Serono, 2005	704	Serostim	Paid kickbacks to induce prescribing and falsified bioelectrical impedance analysis test results to make patients appear to be candidates for drug
King, 2005	124	Altace, Levoxyl, and others	Submitted inaccurate price data to the government, resulting in rebate amounts on its drug products that were lower than they should have been
InterMune, 2006	17	Actimmune	Conducted off-label marketing, including making false statements about drug efficacy to induce prescription writing and creating a "safety registry" to facilitate off-label sales
Bristol-Myers Squibb, 2007	515	Pravachol, Glucophage, and others	Conducted off-label marketing, including using misleading reprints and other sources, inducing prescription writing by offering rebates and gifts to off-label prescribing physicians, and holding continuing medical education meetings to induce writing of unapproved prescriptions
Cell Therapeutics, 2007	11	Trisenox	Conducted off-label marketing, including suppression of data about a dangerous side effect (acute promyelocytic leukemia differentiation syndrome) and manipulation of efficacy studies
Orphan Medical, 2007	20	Xyrem	Conducted off-label marketing, including organizing continuing medical education events with speakers describing unapproved uses of the drug and teaching physicians to falsify billing codes
Medicis, 2007	10	Loprox	Conducted off-label marketing of an antifungal cream, approved for use in adults, for the treatment of diaper rash in children; misrepresented safety data
Merck, 2008	650	Vioxx and Pepcid	Failed to pay proper rebates to government programs and paid providers to induce prescriptions through payments for training, consultation, or research
Cephalon, 2008	425	Provigil, Gabitril, and Actiq	Conducted off-label marketing, including active help in securing government reimbursement for prescriptions for unapproved uses
Eli Lilly, 2009	1,400	Zyprexa and others	Conducted off-label marketing to children and to elderly patients in long-term care facilities; failed to provide information about drugs' side effects

\* Best-price rules state that Medicaid must be granted the lowest price for drugs offered to any private purchaser.

terested agencies. If the evidence supports the allegations, the Justice Department may elect to intervene and take the lead in the enforcement

action. When multiple parties file complaints about the same activity, the first to file is assigned the role of the "lead relator," but other relators

who provide useful evidence may be included. Almost all cases in which the Justice Department intervenes result in judgments against or settlements with the defendant. For the relators in our sample, cases took an average of 4.9 years (range, 1 to 9) from filing to closure.

Under the FCA, relators are eligible to receive 15 to 25% of the recovery. The total relator share is set by the government and then divided among relators. The recovery may be withheld if the relator was involved in generating the allegedly fraudulent activity. After attorney's fees and taxes, 5 of the relators in our sample received less than \$1 million in financial recoveries from their case, 13 received between \$1 million and \$5 million, and 7 received more than \$5 million (1 relator did not provide net estimates).

If the government decides not to intervene, the case may remain sealed and is often dismissed. Whistle-blowers may press forward alone (and earn up to 30% of any recovery), but in practice, solo actions rarely result in substantial recoveries.

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#### RELATORS' ACCOUNTS OF THE EXPERIENCE

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##### DISCOVERY OF AND INITIAL REACTIONS TO THE ALLEGED FRAUD

The relators we interviewed became aware of the troubling corporate behavior in a variety of ways. Whereas all 4 of the "outsiders" came across it in their normal course of business, the triggering event for most (16 of 22) insiders was a career change — starting at a new company (10 of 16) or being promoted to a new position (6 of 16). Changes in the business environment, such as increased competition or new management after a corporate takeover or merger, also contributed to bringing the alleged fraud to relators' attention. One relator described a time when her employer's highest-earning product faced generic competition: "It wasn't until there were extreme competitive pressures and negative effects on earnings that the company's marketing practices became much more aggressive" (Relator 14).

Initially, a large proportion (11 of 26) of the relators refused to participate in the corporate actions that led to the suit. Insiders who took this course reported that their job performances began lagging relative to that of their peers, whose sales were enhanced by the marketing schemes. Nearly all (18 of 22) insiders first tried to fix

matters internally by talking to their superiors, filing an internal complaint, or both. One explained: "At first it was to the head of my department, the national sales director, and the national marketing director. . . . After being shooed aside, I went to the executive vice president over all the divisions of sales and marketing. Then eventually I went to the CEO of the company, the chief medical officer, and the president" (Relator 7). Insiders who voiced concerns were met with assertions that the proposed behavior was legal (4 of 22) and dismissals of their complaints, with accompanying demands that the relators do what they were told (12 of 22).

##### MOTIVATIONS

Although the relators in this sample all ended up using the qui tam mechanism, only six specifically intended to do so. The others fell into the qui tam process after seeking lawyers for other reasons (e.g., unfair employment practices) or after being encouraged to file suit by family or friends. Every relator we interviewed stated that the financial bounty offered under the federal statute had not motivated their participation in the qui tam lawsuit. Reported motivations coalesced around four non-mutually exclusive themes: integrity, altruism or public safety, justice, and self-preservation (Table 2).

The most common of the themes, integrity (11 of 26 relators), was linked by some relators to their individual personality traits and strong ethical standards. One relator reasoned, "When I lodged my initial complaint with the company, I believed what we were doing was unethical and only technically illegal. This ethical transgression drove my decision. My peers could live with the implications of 'doing 60 in a 55 mph zone' because it did indeed seem trivial. However, my personal betrayal . . . so filled me with shame that I could not live with this seemingly trivial violation" (Relator 25). The relators in this group felt that financial circumstances helped to subvert such ethical standards in their colleagues, saying that most colleagues were unwilling for personal or family reasons to jeopardize their jobs.

A slightly less common theme (7 of 26 relators) involved trying to prevent the fraudulent behavior from posing risks to public health. Most of the relators who described this type of motivation felt they had unique professional experiences

**Table 2. Primary Motivations for Initiating Qui Tam Lawsuit.**

Motivation*	Illustrative Remark
Self-preservation (reported by 5 relators)	<p>"If these guys go down I'm not going to be the one that gets blamed for all of this." (Relator 5)</p> <p>"Then in the end they were pushing me to break some more laws. I had just said, 'I'm putting my foot down. I'm being excluded from meetings. They're making decisions that I'm going to do things that are illegal.' So I felt like they were just trying to set me up." (Relator 6)</p> <p>"I thought, 'I'm involved in something that's illegal. This is dangerous to people. . . . Maybe I'm — am I going to get arrested?'" (Relator 11)</p>
Justice (reported by 7 relators)	<p>"[I] was proud to be involved in it because we thought we were on the right side of justice here . . . this was an illegal activity that needed to be reported." (Relator 2)</p> <p>"Shame on them. They should be held accountable for the way they treat people. They should be held accountable for their illegal and unethical behavior." (Relator 12)</p> <p>"I think it's our responsibility. It's our duty. It's not an act of heroism. It's not an act of bravery. It's an act of responsibility." (Relator 24)</p>
Integrity (reported by 11 relators)	<p>"This doesn't just hurt patients and physicians and give industry a bad name. This hurts everybody, whether you're a shareholder [or] a retiree with a pension from them. Everybody's taking a whack on this." (Relator 4)</p> <p>"It was just something that I knew was wrong. I needed to correct it." (Relator 15)</p> <p>"This is not right. We have laws to protect people from this, to protect the public from this . . . so I needed to stand up for my rights not only for every other person in this company but for my young daughters coming after me starting careers." (Relator 22)</p> <p>"I was angry they were trying to get me to do something wrong." (Relator 23)</p>
Altruism or public safety (reported by 7 relators)	<p>"I've got autopsy reports. I've got multiple physician confirmations. I've got the chief medical officer who sent me an email saying, 'Yes. [The side effect] is occurring.' . . . Then they demoted me? I knew there was a problem. That's when I decided to go down that road." (Relator 7)</p> <p>"I think if it had been a drug that was like a cream for diaper rash or something like that I don't know that I would've been so idealistic and bold and brave. . . . I don't think I've got that great of character to be honest with you. But I think this drug kind of scared me. I didn't want to be responsible for somebody dying." (Relator 11)</p> <p>"This was really asking programs designed for the poorest among us to underwrite a company whose profit rates were pushing 20%. The whole deal was being subsidized by programs for the poor." (Relator 16)</p>

\* Some relators identified with more than one source of motivation.

or educational backgrounds that gave them a superior grasp of the negative public health implications of the illegal conduct. Some relators (7 of 26) characterized their action in reporting the fraud as emanating from a sense of duty to bring criminals to justice. Many of these relators were new employees who perceived themselves as being outside the fold in their companies.

Finally, several relators (5 of 26) reported fears that the fraudulent behavior would be discovered and would result in legal consequences for them; therefore, blowing the whistle was a way to protect themselves.

## THE INVESTIGATION

Whistle-blowers reported sharing several common experiences during the investigation phase of the litigation. First, most (15 of 26 relators, 14 of 22 insiders) became active players in the investigation. Their involvement included wearing a personal recording device at face-to-face meetings or national conferences, taping phone conversations with colleagues, and copying requested documents or files. In addition, after the Justice Department officially joined the case and began to obtain internal company documents by subpoena, relators were asked to work closely with de-

partment representatives to explain the evidence being gathered and help build the case.

Second, the workload and pressure were perceived as intense. One relator estimated spending “thousands of hours” on the case over its 5-year duration (Relator 17); another spent “probably 30 hours a week” during the first few years. Some meetings took place at Justice Department offices, with relators traveling at their own expense; others occurred unnervingly close to home. One reported that “a typical day could be meeting an FBI agent in a parkway rest stop. Sitting in his car with the windows rolled up. Neither heat nor air conditioning. Getting wired. Running to a meeting. . . . That might happen at 7 for a meeting at 8” (Relator 16). Another said, “I would have FBI agents show up in the office. I told them, the company people, that they were computer people. Luckily they believed it. . . . That’s amusing now after the fact. But at the time they call you in 5 minutes. They say ‘We’re coming onto your campus’” (Relator 18).

Finally, there was widespread criticism of the Justice Department’s collaborative posture, or lack thereof, during various phases of the investigation. Ten relators reported conflict with the investigators, most frequently at the outset. One remarked, “There was always an undertone of ‘How much were we involved in this?’” (Relator 16). Relators also complained that “the government doesn’t tell you anything” (Relator 5) about the status of the investigation, including when a settlement was imminent. Others were frustrated that “the wheels move really slow” and lamented the years spent waiting in a state of uncertainty (Relator 9).

#### PERSONAL TOLL

The experience of being involved in troubling corporate behavior and a *qui tam* case had substantial and long-lasting effects for nearly all of the insiders, although no similar problems were reported by any of the four outsiders. Eighteen insiders (82%) reported being subjected to various pressures by the company in response to their complaints (Table 3). A common theme was that the decision to blow the whistle had “put their career on the line” (Relator 3). For at least eight insiders, the financial consequences were reportedly devastating. One said, “I just wasn’t able to get a job. It went longer and longer. Then I lost

— I had a rental house that my kids were [using to go] to school. I had to sell the house. Then I had to sell the personal home that I was in. I had my cars repossessed. I just went — financially I went under. Then once you’re financially under? Then no help. Then it really gets difficult. I lost my 401[k]. I lost everything. Absolutely everything” (Relator 17).

Financial difficulties often were associated with personal problems. Six relators (all insiders) reported divorces, severe marital strain, or other family conflicts during this time. Thirteen relators reported having stress-related health problems, including shingles, psoriasis, autoimmune disorders, panic attacks, asthma, insomnia, temporomandibular joint disorder, migraine headaches, and generalized anxiety.

#### SETTLEMENT AND LIFE AFTERWARD

All relators in our sample received a share of the financial recovery. The amounts received ranged from \$100,000 to \$42 million, with a median of \$3 million (net values, in 2009 dollars). The settlements helped alleviate some of the financial and nonfinancial costs of the litigation. One relator likened his large settlement to “hitting the lottery” (Relator 5). But a majority perceived their net recovery to be small relative to the time they spent on the case and the disruption and damage to their careers. After settlement, none of the 4 outsiders changed jobs, but only 2 of the 22 insiders remained employed in the pharmaceutical industry. One ruefully reported that he “should have taken the bribe” (Relator 7), and another noted that if she “stayed and took stock options” she “would’ve been worth a lot more” (Relator 4). The prevailing sentiment was that the payoff had not been worth the personal cost.

Despite the negative experiences and dissatisfaction with levels of financial recovery, 22 of the 26 relators still felt that what they did was important for ethical and other psychological or spiritual reasons. Relators offered a range of advice for others who might find themselves in similar situations (Table 4). Some offered strategic suggestions, such as hiring an experienced personal attorney, and many suggested a need to mentally prepare for a process more protracted, stressful, and conflict-ridden, and less financially rewarding, than prospective whistle-blowers might expect.

**Table 3. Forms of Pressure Reported by Insiders.\***

Type of Pressure	Illustrative Remark
Negative persuasion (reported by 7 relators)	"Then, after I complained, my territory changed. They started giving me more challenging physicians. Then they started giving me different areas farther out to call on. So it made it difficult to do my job." (Relator 15)
Positive persuasion (reported by 4 relators)	"[N]obody spoke to me. Not one person. . . . I was persona non grata." (Relator 21)
Direct intimidation (reported by 5 relators)	"First, they attempted to promote me and bribe me to keep me quiet." (Relator 7)
Loss of employment (reported by 5 relators)	"I was contacted by their lawyers on a couple of different occasions. Including one time which was a random call. Somebody who was basically trying to ask me to drop the lawsuit. That I'd be given some money on the side." (Relator 9)
Blackballing (reported by 5 relators)	"The individuals that threatened me pointed out that the company would hang me out to dry and [said,] 'Even if they find something the company will throw you under the bus and prove that you were a loose cannon and the only person doing it.'" (Relator 25)
	"[They said] 'If you're not playing along with us the way we play, we'll throw you under the bus when and if anything ever hits the fan.'" (Relator 5)
	Q: "Did you try to bring your concerns to your superiors?" A: "Yes." Q: "What happened then?" A: "I was fired." (Relator 9)
	"Then I took a job. Then somehow [company name] called the job. Then I was fired." (Relator 8)
	"I had one interview with [company name] as national trainer. I was actually being offered the job. . . . [I was going to go] to the national meeting. Be introduced as the person in charge basically. I walked in to [the] vice president's office. They asked me to be escorted out of the room with security." (Relator 17)

\* Insiders are whistle-blowers who were employees of the defendant company.

#### POLICY IMPLICATIONS

This study identified several commonalities in whistle-blowers' experiences. Generally, whistle-blowers' first move was to try to address problems internally; they became litigators either accidentally (while pursuing other claims) or as a last resort. The most prevalent motivations reported were personal values and self-preservation rather than financial incentives. These findings provide a number of useful insights into the qui tam mechanism as a tool for addressing health care fraud.

First, the strain the process places on individuals' professional and personal lives may make prospective whistle-blowers with legitimate evi-

dence of fraud reluctant to come forward.<sup>19</sup> Social and medical complications related to the stress of involvement in litigation have been well documented in other legal contexts, such as malpractice,<sup>20</sup> where physicians may resort to extreme measures to avoid being sued.<sup>21</sup> Qui tam litigation, in contrast, involves a choice for those who initiate it. Its capacity to curb fraud may therefore be enhanced if Justice Department investigators and others involved in the process were more cognizant of the tribulations faced by relators, or if relators received needed resources (for example, temporary financial or medical benefits during unemployment) during the course of litigation. The long duration of the investigation process contributed to this stress. The reported back-

**Table 4. Whistle-Blowers' Advice for Others Considering the Qui Tam Process.**

Topic of Advice	Illustrative Remark
Anticipated outcome	"I would say don't expect any money. It's going to be a long time. It's going to be frustrating. But if you're doing it for the right reasons? Then go for it. But if you're doing it because you think you're going to make millions? Don't do it." (Relator 9)
Relationship with government	"The government isn't there for you as much as you think. I really believe that. They're not there for you. They're ultimately there to get the company. You're just a tool. Just remember that you're just a tool for them." (Relator 8)  "It wasn't overly friendly, it was just very methodical. It was very to the point. Very detailed, really. Very comprehensive." (Relator 13)
Investigation process	"The process is a long process." (Relator 4)  "[Can they] afford 5 years of their life in turmoil? . . . If they [can't] I would tell them to find a new job and have a letter written anonymously with any documentation they can put together and send it off to the [Department of Justice]. Tell them to go investigate it. Or it's going to ruin their life." (Relator 7)
Evidentiary support	"Be as accurate as possible, have as much information as possible." (Relator 13)  "Make sure you know really thoroughly, for sure, 200% certainty that what you think you know is accurate and factual." (Relator 19)
Exhaust internal options	"[Bring a qui tam case] as an absolute last resort. Try and resolve it by changing things internally." (Relator 10)  "Build alliances and arguments that demonstrate the value of correcting the wrong. . . . [Take] responsibility for becoming a catalyst for internal change. If you blow the whistle, regardless of your ethical foundation or ultimate success, your ability to live out your dreams is severely compromised." (Relator 25)
Sources of support	"You've got to find some people, because this could go on for a while, like a minister or a shrink who's confidentiality-protected. Part of your ability to do anything about this is keeping yourself together." (Relator 16)  "You have to have strong resolve. Strong family life. To know what you want in life, if you want to risk things." (Relator 23)
Personal lawyers	"The first thing you need to do is get a good lawyer to represent you and guide you through this process because it's very complicated." (Relator 17)  "[Find] somebody that has done it, somebody that has relationships, somebody that will be honest [and] prepare[d] to be involved." (Relator 14)
Deciding not to take action	"Don't do it. Either try to find another job or just shut your mouth and don't sign anything. They're going to keep doing it. So you're not going to make a change. It still goes on." (Relator 21)  "Honestly, I would not advise anybody to do it." (Relator 6)

log of nearly a thousand health care qui tam cases at the Justice Department suggests that this problem may get worse, not better, for relators in the foreseeable future.<sup>22</sup> Shortening the timelines and attendant stresses of qui tam litigation requires more resources for enforcement, an investment that should more than pay for itself.

Second, in many of the personal stories we heard, the financial recovery appeared to be quite disproportionate (in both positive and negative directions) to the whistle-blower's personal investment in the case. More sophisticated approaches to determining relators' recoveries could be used to promote both equity and more responsible whistle-blowing. For example, the FCA does

not distinguish between relators outside and inside the defendant company, whereas we found that insiders tended to contribute much more to the Justice Department investigation and suffered more for their involvement. Such factors should be taken into account in determining compensation.

Third, whereas retaliation is clearly proscribed by the FCA, our report suggests that the protections are not fully effective, particularly for insiders. Often, the retaliation was more subtle than overt harassment. For example, relators reported changes in employment duties that made meeting sales quotas or other expectations impossible, providing a pretext for job termination. For

some relators, the anonymity gained from “sealing” their qui tam cases was undercut by the fact that internal complaints filed beforehand fingered them as obvious suspects. Ensuring responsible whistle-blowing in health care institutions may require broadening the scope, or strengthening the penalties, of the antiretaliation provisions.

This study has limitations. We focused on prosecutions against pharmaceutical companies that were taken up by the Justice Department and led to recoveries. Our findings may not be generalizable to other types of qui tam litigation, and the experiences of relators in our sample may be more positive, on average, than those of whistle-blowers whose cases were not successful. Our findings represent the subjective experiences that whistle-blowers were willing to report in interviews. Responses to some queries, such as motivations and the role played by the prospect of financial gain, may reflect a socially desirable response bias. Finally, responses may be subject to recall bias. Notwithstanding these limitations, our findings suggest that changes to the FCA and qui tam process that mitigate relators’ hardships may help promote responsible whistle-blowing and enhance the effectiveness of this integral component of efforts to combat health care fraud.

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