Specifically, the study has two objectives:

**Broad purpose** – to gain insight into the changing landscape of the pharmaceutical industry

**Objectives**

- More serious or repeated violations
- Reply required within 15 days
- Immediate corrective action required
- Failure to act immediately may lead to criminal prosecution

A total of 151 letters were reviewed, of which 34 (22.5%) were warning letters.

- Average 38 total letters were issued each year through the study period, of which on average 9 were warning letters.
- The number of claims in each warning letter varied from 1 to 8, summing up to 409 claims throughout the study period.

Results

- There was an increase in the total number of letters issued in 2010 (52) compared to 2009 (41), after which the number declined. The decline was mainly attributable to a decrease in the number of warning letters issued in 2011 and 2012.
- Therapeutic class type: majority of all letters – anti-cancer (18.5%) and cardiovascular (13%). Majority of warning letters – analgesics and anti-inflammatory drugs (24.4%) and anti-microbial drugs (21.2%).
- Claim type: highest number of claims – omission/minimization of risk information (29.6%), followed by overstatement of efficacy or unsubstantiated efficacy claims (20.5%).
- 54.3% of all letters were promotional materials targeting health care practitioners.
- 34.5% of claims were Internet-based promotions (websites, sponsored links, etc.).

Conclusions

- Actionable takeaways:
  1. There has been an increase in the intensity of FDA surveillance activities towards protecting general public health.
  2. Average number of FDA letters (untitled and warning) increased from 24 in 2002-2008, to 38 in 2009-2012.
  3. There was a decrease in the number of warning letters over the course of the study period – potential decrease in the severity of promotional claim violations.
  4. Most promotional materials targeted by the FDA were directed towards health care practitioners – potentially due to their greater impact on prescribing behavior.
  5. Numerous healthcare qualitative data sources are available free of charge. Researchers can make use of these sources to arrive at valuable quantitative conclusions.

References