Background

- As the number of prescription medication print advertisements has increased, medication information is more accessible for consumers who are now the major decision makers in the healthcare industry.
- In 2009, a Food and Drug Administration (FDA) guidance was implemented to emphasize factors relevant to the disclosure of risk information. The FDA encouraged all information regarding benefit and risk information to be provided in a clear, concise, and understandable language.
- In 2015 the FDA revised the draft guidance to further detail provisions to better balance benefit and risk information in pharmaceutical print advertisements.
- Some recommendations include a brief summary of the most important side effects, warnings, precautions, and contraindications of each prescription drug.

Methods

- Twenty pharmaceutical advertisements were evaluated representing a variety of therapeutic areas: oncology/hematology, immune-system diseases, ophthalmology, endocrinology, infectious disease, pain relief, and vaccines.
- Utilizing a grid-generating application, a Gridit, a 50 by 50 grid of 2,500 squares was superimposed on each print advertisement.
- Then, the squares that contained benefit information, risk information, additional text, and blank space or images were all counted manually, and percentages were calculated.
- Publication dates of these advertisements ranged from 2008 to 2018, which allowed for the assessment of compliance to both the 2009 and 2015 FDA guidances.
- The percent of risk and benefit information in each advertisement was analyzed and compared to evaluate if there was a trend with the percentages over time based on FDA recommendations.
- Furthermore, a separate sub-analysis was performed comparing one- and two-page advertisements to look for possible trends.

Results

- There was no difference in the spatial allocation of risk versus benefit information to blank space or images.
- One-page advertisements had an average of 1.07 times more benefit than risk, with two advertisements including no risk information.
- Two-page advertisements had an average of 2.54 times more risk than benefit, with only one having more benefit information.
- In all advertisements, at least 50 percent of the space was allocated to blank space or images.

Conclusions

- Overall, advertisements published prior to the 2009 FDA guidance contained a greater percentage of spatial benefit information, while majority of advertisements published after 2009 included a greater percentage of risk information.
- Furthermore, two-page advertisements contained a greater proportion of risk information compared to one-page advertisements.
- There was no difference in the spatial allocation of risk versus benefit information between therapeutic areas.
- Further research is needed to evaluate the impact FDA guidelines have on advertising practices.

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Figure 1: Total Distribution of Print Advertisement

Figure 2: One-Page Advertisements

Figure 3: Two-Page Advertisements