The Impact of Surveillance Initiatives by the Office of Prescription Drug Promotion on the Number and Types of Violations

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BACKGROUND
FDA's Office of Prescription Drug Promotion (OPDP) is responsible for reviewing prescription drug advertising and promotional labeling to ensure that they are not false or misleading. OPDP regulates TV and radio advertisements, all written or printed promotional materials, speaker program presentations, and oral statements from sales representatives. One of the many responsibilities is to oversee and enforce compliance with existing regulations on promotional materials that are false or misleading, including Un truthful and Omissionary claims. OPDP enforces laws that govern the prescription drug promotion industry to ensure that they present risk information adequately and present risk information in a non-misleading manner. The Bad Ad Program is an initiative that responds to stakeholder requests for specific guidance on how FDA determines whether they have violated a specific regulatory requirement.

OBJECTIVES
To evaluate the overall trend in the number of enforcement letters from 2007 to 2013, including:
- Differences in the types of violations cited and the therapeutic categories for those products
- The impact of the Bad Ad Program
- FDA’s oversight of digital media in relation to the number and types of violations

STUDY DESIGN & METHODS
OPDP enforcement letters from 2007 to 2013 that are publicly available on the FDA website were accessed and analyzed. The following information was collected:
- Number of enforcement letters
- Category of violation (Efficacy, Indication, Unsubstantiated Claims, Superiority, or Risk)
- Type of violation
- Therapeutic area
- Violation due to risk information

The collected data was used to identify trends in the number of enforcement letters, the types of violations cited, the therapeutic category of products that received violations, and additional mandatory, corrective actions. In addition to this, OPDP also reviews complaints about alleged promotional violations via the Bad Ad Program.

RESULTS (CONTINUED)
In May 2009, the FDA released a Draft Guidance for Industry on how to present risk information in labeling and patient education. The Draft Guidance outlines the characteristics of good risk management practices and provides examples of how to adequately present risk information. According to the Food Drug Administration Modernization Act, FDA is expected to release guidance on the use of digital media by June 2014.

CONCLUSIONS
- After the launch of the Bad Ad Program, there has been a decline in the total number of letters.
- The letters resulting from complaints through the Bad Ad Program were not a significant contributor to the total increase in enforcement.
- Violations due to risk information were the most frequently cited, most likely due to the increased safety concerns with their use.
- OPDP is more vigilant over the presentation of risk information in promotional pieces being that pharmaceutical companies now have multiple years of OPDP’s oversight on the presentation of risk information.

LIMITATIONS
- The data collection and trends analysis conducted were prone to human error.
- The letters resulting from complaints through the Bad Ad Program were not a significant contributor to the total increase in enforcement.

DISCLOSURES
Authors of this presentation have the following to disclose concerning possible financial or commercial relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation:
- Sagar Shah and Jamie Jung-Hee An report that they have received honoraria from paid employees of Rutgers University participating in presentations at various meetings.
- The authors report no relationships with the National Institute of Mental Health and Independent Medical Education Companies, respectively, at Bristol-Meyers Squibb.