

Evaluation of Risk Versus Benefit Information in Direct-To-Consumer (DTC) Prescription Drug Television Advertisements

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Abstract

Background: The FDA's Presenting Risk Information draft guidance from May 2009 states that the time of risk versus benefit is a factor taken into consideration when evaluating audio and video direct-to-consumer (DTC) broadcasts. The objective of the study is to evaluate the proportion of risk narration on television (TV) advertisements in comparison to the actual proportion of serious adverse effects findings across select therapeutic areas. **Methods:** The study reviews prescription drug TV advertisements between the years 2010 and 2015 separated by therapeutic class. Indicators to assess risk versus benefit are as follows: total benefit time, total risk time, total ad time, percentage proportion of risk, and number of serious adverse effects (SAEs) listed in the package insert. The objective is establishing proportion of risk-to-benefit narration across therapeutic areas and the proportion of risk narration compared to the number of SAEs in the package insert. These outcomes will reflect whether TV advertisements abide by the "fair balance" rule and if the time spent on risk narrations is proportional to the number of SAEs across therapeutic areas. **Results:** An analysis of risk versus benefit showed that there was a vast range of percentage differences in risk versus benefit narration across the products selected. The majority of the products narrated showed a 40% to 60% risk-to-benefit ratio. Six out of the 10 products evaluated communicated applicable black box warnings. There was variability among the SAE percentages presented between products. **Conclusion:** Lack of consistency exists between risks versus benefit proportions among different drug products.

Keywords

direct-to-consumer, advertising, pharmaceutical advertising, television, prescriptions

Background

Billions of dollars are spent on pharmaceutical marketing on a yearly basis, from face-to-face sales and promotional activities to samples provided to physicians. One modest contributor to spending is direct to consumer advertising (DTCA), which was reportedly estimated to be around \$3 billion in 2012 with an upward trend to more than \$5 billion in 2015.¹ DTCA is not legal in every country; in fact, the United States and New Zealand are the only 2 countries that allow this type of marketing. DTC is usually advertised as product claim, reminder, or help-seeking advertisements. Product claim ads advertise a medication, including its name, indication, safety and efficacy claims. Reminder ads include a product name and basic information but no indications as it assumes patients are already familiar with the medication. These ads also do not report any safety or efficacy-related claims. Help-seeking ads include information on a medical condition only without mention of any specific product or product class, prompting the patient to contact a doctor. These types of ads are not regulated by the

FDA, but rather by the Federal Trade Commission.^{2,3} Product claim ads are the focus of this research as this is the type of advertisements where balanced information on the risks and benefits of a medication is required.

The FDA was given authority to regulate prescription drug labeling and advertising in 1962. After a series of rules and regulations of how to present or broadcast the information, the FDA ultimately passed a regulation in 1997 that required DTC advertisements to include a "major statement" that presents the most important risks and "adequate provision" of resources to

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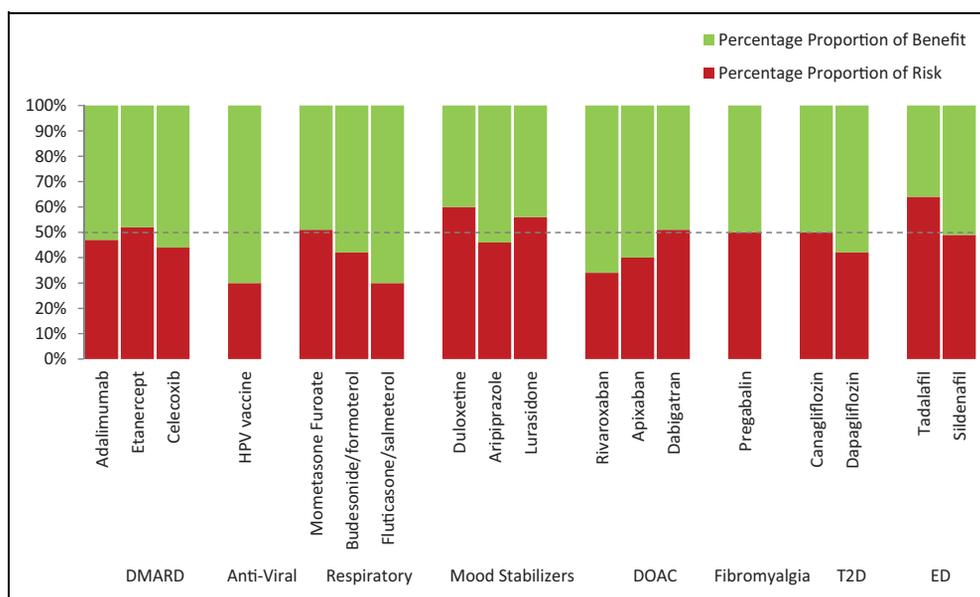


Figure 1. Percentage of risk versus benefit narration in television advertisements.

obtain additional information about the drug to satisfy the “fair balance” requirement. This requirement dictates that risk and benefit information of drug products be presented in a manner that is balanced both in their visual and audio content.⁴

Upon a review of the literature, a study was found that assessed the different ways the risks and benefits were communicated in promotional drug labeling or print advertising. It was found that numeric presentation of the information increased patient understanding of risks and benefits, compared with non-numeric presentation. However, the study concluded that it would be best practice to present both forms of information to consumers, patients, and clinicians.⁵ To our knowledge, no studies have been conducted to evaluate the temporal aspect of television advertisements per the FDA guidance.

Methods

Two authors simultaneously reviewed the prescription drug television advertisements from pharmaceutical companies between 2010 and 2015 that were available on YouTube and adpharm.net. Television advertisements were reviewed for each product individually, and indicators to assess risk versus benefit were collected on each product for

- total advertisement time (in seconds),
- total communicated benefit time (in seconds),
- total communicated risk time (in seconds),
- percentage of time spent on risks,
- percentage of time spent on benefits,
- communication of black box warning (if applicable), and
- number of serious adverse events (SAEs) and warnings communicated in advertisements compared to number of SAEs and warnings listed in the package insert.

A comparative analysis was performed using the above variables. The primary outcomes included (1) proportion of risk to benefit as a percentage across therapeutic areas and (2) correlation between risks narrated in advertisements and SAEs listed in package inserts. The risk versus benefit proportions were rounded to the nearest whole number. The analysis of SAEs consisted of 2 parts: (1) number of black box warnings communicated in the advertisement for applicable products versus their package inserts, and (2) the percentage of serious warnings and precautions communicated in the advertisement compared to the package insert information, calculated as a range from 0% to 100% in increments of 20%.

Results

An analysis of DTC television broadcasts of select drug products showed that there was a vast range of percentage difference in risk versus benefit narration, both within and across drug classes. A graphical representation of the percentages of risk and benefit timing for different prescription drug products in television advertisements is presented in Figure 1. Results show lack of consistency between drug products in the same therapeutic area.

An identification of basic trends in the risk-to-benefit proportions in television commercials is depicted in Table 1. The majority of the prescription products have a 40% to 60% ratio of risk-versus-benefit narration. Some specifics of note are that while human papillomavirus 9-valent vaccine (Gardasil) and fluticasone/salmeterol (Advair) are medications with minimal risk narration; tadalafil (Cialis), duloxetine (Cymbalta), and lurasidone (Latuda) have a higher percentage of risk mentioned in commercials.

Of the 10 prescription products evaluated where a black box warning was applicable according to the package insert,

Table 1. Trends in Risk-to-Benefit Narration in Television Advertisements by Prescription Drug Product.

Prescription Product	Risk-to-Benefit Narration Range
Fluticasone/salmeterol, rivaroxaban, HPV vaccine	30:70
Adalimumab, celecoxib, budesonide/formoterol, apixaban, dapagliflozin	40:60
Etanercept, mometasone furoate, aripiprazole, dabigatran, canagliflozin, sildenafil, pregabalin	50:50
Duloxetine, lurasidone	60:40
Tadalafil	70:30

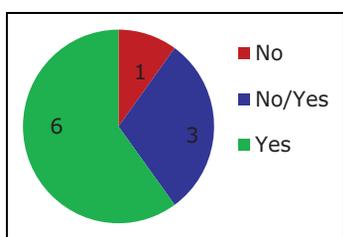


Figure 2. Inclusion of black box warning.

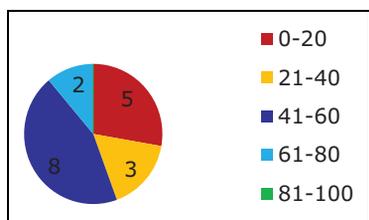


Figure 3. Percentage of inclusion of serious warnings (Range).

6 products communicated this warning in their television advertisement (Figure 2). The 3 direct oral anticoagulants (DOACs) partially communicated this warning, and 1 product completely failed to do so. Specifically, the black box warning for DOACs include 2 warnings, and the advertisements evaluated for this study only communicated 1 of the 2 warnings.

Out of the 18 prescription products evaluated for percentage of serious warnings overlapping with package insert information, 5 products communicated 0% to 20% of warnings, 3 products communicated 21% to 40%, 8 products communicated 41% to 60%, 2 products communicated 61% to 80%, and no products communicated 81% to 100% of the warnings. This breakdown is illustrated in Figure 3.

Discussion

The results from this study should be interpreted carefully as several limitations exist in this analysis. The study uses only the most recent television advertisement located online at the time of data collection. However, this may not account for the

latest commercials broadcasted on television. Additionally, package inserts were pulled from the most up-to-date sources (manufacturer website) and may not accurately reflect the date of originally aired advertisement. Some drug products aired multiple advertisements for the same product and communicated inconsistent information, making it difficult to interpret risk-versus-benefit information comprehensively.

These outcomes were collected to temporally reflect the “fair balance” rule in television advertisements and if the risk narration correlated with the SAEs listed in the package inserts of each product. The FDA does specify, however, that information should generally be presented in a balanced manner to decrease bias and this will depend on the drug. It does not dictate that an equal amount of specific time should be given to risks and to benefits.⁶

Nevertheless, lack of consistency does exist based on our analysis between risks versus benefits for different drug products within the same therapeutic area. This may lead to commercial message advantages for one product over another and misinformed patients. Moreover, the use of black box warnings is currently inconsistent between various therapeutic areas.

Conclusions

The temporal aspect of presenting risks versus benefits in television pharmaceutical advertisements is one of many ways to assess adherence to judging the Fair Balance rule mandated by the FDA. Lack of consistency exists between risks versus benefit proportions among different drug products. Further research is needed to better characterize the balance between risk and benefit messages and how patients and consumers interpret these DTC advertisements.

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