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Pharmaceutical Advertising

The Cost for Fantasy Over Reality Evidence for the Prescribing Clinical Nurse Specialist

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In 2006, I wrote an article about pharmaceutical advertising and clinical nurse specialist (CNS) practice.[1] After counting 16 pharma television commercials in a short period one winter evening, I decided to examine again direct-to-consumer pharmaceutical advertising (DTCPA). Findings reveal that there is more, in fact, a lot more, big pharma advertising than 13 years ago. This second article offers evidence for the CNS practicing in current DTCPA climate that promises the consumer happiness regardless of disease, financial burden, and adverse effects often excluding safer and as effective interventions.[1]

MEDICAL AND PHARMACEUTICAL MARKETING SINCE 1997 IN THE UNITED STATES

Medical marketing includes pharmaceutical marketing, disease awareness, health services and practices, and testing. Spending for all 5 categories increased significantly from 1997 through 2016 from $17.7 billion to $29.9 billion, with the greatest expenditures for the marketing of professionals (88% of total spending). During the same period, marketing for prescription drugs and disease awareness increased from $17.1 billion to $26.9 billion with an associated increase of 180% in drug spending ($116.5 billion to $328.6 billion). Advertisements alone increased in number from 79 000 to 4.6 million. Table 1 describes the spending associated with this increase in DTCPA.[2] The expenditures reported in Table 1 are probably underestimated because related expenses are not accounted for such as employee salaries, training, product research, evaluations, rebates, lobbying, and campaign contributions.[2] Television is the most utilized tool for DTCPA. In 2011, it was estimated that the average consumer viewed up to 30 hours of DTCPA a year.[3,4]

Direct-to-consumer pharmaceutical advertising is the most common health communication regulated by the Food and Drug Administration (FDA).[4–6] Advertisement of a drug for an indication not approved by the FDA or off-label drug promotion is prohibited.[7] Over the past 20 years, there has been significant decline in advertising for allergy, cholesterol, and osteoporosis medications related to change to over-the-counter access or loss of patent protection.[2] In a recent study of DTCPA, all English-language ads aired in the United States from January 2015 to July 2016 were evaluated.[7] Ad length, regulatory compliance, claims, and presentation of risks and benefits were assessed. The sample included 97 unique DTCPA ads representing 60 medications and 67 unique drug-indication combinations. Zero percent of the ads provided a quantitative report of drug risks, and 26% provided a numeric description of drug efficacy. Thirteen percent of the ads were labeled as suggesting off-label use for weight loss and reducing blood pressure. The most commonly ads were for inflammatory conditions (18%) and for diabetes or diabetic neuropathy (16%) followed by bowel and bladder dysfunction, infection, or allergic reactions, with 76% of the ads for medications treating chronic conditions. Very few of the ads were completely compliant with FDA regulations.[7]

DTCPA EFFECTS AND CONSUMER RESPONSES

Direct-to-consumer pharmaceutical advertising has been permitted in the United States since 1985. Draft guidance provided by the FDA in 1997 with final regulations in 1999 requires that DTCPA provide all risk information with directions for the consumer to obtain more information. Relaxation of some of the rules in 2004 permitted pharmaceutical companies to present only major risks and use simple and easy-to-understand language for the consumer.[7,8]

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Table 1. Annual Spending for Prescription Drug Advertising—United States 1997 Versus 2016[2]

Prescription Drug Type	1997 (US $)	2016 (US $)
Diabetes/endocrine	22 million	725 million
Dermatology conditions	67 million	605 million
Pain/central nervous system disorders	56 million	542 million
Arthritis	27 million	484 million
Cardiac	0	379 million
Cancer	3 million	274 million
Immunology	11 million	218 million
Gastrointestinal	61 million	215 million
Depression	40 million	193 million
Impotence	7 million	147 million
Contraception	41 million	119 million
Menopause	40 million	106 million

Critics believe current rules for DTCPA are not enough and are not adequately enforced.[4] While print media must provide all risks from the approved FDA label, broadcast media is only required to provide major risks with a source to access the FDA-approved label information.[7]

Consumer responses to DTCPA are certainly a function of observing the ad within a myriad of other internal and external factors described in Table 2.[9] Two primary elements are part of any DTCPA message: regulatory requirements and promotional elements that *together* create the ad message. The promotional element has rational and emotional ingredients with primary emphasis on the emotional to increase the persuasive impact of the ad message. Eliciting an emotional rather than cognitive response will more likely to influence consumer memory and action to seek the product. Additionally, reports of risk and adverse effects are blended within the ad's visual elements of fantasy, sexual appeal, youth, happiness, and success. When the consumer requests the prescription from the care provider, the emotional imagery is what is remembered with adverse effects and risks perceived as not significant,[10,11] hence the disappointment and anger when the provider refuses to prescribe based on best practices or requests consideration of other therapies.

The effects of relaxation of advertising regulations by the FDA for prescription drugs in 1997 are still being calculated.[12] Types of advertising can include the reminder ad that provides the name, dose, and price information without benefit claims. More common is the product claim that includes name, indication, efficacy, and safety claims. As pathways for advertising continue to expand, the discussion will continue for the United States and New Zealand, the only countries that permit DTCPA.[11] Is DTCPA a public health benefit or a threat? What is the degree of pressure on prescribers as DTCPA expands?[4,12] Table 3 describes both sides of this discussion regarding the pros and cons of DTCPA.[4]

WHAT NOW?

Many DTCPAs promote high-priced medications that have limited usefulness for the average viewer. Ads encourage patients to seek expensive drug therapy that is sometimes the wrong therapy. Rising healthcare costs are fueled by DTCPA. Current targets for DTCPA are caregivers and children of aging parents with focus on cancer, Alzheimer disease, and constipation related to the opioid crisis.[11] Prescription drug spending in the United States accounted for 10% of health spending in 2016 at $329 billion compared with 1995 ($56 billion). Direct-to-consumer pharmaceutical advertising may be responsible for nearly 19% of the growth of demand and drug expenditure.[13]

There are many calls for changing DTCPA including delaying advertising for new product, banning specific product ads, establishing regulations for web-based advertising, and providing cost information.[4] Some have called for a moratorium on advertising and research to uncover how much are consumers having to bear in drug costs related to DTCPA.[8] The Office of Prescription Drug Promotion research (part of the FDA) carries on an active research program examining DTCPA and professional promotional prescription drug materials. The goal of Office of Prescription Drug Promotion is science-based policy and protection of

Table 2. Factors Driving Consumer Purchase of Over-the-Counter Pharmaceutical Products[9]

• Awareness of the product
• Corporate image
• No. of promotion exposures
• Consumer need
• Available information
• Available alternatives
• Aesthetics—color, shape, packaging, taste, brand name
• Past experiences
• Reports from users and/or friends
• Education level
• Income
• Age
• Profession or work experience
• Physician or care provider advice
• Pharmacist advice
• Cost of therapy

Table 3. Advantages and Disadvantages of Direct-to-Consumer Pharmaceutical Advertising (DTCPA)[4]

Advantages of DTCPA	Disadvantages of DTPCA
Patient education	Misinformation/inadequate information
Encourages contacting physician/care provider	Lack of connection to behavior modification
↓ Underdiagnosis	Lack of connection to comparable treatments
↓ Undertreatment	Advertising exceeds 8th-grade reading level
↑ Awareness of alternatives	Overemphasis on drug benefits over adverse effects
Decreases stigma of disease	Adverse effects and visual images do not match
Product competition	Less confidence in healthcare provider
Encourages compliance with use	Increase drug cost to support DTCPA

public health.[14] The web site is a starting point for information regarding DTCPA.

Finally, if the relationship between the clinician and the patient were stronger, perhaps there would be less consumer need for direction, diagnosis, and treatment information from DTCPA. The prescriber is caught in an abyss between DTCPA and patients seeking the promises of the DTCPA message. The CNS and other prescribers are in the best position to offer interventions based on reality, not fantasy for the patient enduring the burdens of illness and therapy, which is often excluded in DTCPA message.

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