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 that the office oversees is initiating enforcement actions on promotional materials that are false or misleading, including Untitled and Warning Letters. Untitled letters demand cessation of the promotional activity, while Warning Letters specify additional mandatory, corrective actions. In addition to this, OPDP also reviews complaints about alleged promotional violations via the Bad Ad Program.

In May 2009, the FDA released a Draft Guidance for Industry on how to present risk information in prescription drug and medical device promotion. The Draft Guidance illustrates FDA's current thinking on factors that are relevant to the disclosure of risk information and responds to stakeholder requests for specific guidance on how FDA determines whether they adequately present risk information.

The use of social media in the pharmaceutical industry has become prominent over the past five years. Despite the wide use of internet and social media by pharmaceutical companies for the promotion of prescription products, there has been a lack of regulatory guidance from OPDP. According to the Food Drug Administration Modernization Act, FDA is expected to release guidance on the use of digital media by June 2014.

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 areas for those products
- The impact of the Bad Ad Program
- The effect of FDA's Draft Guidance on the presentation of risk information on the types of violations cited
- FDA's oversight on digital media in relation to the number and types of violations

STUDY DESIGN & METHODS

OPDP enforcement letters from 2007 to 2013 that are publically available on the FDA website were accessed and analyzed. The following information was collected:

- Total number of enforcement letters, including warning and untitled letters
- Most frequently cited types of violation in enforcement letters
- Most frequently cited therapeutic category for drug products associated with violative promotional activity
- Number of letters that cited digital media based communication related violations

The collected data was analyzed to identify trends in the number of enforcement letters, the types of violations cited, the therapeutic category of products that received violations and number of letters with violations on digital media pieces.

RESULTS

- The total number of enforcement letters has increased from 2007 to 2010 **[Figure 1.]**
  - Since the launch of the Bad Ad Program in May 2010, nine letters have been released due to this initiative
  - Following 2010, there has been a continuous decrease in the total number of enforcement letters with each year
- Since the release of the FDA Risk Draft Guidance in 2009, there has been an increase in the number of enforcement letters that cited violations due to risk information compared to other violations **[Figure 2.]**
  - There was a significant increase from 15 violations in 2008 to 37 violations in 2009 and 44 violations in 2010
  - In 2011 (n=24), however, there was a decrease in the number of letters, and this decrease continued in 2012 (n=16), followed by a slight increase in 2013 (n=19)

RESULTS (CONTINUED)

Figure 1.

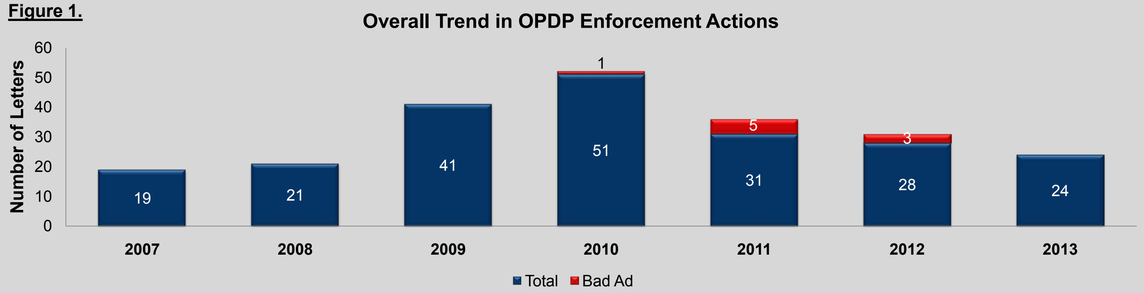
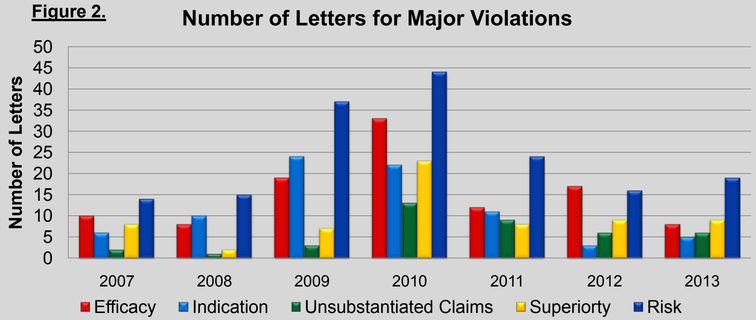


Figure 2.



Category	Type of Violation(s) Included:
Efficacy	Overstatement of efficacy, unsubstantiated efficacy claims, and misleading efficacy claims
Indication	Broadening of indication, inadequate/misleading communication of the indication, failure to state full indication, and omission of indication
Unsubstantiated claims	All unsubstantiated claims, except those relating to efficacy or superiority claims
Superiority	Unsubstantiated superiority claim or misleading comparative claim
Risk	Omission and minimization of risk

Figure 3.

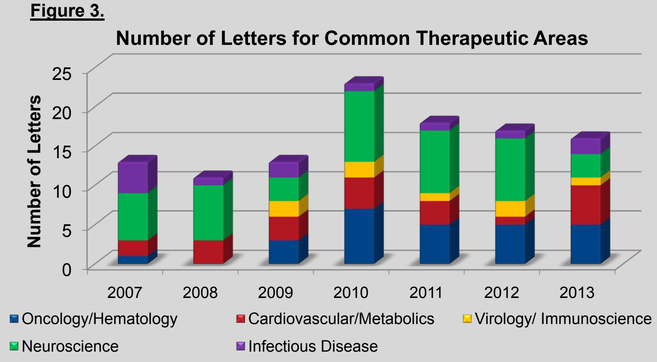
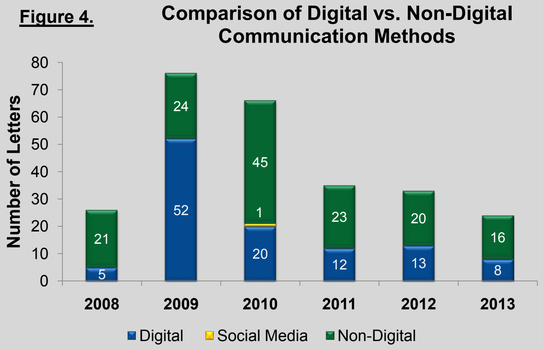


Figure 4.



RESULTS (CONTINUED)

- From 2007 to 2013, violations due to risk information were the most frequently cited compared to any other violations, including violations related to efficacy claims and misleading presentation of indication **[Figure 2.]**
  - The number of efficacy violations that were cited in enforcement letters increased significantly from 2009 (n=18) to 2010 (n=33)
  - From 2008 (n=10) to 2009 (n=24), there was a significant jump in the number of violations due to the misleading presentation of indication
- From 2007 to 2013, majority of the products that were cited for violative promotional materials were concentrated in the neuroscience therapeutic area (20.5%) **[Figure 3.]**
  - Starting in 2010, there was an increase in the number of violations for promotional pieces for oncology/hematology prescription products
  - 10.5% of products cited over the past seven years were in the oncology/hematology therapeutic area, the second most common therapeutic area with violative materials
- From 2008 to 2013, the frequency of communication platforms triggering a violation reveals that 2009 was the only year that violations for digital media communication platforms were more frequent than traditional media methods **[Figure 4.]**
  - There has been one letter in the past eight years regarding the use of a Facebook Share Widget, a social media platform

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 the omission or minimization of risk information were the most frequently cited
  - OPDP is more vigilant over the presentation of risk information in promotional pieces being that pharmaceutical companies now have the guidance and are more aware of OPDP's oversight on the presentation of risk information
- Products in the neuroscience and oncology/hematology therapeutic areas were the most frequently cited, most likely due to the increased safety concerns with their use
- Despite the increased use of digital media and social media platforms in the past couple of years by pharmaceutical companies for the promotion of pharmaceutical products and the lack of regulatory guidance on the use of these platforms, the number of letters regarding digital and social media has been considerably low compared to the total number of letters released
  - In 2009, 14 enforcement letters were released due to paid search advertising (sponsored links), therefore, the large increase in letters for digital media vehicles compared to other years may be over expressed
  - Due to the absence of definitive guidance, pharmaceutical companies have been more cautious in utilizing digital and social media platforms

LIMITATIONS

- The data collection and trends analysis conducted were prone to human error
- A number of observations were subjective and speculative in nature
- Data for enforcement letters was only collected for the most frequently cited violations and for products in the most frequently cited therapeutic areas
- Data collection was limited to publicly available resources on the FDA website

DISCLOSURES

Authors of this presentation have the following to disclose concerning possible financial or personal 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 are paid employees of Rutgers University participating in Post-Doctoral Fellowships in the Promotion Integrity and Independent Medical Education Departments, respectively, at Bristol-Myers Squibb.