Does Direct-to-Consumer Prescription Drug Advertising Achieve a Mechanistic Fair Balance? A Critical Review of the Literature and Debate

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The pharmaceutical industry is one of the most advertising-intensive industries. With the exponential growth of Direct-to-Consumer Prescription Drug Advertising (DTCA), there have been a large number of attempts to investigate the effectiveness of DTCA in various media, medications, and consumer groups. However, little attention has been paid to the history of the US Food and Drug Administration (FDA) regulations of DTCA and the status of DTCA practices in terms of regulatory compliance. Thus, this current study identifies a research gap in DTCA and highlights a new avenue that can be explored in future research.

Keywords: direct-to-consumer drug advertising, fair balance, prescription drug promotion

Introduction

The pharmaceutical industry is one of the most advertising-intensive industries (Brekke & Kuhn, 2006). Thus, since the inception of Direct-to-Consumer Prescription Drug Advertising (DTCA) in the early-1980s, it has experienced a dramatic growth in terms of DTCA spending and research. DTCA refers to any promotional effort by a pharmaceutical firm to present prescription drug information to consumers via the mass media (Wilkes, Bell, & Kravitz, 2000). Due to the controversy surrounding DTCA, there are only two developed countries that permit it: the United States and New Zealand (Hoek & Gendall, 2002). Among the controversial issues is that DTCA encourages the inappropriate use of medications and drives up drug spending (Donohue, Cevasco, & Rosenthal, 2007). While DTCA was a radical idea little less than 30 years ago, it has grown significantly over the last three decades and extended into a variety of health conditions.

With the exponential growth of DTCA, there have been a large number of attempts to investigate the effectiveness of DTCA in various media, medications, and consumer groups. However, little attention has been paid to the history of the US Food and Drug Administration (FDA) regulations of DTCA and the status of DTCA practices in terms of regulatory compliance. The purposes of the current study are three-fold: (1) summarizing the foundations of FDA regulations on DTCA, (2) investigating the industry’s response to filling requirements in FDA regulations by reviewing the extant literature in DTCA, and (3) identifying regulatory issues in DTCA.
History of Direct-to-Consumer Pharmaceutical Advertising Regulations

In 1708, Boston’s Nicholas Boone advertised the first patented medicine in an American newspaper (Young, 2015), inspiring others to promote their patented medicines as well (Wilkes et al., 2000). For the next 200 years, patented drugs such as Pectoral Drops, Balsam of Life, and Cordial appeared in newspapers, magazines, and medicine shows. By the early 1800s, the pharmaceutical industry and the press had developed a mutually beneficial relationship. For example, newspapers received the biggest proportion of their income from drug advertising, and the drug industry spent more to promote their products than other industries.

With the enactment of the Federal Food, Drug, and Cosmetic Act in 1938, the US Food and Drug Administration (FDA) was given the authority to oversee the safety of food, drugs (both prescription and over-the-counter), and cosmetics. However, the Federal Trade Commission (FTC) still had the authority to control drug advertising and medical devices. In 1962, the Kefauver Harris Amendment, also known as the Drug Efficacy Amendment, introduced requirements for pharmaceutical advertising to include, for example, information about the effectiveness, safety, and side effects of drugs, the size of warning/side effect statements (e.g., font size) and the benefits and risks of taking the drugs (Peltzman, 1973). Furthermore, the Kefauver Harris Amendment transferred responsibility for prescription drug advertising from the FTC (which still had the authority to regulate advertising for over-the-counter drugs) to the FDA (Calfee, 2002).

Even though the legal groundwork for drug advertising was laid in 1962, there is no specific point in time when the pharmaceutical industry began to open it to patients/consumers. However, of particular importance, during the late 1960s and early 1970s the FDA utilized the Patient Package Insert (PPI). PPIs, first developed in 1968, ultimately led to DTCA (Pines, 1999). The first PPI was designed to promote isoproterenol inhalation products (Federal Register, 1968). Then the concept of the PPI was extended to birth control pills and estrogen replacement therapy. To provide medical information to patients, during the 1970s, the FDA increasingly and consistently required information about prescription medicine to be provided directly to consumers (Federal Register, 1979).

Until 1981, the pharmaceutical industry had promoted drugs and medical equipment exclusively to physicians and other health care professionals because only physicians are responsible for the diagnosis of patients’ health conditions, and have the authority to prescribe drugs (Weissman, Blumenthal, Silk, Zapert, Newman, & Leitman, 2003). In addition, pharmaceutical marketers believed that promoting drugs directly to consumers would be suicidal due to the fear that physicians would never prescribe drugs that bypassed them. Thus, promoting prescription drugs to non-medical-professionals was inconceivable. Before DTCA was implemented, health care decisions were dominated by physicians because they monopolized the medical/medicine information. The traditional pharmaceutical marketing program consisted of: (a) advertising in medical journals; (b) educating physicians about the pharmaceutical firm’s latest offerings; and (c) the provision to doctors by mail of drug information.

In the late 1970s and early 1980s, as the perception that consumers had the right to know about drug information for better medical services emerged, pharmaceutical companies sought to promote their products directly to consumers. As part of this trend, a book about prescription drugs—the *Physician’s Desk Reference* (PDR)—became available in consumer bookstores. The PDR was written exclusively for physicians and health care professionals, and from it, consumers were able to gain access to drug information and learn about the effects of drugs.
The breakthrough of implementing drug advertising came from British-based Boots Pharmaceuticals, which advertised its ibuprofen product, Rufen. A second DTCA was undertaken by Merck Sharp & Dohme, which advertised its pneumonia vaccine, Pneumovax in Reader’s Digest in 1981. The advertisements for Rufen and Pneumovax raised questions in terms of the potential negative effects of DTCA. For example, physicians at the FDA believed that even though there was a public health benefit in advertising a prescription drug, DTCA could provide incorrect information regarding drug uses (Hoen, 1998).

In 1982, then-FDA Commissioner Arthur Hull Hayes, Jr. spoke to the Pharmaceutical Advertising Council, summarizing the status of DTCA as the FDA saw it and predicting exponential growth in DTCA. Even though the Commissioner did not intend to advocate for DTCA, the pharmaceutical companies interpreted the speech as the FDA’s approval of DTCA, and they began to advertise their products directly to consumers. In September of 1982, the FDA officially requested that the pharmaceutical industry voluntarily avoid advertising its products directly to consumers, and the industry halted the promotion of its products.

Over the next two years, the industry and the FDA investigated the impact of DTCA on consumers, which is considered the early research on DTCA. During the investigation period, only price comparison advertisements were allowed. There were two noteworthy studies that significantly influenced the FDA’s thinking about DTCA. One study found that consumers tended to acquire more information about the positive aspects of products than about the negative aspects (Morris & Millstein, 1984). Another study showed that consumers preferred prescription drug information in detail and would consider DTCA favorably (Morris, Brinberg, Klimberg, Rivers, & Millstein, 1986).

The studies of Morris and Millstein (1984) and Morris et al. (1986) indicated that the FDA had opened the door for the pharmaceutical industry. However, the FDA felt that DTCA should be controlled and the pharmaceutical industry needed specific guidance regarding DTCA. On September 9, 1985, the FDA announced guidelines stipulating that DTCAs should be fairly balanced in terms of benefit and risk information (Calfee, 2002). Subsequently, pharmaceutical companies began to more broadly promote their products directly to consumers in print in accordance with the FDA’s guidelines. Although the FDA did not restrict broadcast DTCA, the industry could not utilize television to promote its products because it was impossible to meet the legal criteria (e.g., a detailed “brief summary” of risks, a lengthy “major statement” of risks, and “adequate provision” for consumers to acquire full FDA-approved prescription information) (Calfee, 2002). Specifically, prescription drug marketers were unable to provide all of the risk information to patients in a limited amount of time. Nevertheless, DTCA consistently increased from $12 million in 1989 to $55 million in 1991, $164 million in 1993, $340 million in 1995, and almost $1 billion in 1997 (Wilke, 1997a; 1997b). The number of drugs that utilized DTCA gradually increased from six in both 1994 and 1995, to nine in 1996, and 14 in 1997 (Pines, 1999).

The Fair Balance of Medical Information

The pharmaceutical industry reached a turning point in the late 1990s. In January 1997, the then-Commissioner Dr. David A. Kessler left the FDA. Since he opposed the television advertising of prescription drugs, his departure from the FDA provided momentum for a new television advertising policy. In August 1997, the FDA issued the “Draft Guidance for Industry on Consumer-Directed Broadcast Advertisements”, which removed the obstacles for advertising drugs on television (FDA, 1997). This draft guidance indicated the ways in which an “adequate provision” could be met: (a) a toll-free number to call for
more information; (b) concurrent print advertisements containing a brief summary of the risks; (c) a web address to access further information about the drug; or (d) specific drug information that could be obtained from publicly accessible locations, such as hospitals and pharmacies (FDA, 1997).

According to Food and Drugs (2000), there is a list of over 30 FDA regulations concerning the misuse of Direct-to-Consumer Advertising (DTCA). One of the top considerations of the list is that DTCA “present[s] a fair balance between information about effectiveness and information about risk” (FDA, 1999, p. 2). The FDA stipulates that the main goal of fair balance is to protect consumers from biased pharmaceutical information. Pharmaceutical companies often hide information on the risks of a drug while overemphasizing its benefits. Thus, the FDA requires that DTCA fairly balances the negative and positive effects of a drug so that consumers can better understand their medical decisions.

The doctrine of fair balance dictates that not only the content (e.g., the benefits and risks of the use of a drug) but also the presentation (e.g., the amount of space in print advertisements and the amount of time in broadcast advertisements) of the risks and the benefits should be similar. However, according to the FDA (1999), fair balance does necessarily mean allocating equal space or time to the risks and benefits of an advertised drug in broadcast or print ads. Instead, the FDA notes that the appropriate amount of time or space given to benefits and risks to achieve a fair balance depends on a drug’s risks and how both its benefits and risks are presented.

**The Research Gap in Direct-to-Consumer Pharmaceutical Advertising and the Conclusion**

A number of studies have investigated the doctrine of fair balance in DTCA and its impact on consumer behavior. For example, Kees, Bone, Kozup, and Ellen (2008) studied the impact of the formats and the types of risk information on a pharmaceutical website and found that one’s perceived risk depends on the content and format of the information. In addition to considering the effects of the presentation of information, researchers have studied the content of DTCA for drugs to explore how the industry deals with compliance maintenance by leading consumers toward the benefits rather than the risks. For instance, Huh and Cude (2004) examined the quality and quantity of risk information provided on prescription drug websites and found an imbalance between risk and benefit information in terms of font size (e.g., risk information written in a small font) and information accessibility.

Although broadcast ads account for the greatest portion of a pharmaceutical company’s media expenditures, little attention has been paid to the application of the fair balance provision in broadcast ads. Kaphingst, DeJong, Rudd, and Daltroy’s study (2004) remains the one attempt at analyzing the fair balance of the content of DTCA. It examined to what degree various presentational methods (e.g., presentation technique, speed change, and tone change), terminology (medical terminology vs. lay terminology), and information sources were used to present the benefits and risks of a drug. Recent studies (e.g., Adams, 2016) have assessed how much the pharmaceutical industry complies with the fair balance and the adequate provision requirements in an online media setting and found that online ads provide consumers with more information on the benefits of using the advertised drugs than on the risks.

The extant literature’s focus has been on the adequacy of the amount of time (for TV commercials) or space (for print ads) needed to present risk information in DTCA. However, the relationship between the presentational manner of risk-benefit information and its comprehensibility has not been investigated. In terms of consumer protection, it is worth examining the comprehensibility of risk-benefit information in DTCA since
the information is often delivered in different modes. For instance, it is easy to notice differences between benefit and risk information in DTCA in speech pace, tone, and pitch, and in the number of pauses and emphases. For instance, in DTCA, benefit information is delivered at a normal pace, while risk information is presented at a rapid pace to deliver it in less time. However, such prosodic features (e.g., speech pace, tone, and pitch) of speech are considered essential for understandability (Kreiman & Sidtis, 2011). Moreover, an appropriate combination of prosodic features makes one’s speech more pleasant and intelligent sounding (Zellner, 1994).

This current study identifies a research gap in DTCA. The extant literature examining a fair balance in DTCA has paid significant attention to the technical adequacy (e.g., simple comparisons of information length) of the amount of time (radio and television commercials) or space (print media) needed to present risk and benefit information but little attention to its prosodic features. However, since the fair balance doctrine has been initiated to protect consumers, it is necessary to consider the ways of how consumers actually process medical information when evaluating fair balance and adequate provision requirements in DTCA. Thus, this study recommends that future research should take prosodic features of speech into account in evaluating the fair balance of DTCA to test the comprehensibility of benefit and risk information and to examine to what degree the pharmaceutical industry complies with the doctrine of fair balance.

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