

Are More Pharma cGMP Whistleblower Cases on the Way? Experts Think So.

483's Accountability cGxP's, FDA and Regulatory Issues Dodd-frank Ethics FDA John Fleder Category: Leslie Wood management Michael Gregor Nolan And Auerbach Peter Rost Pfizer Pharma Workforce and Staffing Pharmaceutical Industry Conflicts of Interest Pharmaceutical industry management Quality Robert Riordon Submitted by Taxpayers Against Fraud (taf) The Pharma Industry Whistleblowers pharmamanufacturing on Wed, 11/17/2010 - 20:47.

Most of the U.S. Department of Justice's major pharma-related decisions invoking the False Claims Act recently have involved illegal marketing and sales. So far, GSK's is the only one to deal with current good manufacturing practices (cGMP's). Read on for a [roundup of the top 20 recent cases](#) from Taxpayers Against Fraud (TAF).

However, we may expect more False Claims cases to reach the courts, legal experts say, and an increasing number of them may invoke cGMP's. Compliance Guru's Michael Gregor is currently providing expert testimony in one cGMP whistleblower case, in the Northeastern U.S., which may or may not reach the legal system. In [this audio interview](#), he can't talk about the specifics of that case, of course, but looks at common threads linking GSK's whistleblower's complaint with recent 483's and other FDA citations.

Promising to spur more False Claims cases, legal experts agree, are the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, and healthcare reform (if it does really happen). [Read here](#) for the rather cynically-titled "Champagne Wishes and Caviar Dreams" in the Pharma Compliance blog. More cases are likely, too, to invoke cGMP's, say the *qui tam* experts, Nolan and Auerbach, in [this brief commentary](#) on their website.

For any drug company, it will be critical to ensure compliance with cGMPs and to examine potential vulnerabilities. [Here is an excellent checklist](#) by Nolan and Auerbach's Kenneth Nolan in the Pharmaceutical Manufacturing Handbook, under civil cases.

Also clear is the fact that any employee who alleges cGMP problems must be treated with respect, and not like a pariah. For any managers who need financial rather than ethical motivation, John Fleder, of Hyman, Phelps & McNamara writes compellingly in [this article](#) of the reasons why whistleblowers should be treated with kid gloves.

Remember Mark Livingston's cGMP case against Wyeth? In [this interesting analysis](#), Robert Rierdon and Leslie Wood of Alston & Bird analyze reasons why that precedent-setting case, which invoked Sarbanes-Oxley, failed.

For any of you who might be looking at data integrity or other big issues in your day to day jobs...here's a [miniquiz from TAF](#) that can help you decide whether or not you might actually have a case. Speaking of pharma whistleblowers, today brought news from Peter Rost on his long-standing case against Pfizer/Pharmacia....the Court of Appeals has reversed district court judgment on the terms of his employment protection under New Jersey state law, asking that district court revisit his claims (which, given his title at the company, could be substantial....could Pfizer have to sell another jet, or maybe a helicopter?) For anyone who has the stomach for all the legalese, here's a [brief official document](#). Employment in the drug industry is becoming increasingly tenuous....here's hoping that your daily work is interesting, but your workplaces are as boring and humdrum as possible (at least as far as cGMP and other legal/ethical violations are concerned).

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