*Periodically, we will send you a **concise** update on current events in the healthcare compliance arena **as it relates specifically to pharmaceutical and medical device manufacturers** that may have an impact upon your business and operating procedures. These news items and analyses are intended for informational purposes only.*

Recently the *New England Journal of Medicine* published a special report titled "Whistle-Blowers' Experiences in Fraud Litigation against Pharmaceutical Companies". The analysis provides for interesting insight into the motivations and experiences of whistle-blowers in the drug industry.

It is reported that 90% of health care fraud cases are qui tam actions, and it is well known that enforcement actions against pharmaceutical manufacturers have become the most lucrative type of health care fraud litigation on the basis of recovery amounts. The authors in the NEJM report, three Harvard professors, examined 17 qui tam cases in the pharmaceutical industry involving 42 whistle-blowers, and conducted interviews with 26 of them. 85% of the whistleblowers interviewed were employees of the defendant company.

Interestingly, the triggering event for the qui tam action for almost three fourths of cases was some form of change in routine business operations. Either starting new employment at a company, changes to a new position within an existing company, or significant business environment changes were listed as key reasons for the onset of the action. For example, one relator described, "It wasn't until there were extreme competitive pressures and negative effects on earnings that the company's marketing practices became much more aggressive."

According to the relators, less than 25% of the sample interviewed specifically intended to file a qui tam suit. The remaining pursued the qui tam process after seeking lawyers for other reasons (such as unfair labor practices), or after being encouraged by family or friends. The most common theme for motivation was integrity. "I believed what we were doing was unethical and only technically illegal". Relators further conveyed that most of their colleagues were unwilling to come forward with complaints for fear of jeopardizing their jobs.

Most of the realtors became active players in the investigation, including wearing personal recording devices at face-to-face meetings or national conferences, taping phone conversations with colleagues, and copying requested documents or files.

Retaliation by the defendant company is clearly proscribed by the FCA (retaliatory protections were strengthened with the passage of PPACA); however relators conveyed retaliatory behaviors in both direct and subtle manners. Changes in sales territories making attainment of sales quotas reportedly impossible, little to no communication with colleagues, loss of employment, and "blackballing" throughout other companies were often cited.

The NEJM report provides an interesting insight into the motivations of qui tam relators, but more importantly serves as a reminder for Compliance Departments to ensure a mechanism to encourage

employees to report potential problems free of any possible retaliations. The entire report can be viewed at http://www.nejm.org/doi/full/10.1056/NEJMsr0912039.

As always, if you have any questions, comments, or concerns we can be reached at sreardo23@centurylink.net or at (908) 370-4085.