

**FOOD AND DRUG ADMINISTRATION
HEARINGS ON
DIRECT TO CONSUMER ADVERTISING
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**JAMES H. DAVIDSON
DAVIDSON & COMPANY
OF POLSINELLI SHALTON WELTE SUELTHAUS LLC**

**EXECUTIVE DIRECTOR
THE ADVERTISING COALITION**

Good morning Ladies and Gentlemen. I am Jim Davidson and I serve as Executive Director of The Advertising Coalition, a coalition of trade associations and companies that includes advertisers, advertising agencies, advertising professionals, broadcast, cable, newspaper and magazine media.

The professionals that lead these organizations and their members view themselves as having a tremendous responsibility to their readers, viewers, consumers, clients and companies to provide valuable information in the form of advertising. In a moment I will share with you some feedback from members of one audience.

We are grateful to FDA for its positive leadership in finding better ways to communicate information about healthcare and prescription medicines to consumers. You consistently have offered constructive forums for examining DTC advertising and out of those forums you have put forward positive guidance for improving this form of communication.

The FDA regulations and guidance recognize that advertising – in its varying formats – is a primary means of getting the attention of consumers and providing them with the information they need to participate in important decisions about their health care. They also recognize that in our fragmented media environment advertisers must use multiple outlets – some to gain the attention of consumers with information and others to provide detailed information, in a form that consumers can consult at their own time and pace.

FDA requires print advertisements for prescription drugs to include the lengthier, more complicated “brief summary” of the product’s side effects, contraindications, and effectiveness.

Broadcast advertising, on the other hand, must contain a statement of a product’s major side effects and contraindications and must either make “adequate provision” for dissemination of the product’s package labeling or present a brief summary of the side effects and contraindications in the advertisement. The adequate provision requirement can foster a complementary relationship for broadcast advertisements to use print publications to disseminate more detailed information to consumers who may not use the Internet or other sources to seek information about a product being advertised.

I want to address four aspects about DTC advertising that illustrate the important role it plays and will continue to play in the future.

- DTC advertising is protected commercial speech.
- DTC advertising has motivated millions of Americans to seek advice from their doctors, and a significant proportion of those seeking help suffer from high priority conditions.
- DTC advertising raises awareness about under diagnosed conditions and helps address public health disparities.
- Industry self-regulation promises to further enhance the quality of DTC advertising.

DTC Advertising is protected commercial speech

I would like to affirm a message that you have heard from others – DTC advertising is an important form of communicating health information and will continue doing that into the future. It serves neither the public interest nor the public health to seek a ban on speech that is imposed by the government either permanently or for arbitrary periods. An important part of our nation’s First Amendment heritage is based not upon banning speech but on encouraging more speech.

The U.S. Supreme Court has spoken quite clearly for nearly 30 years that advertising and commercial speech enjoy many of the same degrees of protection accorded to political speech. It is noteworthy that one of the earliest cases and the most recent Supreme Court case on commercial speech involved government restrictions on the advertising of prescription drugs. Justice Blackman, writing for the majority in the 1976 *Virginia Pharmacy Board*¹ case, explained why: “As to the particular consumer's interest in the free flow of commercial information, that interest may be as keen, if not keener by far, than his interest in the day's most urgent political debate.”

Twenty-six years later, Justice O’ Connor wrote, “. . . if it is appropriate for the statute to rely on doctors to refrain from prescribing compounded drugs to patients who do not need them, it is not clear why it would not also be appropriate to rely on doctors to refrain from prescribing compounded drugs to patients who do not need them in a world where advertising was permitted.”² The decision struck down a prohibition on advertising compounded drugs.

¹ *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976)

² *Thompson v. Western States Medical Center*, 535 U.S., 357 (2002).

Successful advertising informs and motivates its readers and viewers. To achieve this goal advertisers must respect their audiences and offer them information that they can understand and use, and upon which they can rely. Anything less and they risk breaking an intangible bond of trust that exists with their audience. Advertising that does not inform or that misleads its audience likely will not get a second chance. Moreover, FDA has extensive powers to regulate ads it determines to be misleading and untruthful. FDA has demonstrated that it is prepared to use that authority to sanction DTC advertising.

DTC advertising has motivated millions of Americans to seek advice from their doctors

According to *Prevention* magazine, an estimated 62 million Americans say they have spoken to their doctors about an advertised medicine. Various surveys, including those conducted by FDA, suggest that between 25 and 30 million Americans have been prompted by an ad to talk to their physician for the first time about a medical condition.

Nevertheless, if you asked the Surgeon General of the United States, the Director of the Centers for Disease Control and the HHS Assistant Secretary for Health, I doubt any of them would say that too many Americans are making appointments with their doctors to seek health care. One of our greatest challenges is to find ways to increase the health literacy and awareness of our population and to motivate Americans to seek healthcare assistance when it is needed. The message does not have to be presented in a pristine, white-jacketed format, but in any medium that will prompt a question or further research by the consumer. Advertising should inform and motivate – but it need not be encyclopedic. As former Commissioner McClellan has said – “Less is more.”

DTC advertising has demonstrated its ability to play an important and effective role in raising public awareness of healthcare conditions and treatments, and it has helped to lower their anxiety or embarrassment by removing the stigma from discussing certain diseases even with family members or medical professionals.

A significant proportion of those seeking help suffer from high priority conditions

Harvard University, Massachusetts General Hospital and Harris Interactive determined that 35 percent of 3,000 people surveyed said they sought medical advice after seeing an advertisement. This was consistent with earlier FDA and *Prevention* magazine surveys, but it offered an important new insight – 25 percent of those who went to their doctor received a new diagnosis. Of those, 43 percent were for “high priority” conditions³ including hypertension, diabetes, high cholesterol levels and depression.

DTC Advertising Can Highlight Under Diagnosed and Under Treated Conditions

Instead of looking for ways to limit this speech, DTC advertising expands awareness of health conditions and care for the under diagnosed and underserved populations in our

³ As defined by the Agency for Healthcare Research and Quality.

society and helps reduce disparities between different population groups in their access to health care.

The Silent Killer – According to the Centers for Disease Control, nearly one out of three adults has high blood pressure, or 65 million Americans.⁴

- 30%, or 19.5 million, don't know they have this silent killer
- 11% are not receiving therapy
- 25% are receiving inadequate therapy

Diabetes is the 6th leading cause of death in the U.S.

- 21 million Americans affected – that is 7% of the U.S. population
- 6 million of them don't know they have diabetes.⁵

More than 20 percent of men who went to a doctor seeking treatment for erectile dysfunction were diagnosed with high blood pressure, diabetes or heart disease.⁶

Depression

- Nearly 40 million Americans suffer from a depressive disorder
- Yet only 4 to 8 million Americans are in active treatment for depression

Between 1987 and 1997 the percentage of Americans being treated for depression more than tripled nationwide from 0.7% to 2.3%.⁷

Dr. Mark Olafson, Associate Professor of Clinical Psychiatry at Columbia University and the New York Psychiatry Institute, attributed the expanded treatment in part to the increased number of “multi-million dollar marketing campaigns.”⁸ Other factors included a decrease in the stigma associated with depression and the arrival of more powerful drugs to treat depression.

Osteoporosis and Bone Health

Dr. Richard Kravitz at the University of California at Davis has said that the private sector's financial resources and ability to reach a huge market can be brought to bear on the public health issue of bone health. “DTC apparently works . . . several studies show that DTC ads are read and acted upon.” DTC advertising encourages patients to seek

⁴ U.S. Department of Health and Human Resources, Centers for Disease Control and Prevention.

⁵ Ibid.

⁶ Data collected from pharmaceutical manufacturers.

⁷ Centers for Disease Control and Prevention.

⁸ Vedantam, Shankar, “Report Shows Big Rise in Treatment for Depression,” *The Washington Post*, January 9, 2002, page A1.

care when needed and allows for more informed decision making, more active involvement in care planning, and a greater understanding among patients of their conditions, according to Kravitz.⁹

Access to Information by Under Served Communities

DTC advertising offers another important means for raising public awareness of under diagnosed diseases – it can help address health disparities in underserved populations. Dr. Jane Delgado, President and CEO of the National Alliance for Hispanic Health, told a House Energy and Commerce Subcommittee that, “Access to information is a critical piece in the access picture for Hispanic and other under served communities.”

“New research is showing that health care disparities among black, Hispanic, and white Americans cannot be explained wholly by disparities in income and health insurance coverage among these groups . . . other factors such as lack of information play a critical role,” Dr. Delgado said.¹⁰

Finally, 90 percent of the African American physicians surveyed by the National Medical Association said they had been asked their medical opinion because their patients had seen prescription drug ads. NMA said their findings are particularly important in light of a Commonwealth Fund study that minorities lag behind in health care quality and are more likely to have communication problems with their doctors than caucasian patients.¹¹

The Woman’s Day Survey

Now, I encourage you to listen to those most directly affected by DTC advertising. *Woman’s Day* magazine reaches 20 million, or 1 in 5, American women. The publisher of *Woman’s Day*¹² is a member of the Magazine Publishers of America, which in turn is part of The Advertising Coalition. Through research to its 100,000+ reader panel, *Woman’s Day* received hundreds of examples of how prescription drug advertising positively affects lives and encourages a dialogue between readers, family members and doctors. Here are a few of their stories.

⁹ Dr. Richard Kravitz, M.D., M.S.P.H., University of California, Davis; Direct-to-Consumer Advertising, Panel on Promoting Awareness and Action, Report of the Surgeon General’s Workshop on Osteoporosis and Bone Health, December 12-13, 2002, Washington, D.C.

¹⁰ Dr. Jane L. Delgado, U.S. House of Representatives, Subcommittee on Health

¹¹ “African-American Doctors Say DTC Ads Raise Disease Awareness, Bolster Doctor Patient Ties,” National Medical Association, Press Release, October 29, 2005

¹² Hachette Filipacchi Media, U.S.

Migraine Headaches

“Advertisements for [product] prompted me to visit my physician to seek relief for my migraine headaches. I now take [product] and feel like I have been given my life back. I can live again instead of worrying about getting a migraine.”
Debbie P., Age 51, Painesdale, MI

Mental Health/Two Stories

“I suffered from severe depression and anxiety. I was trying to find something to even out my moods. I discussed many medications with my doctor. I had found an ad for [product] and spoke to him about it. It turned out to do miracles for me – and my children's well being – as it continued to improve my quality of life.”
Samantha J., Age 32, Bedford, TX

“My mother was very depressed and after months of being on a prescription, she was not feeling any better. I read about [product] and talked to her about getting her prescription changed. She talked to her doctor, got the new product, and we saw a change immediately.” Cindy W., Age 49, Muncy, PA

Osteoporosis

“As I was waiting for the results of my second bone density test, I remembered seeing an ad for [product] which allowed me to review the medication. Upon meeting with my doctor, it was his suggested medication, and the ad enabled me to ask questions at the time of my appointment.” Cindy H., Age 55, Geneva, NY

Industry self regulation promises to enhance pharmaceutical advertising

I want to devote a moment to an important component for improving the quality of DTC advertising. The pharmaceutical industry has undertaken a major new initiative to address public concerns about DTC advertising and to establish new industry standards for print and broadcast advertising.

Three months ago the Pharmaceutical Research & Manufacturers of America announced a program of self regulation for prescription drug advertising. Beyond just meeting the legal requirements in FDA regulations that require advertising to be accurate and not misleading and to reflect balance between risks and benefits, the principles adopted by PhRMA show that member companies are committed to delivering messages that educate patients and consumers and encourage them to seek guidance from their health care professionals.

The PhRMA guidelines are an important element in what promises to be a strong program of self-regulation. I would note the observation of Deborah Majoras, Chairman of the Federal Trade Commission, on the importance of advertising self-regulation: “[T]he FTC’s experience has been that effective self-regulation can have tremendous

benefits . . . industry-generated action can address problems more quickly, creatively, and flexibly than government regulation."

Conclusion

While offering constructive criticism over the years, FDA also has been a positive force for encouraging the use of DTC advertising to inform all Americans and particularly to reach under diagnosed and under treated Americans. The support and guidance of this agency has provided vital leadership to expand and improve advertising of prescription drugs.

Looking forward, we need to focus on the important power that information – in the form of DTC advertising – brings to improving the public health of our nation. Critics of DTC advertising raise fears of potential harm that could result from these ads, but never focus on the harm that would occur if the information were stopped – even if for only a year or two.

However when you consider that more than 62 million patients have talked with their physicians after seeing a DTC advertisement and advertising prompted 29 million patients to mention a medical condition to their physicians for the first time – it is a powerful force for promoting good health. How many of the 25 percent of new diagnoses identified in the Harvard-Harris survey would have never occurred without the prompting of an ad? I hope we never have to weigh that risk.