



# Still the Great Debate – “Fair Balance” in Direct-to-Consumer Prescription Drug Advertising

## Comment on “Trouble Spots in Online Direct-to-Consumer Prescription Drug Promotion: A Content Analysis of FDA Warning Letters”

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### Abstract

The above titled paper examined the Food and Drug Administration's (FDA's) warning letters and notice of violations (NOV) over a 10-year period. Findings from this content analysis reinforced what has been the primary issue for prescription direct-to-consumer advertising (DTCA) since its beginning, the fair balance of risk and benefit information. As opposed to another analysis in 2026 about this still being an issue, is there anything that can be done to prevent this problem from continuing?

**Keywords:** Food and Drug Administration (FDA), Direct-to-Consumer Advertising (DTCA), Notice of Violations (NOV), Office of Prescription Drug Promotion (OPDP), Fair Balance

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In the research paper and content analysis addressed by this commentary, Hyosun Kim thoroughly examines a 10-year stretch of Food and Drug Administration (FDA) warning letters and notice of violations (NOV) to identify problem areas in online direct-to-consumer advertising (DTCA).<sup>1</sup> The author sought to answer four research questions:

- What online promotions were most targeted by the FDA?
- Which drug categories were most targeted?
- What are the FDA's most common complaints/areas of issue?
- Which allegations match which online promotion?

Each research question was answered by the author, as “marketer controlled” elements such as the medication website were the most cited, cancer the most prominent medication category and risk information problems the most common complaint. Outside of the article's organization and placement of certain material, I had minimal qualms with the research and think it brings back into play the most debated subject in the DTCA realm. The author's results pointed to the FDA's focus and an area pharmaceutical manufacturers still to this day, over 18 years after the moratorium on DTCA was lifted, struggle – the ‘fair balance’ requirement in the amount of risk versus benefit information presented in any promotional item and outlet (which means even on the 140-character limit microblog site Twitter). The remainder of this commentary will address Kim's article, examine other current DTCA research, and pose possible solutions in the form of questions that need to be addressed with future research.

As Kim's article highlights, the FDA's decision in 1997 to lift its moratorium on DTCA led to a rapid increase in promotional spending, peaking in the mid-2000s. This created an overwhelming environment for the FDA to follow, track, and monitor, with 262 letters identified over the 10-

year period (all letters – not just the ones focused online). Also during that time, the FDA has extensively researched consumer response to DTCA and put out guidance documents for the pharmaceutical industry to better understand how to exist in the space without consequence.<sup>2-5</sup> Still, though, the fair balance requirement and how risks and benefits should be communicated is a complicated issue. From an overall perspective, the practice of DTCA has been postulated to have benefits and risks in and of itself. Through both research and opinion papers, pros and cons for the impact of DTCA in the areas of drug utilization, the physician-patient relationship, consumer knowledge/education, health outcomes, adherence, broad social outcomes, and legal issues have been examined.<sup>6</sup> Further, given the practice only exists in the United States and New Zealand, it begs the question as to whether or not it should even exist at all? Could DTCA be altered in some way or removed altogether and put an end to the seemingly never-ending ‘fair balance’ issue?

Over the last few years, numerous media and academic outlets from *Prevention Magazine*,<sup>7</sup> to the Huffington Post,<sup>8</sup> and even *Nature Biotechnology*<sup>9</sup> have addressed the big picture question surrounding DTCA from both the positive and negative side. Further, various associations have also put their two cents in, including the American Academy of Physician Assistants (AAPA), which states “that any DTCA by pharmaceutical companies be based on disease state only, without mention of a specific drug by name or category,”<sup>10</sup> and even more recently (November 2015), the American Medical Association (AMA) called for an all-out ban on DTCA. The AMA felt a ban “reflects concerns among physicians about the negative impact of commercially-driven promotions, and the role that marketing costs play in fueling escalating drug prices...DTCA also inflates demand for new and more expensive drugs, even

when these drugs may not be appropriate.”<sup>11</sup> Thus, what does this mean for the future of DTCA and how can the fair balance dilemma be solved?

Over the past 6 years, my colleagues and I have researched the impact of disease-specific DTCA. Disease-specific DTCA, also referred to as help-seeking, is defined by the FDA as “one which discusses a disease or condition and makes no mention or representation of a particular drug or device.”<sup>12</sup> Under this guidance, these communications are exempt from regulation by the agency unless there is only one drug or device used in the disease/condition. Thus, these ads focus only on the disease state and theoretically eliminate the need for a ‘fair balance’ of risk and benefit information as no specific product is mentioned and the only distinguishing factor in a disease-specific DTCA being the company name and logo. Beginning in 2010 and up to the present day, we have compared disease-specific DTCA to product-specific DTCA in drug inquiry intention and information seeking behavior,<sup>13</sup> effectiveness from an attitudinal perspective,<sup>14</sup> and animation<sup>15</sup>; examined celebrity, endorser type, and gender roles in disease-specific DTCA<sup>16,17</sup>; and, recently, disease-specific DTCA’s role in medication adherence.<sup>18</sup> From a consumer response perspective, what has all the research told us? That while certain aspects of product-specific DTCA are more noticed or memorable to consumers, the overall intent of the ads (inducing information seeking and conversations with physicians) is achieved more significantly with disease-specific DTCA.

Kim accomplished at least one thing with this detailed content analysis; it has indirectly renewed a debate that has existed since Boots Pharmaceutical showed us the first DTCA for Rufen®.<sup>19</sup> Thus, what is the best solution? Is it a ban of DTCA altogether? Is it a switch to disease-specific DTCA only as the AAPA would have and our research shows would not necessarily be detrimental to the manufacturers? What about a dollar-for-dollar requirement of manufacturers in the two areas (ie, for every dollar spent on product-specific DTCA the company must also spend that amount on disease-specific DTCA)? Ultimately more research, both from academicians and the FDA, should continue to examine this topic. My own next steps include assessing the risk-benefit relationship in disease versus product-specific ads and further analyzing the possible impact of DTCA on medication adherence. I end with a challenge to all of those who analyze and study DTCA. Let’s work together to eliminate the fair balance dilemma, either through alternative measures/regulations or improving the current structure and practices to eliminate the gray, make decisions for manufacturers clear, and give the general consumer fair and balanced information.

#### Ethical issues

Not applicable.

#### Competing interests

Author declares that he has no competing interests.

#### Author’s contribution

BLR is the single author of the paper.

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