

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.



Aside from the numerous websites such as www.whistleblowercenter.com, www.whistleblowers.org, and www.taf.org that provide legal referral services for individuals to private attorneys who can represent them in filing a private whistleblower lawsuit, the State Attorney Generals are now actively encouraging enforcement via qui tam. For example, most recently Indiana's Attorney General Greg Zoeller has been reaching out to health care and pharmaceutical workers to advise them of their rights as whistleblowers to stop fraud under the state and federal versions of the False Claims Act.

To encourage whistleblowers to file and in turn expose health care fraud, Zoeller is raising public awareness of the False Claims Act via informational meetings, a promotional handout, Web content and outreach to plaintiffs' attorneys who file such cases initially. The effort is supervised by Deputy Attorney General Allen K. Pope, director of the Attorney General's Medicaid Fraud Control Unit (MFCU).

"If individuals on the inside are aware of fraud involving a government contract, and reporting it internally has not stopped the fraud, they may be reluctant to come forward for fear of being ostracized from future employment in their chosen profession. While we would hope people would report fraud because that's the right thing to do, we understand that the potential of a substantial financial reward may be necessary to prompt insiders to come forward," Zoeller said.

"The idea is to persuade workers already concerned about fraud to raise those claims under the False Claims Act. The private citizen acts, in effect, on behalf of the government to recover public funds wrongly paid out due to fraud. That in turn triggers our office to investigate and join the suit. It is often a lengthy process, but it can achieve great results in reimbursing the taxpayers - and it's a necessary tool to discourage and stop health care fraud," Zoeller said.

Meanwhile, it seems that a cottage industry of "professional whistleblowers" has been generated as it relates to the prosecution of pharmaceutical manufacturers for off label violations. The recent AstraZeneca settlement included a sales representative, James Wetta, as a qui tam relator. It is reported that Mr. Wetta will share some \$45 million with the other relator in the case Dr. Stefan Kruszewski. What is particularly interesting is that both relators' have a history with successful qui tam actions. Wetta was a relator in the Eli Lilly case as a sales representative (Eli Lilly settled for \$1.4 billion) where he shared in the \$100 million awarded to 8 former Lilly employees. Dr. Kruszewski was a relator in the Pfizer case where it is reported that he was awarded \$29 million (Pfizer settled for \$2.3 billion). Another physician, Dr. Joseph Piacentile, has been a qui tam realtor against Medco Health Solutions (settled for \$155 million in 2006), Bristol Myers Squibb (settled for \$515 million in 2007), Cephalon (settled for \$425 million in 2008), and Forest Laboratories (settled for \$313 million in 2010).

The ever increasing incentives for whistleblowers to come forward need not be a source of trepidation for compliance professionals. According to the OIG Guidance, "the failure to prevent or detect the

instant offense does not necessarily mean that the program is not generally effective in preventing and detecting criminal conduct". The increasing trend and encouragement of qui tam actions simply stresses the mounting importance of having policies and procedures in place to evidence a robust compliance effort effective in discovering potential non-compliant activities.

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