

Whistleblowers and Where The Government Gets Their Information

SARENA STRAUS

Senior Counsel & Senior Associate Director

Legal



What is the government source for claims: The What the Who and the Where

Landscape of Government Investigations is shifting



According to a 2008 Washington Post Article, of Twenty Billion Dollars recovered since the FCA was amended in 1986, nearly 12 billion was collected with the assistance of whistle-blowers and their attorneys and

Even if no new cases are filed, it would take the DOJ ten years to clear its desk of claims.

Taxpayers Against Fraud:

- Over 180 pharma fraud cases covering more than 500 drugs are now under investigation by the DOJ under the FCA

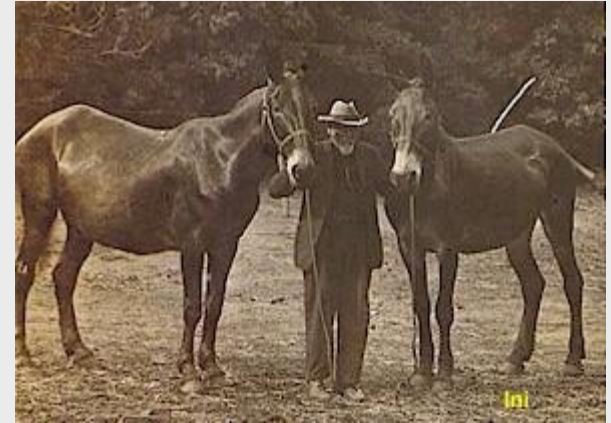
Lew Morris, OIG Chief Counsel

- “...our inventory of cases is continuing to grow, particularly in the area of off-label marketing. We have dozens and dozens of qui tams that have been filed in off-label marketing.”

What Do These Three Images Have in Common?



The Civil War and.....



Also known as The Lincoln Law

Passed in 1863 in response to contractors providing bad supplies to the Union Army.

A reward was offered in what is called the qui tam provision, which permits citizens to sue on behalf of the government and be paid a percentage of the recovery.

- *qui tam pro domino rege quam pro se ipso in hac parte sequitur*
- ("he who brings a case on behalf of our lord the King, as well as for himself")

Government Contractors remained the primary focus of the claims until the 90s when this shifted toward healthcare fraud. Healthcare Fraud remains the primary source of whistleblower and government claims.

- Reward to whistleblowers is between 15 and 30 percent of recovery based on what the whistleblower reports

FCA and Courageous Leadership

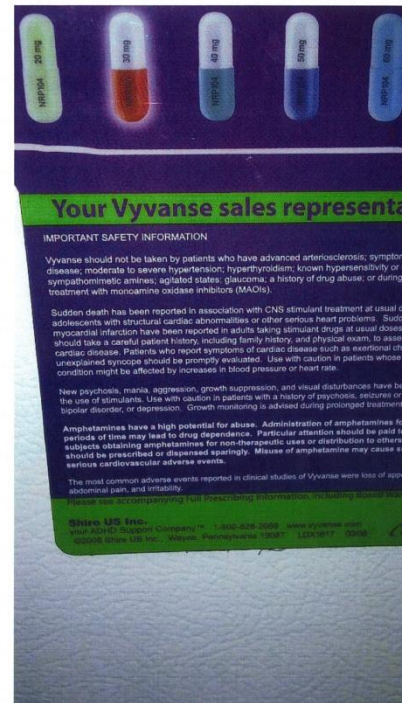
Are They Contradictory or Compatible?



2010: GSK settlement of 750 Million

- 96 million went to the whistleblower
- [60 Minutes Video](#)
- GSK has said little about these claims other than that there were no reported injuries from the non-compliance and that the failures in the PR plant were not indicative of GSKs overall commitment to quality. There is little public comment on how the complaints were handled.
- What did they do wrong and what could they have done better?
 - Address the EEs concerns or if they were, make sure she was in the loop
 - Recall may have been appropriate in certain instances
 - RIFing Whistleblower is risky
 - We only have her side of the story – leads to implication that her concerns were not adequately addressed, which may or may not be true

- Launched in May of 2010
- Administered by DDMAC
- Educate health care providers about their role in ensuring that prescription drug advertising and promotion is truthful, and not misleading
- Still not well-known by Physicians, but can expect program to grow
- To date, 5 Warning Letters issued as a result of campaign
 - Oral Rep Statement minimized risk of a drug
 - YouTube Rep Video
 - Website minimized important risks



Background: Branded magnet disseminated to HCPs in 2008 – photographed in 2011 & submitted to DDMAC as Bad Ad

Violation: Minimization/Omission of Risk Information

- Branded magnet (boxed warning drug) made efficacy claims in absence of functional risk info.
- As shown in picture submitted to DDMAC appear to be balanced
- When used as intended (to hold sales rep business card), risk info was completely obscured
- Directional statement (still visible with card) not sufficient to balance claims

Social Media Guidance

Following Issues Identified by DDMAC:

- Responding to unsolicited requests
- Fulfilling Regulatory Requirements when using tools associated with space limitations
- Fulfilling post-marketing submission requirements
- Use of links on the Internet

What Can We Do in the Meanwhile?

- **FOLLOW THE REGULATIONS**
- **THE REGULATIONS AREN'T GOING TO CHANGE**
- **MAKE CERTAIN THE PRODUCT IS FAIR AND BALANCE**



“There will be guidance on some specific matters, but there will be no new regulations or new standards. Look at our recent Warning Letters involving social media...[t]hese Warning Letters cite existing rules and do not make new policy.”

1. Be proactive
2. Respond to internal complaints
 - Take complaints seriously
 - Investigate them carefully
 - Keep the WB informed to the extent possible
3. Don't assume that if the government doesn't pursue a claim you can rest on your laurels
4. Keep Current with the laws and regulations
5. More Transparency