Risk versus Benefit Evaluation in Direct-to-Consumer Prescription Drug Advertisements

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Background

In May 2009 the U.S. Food and Drug Administration (FDA) released a draft guidance titled Presenting Risk Information, which conveys the allocation of risk versus benefit as a key factor considered in the evaluation of direct-to-consumer (DTC) consumer advertisements. The FDA strongly suggest the information presented is in a comparable and "fair-balanced" manner.

The 2015 revised draft guidance details recommendations disclosing risk information in consumer-directed print advertisements and promotional labeling for prescription drugs. Additionally, the FDA recommends including information on contraindications, black box warnings, specific key warnings and precautions, as well as adverse reactions while emphasizing the need to include only clinically significant information on the most serious and most current information with the product.

Objective

The objective of this study is to evaluate the risk versus benefit content distribution found within currently broadcasted television (TV) advertisements.

Methods

This study reviews 33 prescription drug TV commercials aired between January 2017 and October 2018, separated by the product's respective therapeutic treatment area. This includes respiratory disease, diabetes, gastrointestinal disease, oncology, autoimmune disease, ototoxicity, and cardiovascular disease.

For each advertisement, indicators for assessing risk versus benefit include total duration of advertisement (in seconds), time dedicated to benefit (in seconds), time dedicated to risk (in seconds), percentage proportion of risk information, percentage proportion of benefit information, and communication of black box warnings or risk evaluation and mitigation strategy (REMS) information for the drug product, if applicable. An allocation to risk versus benefit is not the sole predictor of "fair balance", an assessment of warning issuance limited within the study dates was performed.

An analysis was performed using the aforementioned indicators. The primary outcomes analyzed are the following: (1) proportion of benefit vs. risk information portrayed within the advertisements, and (2) presence of important safety information, including boxed warnings and REMS programs.

Results

An analysis of DTC television broadcasts of select drug products from January 2017-October 2018 identify a vast range of percentage difference in risk versus benefit narrative. A graphical representation of the percentages of the distribution of benefit versus risk content is shown in Figure 1. A total distribution of advertisement time in Figure 2, as companies have not only reported risk versus benefit of their study drug, but also miscellaneous information that neither fall in the category of risk nor benefit.

- 57.0% of ads portrayed more time allotted to benefit portrayal
- 30.3% of advertisements have more time allotted to benefit portrayal
- 12.1% of advertisements have an equal balance of risk versus benefit portrayal

Discussion

Of the 33 advertisements analyzed within this study, 69.7% are portrayed in the "fair balance" nature described in the previously mentioned FDA guidance. While 30.3% of DTC television advertisements portrayed an increase in reporting benefit over risk, it is important to mention that time dedicated to benefit versus risk narration is not a sole predictor of "fair balance".

The FDA has issued a total of 13 warning letters from 2017 to 2018 (6 in 2017 and 7 in 2018 respectively), two of which pertain to video promotions. The grounds for these warning letters include omission of risk information and/or making false or misleading claims and/or representations about safety, efficacy, and/or risks associated with drug treatment. None of the warning letters mentioned above were issued in relation to products or commercial advertisements analyzed within this study.

Limitations

- This study solely uses advertisements located online from the date of data collection, which do not correlate to the latest commercials broadcasted.
- Some drug products aired multiple advertisements within the discussed timeframe, and analysis was only performed on one commercial per product.
- Subjectivity exists in the assessment of time allocation to risk versus benefit information.

Conclusions

Despite FDA guidance, inconsistency exists between risk versus benefit information portrayed within direct-to-consumer prescription drug television commercials. This study's analysis of important safety information (boxed warning and/or REMS) is consistent within the advertisements analyzed.

Further research is needed to assess what message consumers receive from these advertisements to derive the comprehension of these promotions.

Disclosure

The authors of this presentation have nothing to disclose concerning possible financial or personal relationships with commercial entities.