

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

**Direct-to-Consumer Promotion of Regulated Medical Products
Docket No. 2005N-0354**

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Comment Submitted Electronically and by Postal Mail

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Introduction

I welcome the opportunity to submit this comment in response to the Food and Drug Administration's (FDA) request for comments regarding direct-to-consumer (DTC) advertising of prescription drugs. I am a third year law student at Villanova University School of Law writing on my own behalf. As an undergraduate student at Bloomsburg University of Pennsylvania I earned a Bachelor's degree in Marketing. Though I did not pursue a career in marketing so that I could attend law school, I still have an interest in and a general working knowledge of the subject. Additionally, I attended the first part of the public hearing on this topic on November 1, 2005. I found it engaging and informative and it prompted me to write this comment.

I am also interested in this subject because I take one of the most advertised drugs today, Zoloft. I do not suffer from depression, but rather, from severe PMS. About two years ago I went to my gynecologist complaining of how bad my mood swings had become and she prescribed me Zoloft. At first I was reluctant to take it, because, from what I had learned from the advertisements, I thought that Zoloft was for treating depression. But I was not depressed; I just had out of control hormones. My doctor

finally convinced me to try it. It was amazing. My PMS completely disappeared. However, if my doctor had not talked me into trying it, I would still be suffering.

The only reason I was reluctant to try the drug was because the advertisements told me it was for depression. Had I never seen the advertisements and had simply gone to my doctor complaining of severe PMS, I would never have even considered not taking the drug she prescribed. This is one of the reasons that I believe the FDA should increase its regulation on DTC advertising, or do away with it altogether. Although I understand the benefits that DTC advertising offers, such as encouraging doctor communication, patients can realize those same benefits through highly regulated advertisements that let doctors decide what is right for their patients.

This comment will examine how the current scheme of DTC advertising is not in the best interest of consumers and how new regulations on DTC advertisements will benefit the patients. I will address two of the six issues mentioned in the request for comment. First, I will address whether changes in the requirements for disclosures of certain information in broadcast advertising could improve the usefulness of the information for consumers. Then, I will address whether current DTC promotion presents the benefits and risks of using prescription drugs in an accurate, non-misleading, balanced, and understandable way.

Changes in the Requirements for Disclosures of Certain Information in Broadcast Advertising Could Improve the Usefulness of the Information for Consumers

Rather than changing the requirements for disclosure in DTC advertisements in the direction of more disclosure, the new regulations of DTC advertisements should provide for less information presented to the consumer. Although this seems counterintuitive, in this case, less is more. Current DTC advertisements have resulted in America being a “self-medicated” society.¹ When a patient comes into a doctor’s office and requests a specific drug that he has seen advertised in the media, the doctor writes the exact prescription more than 70 percent of the time.² As a result, Americans are over-medicated. The average number of prescriptions per person in the United States increased from 7.3 in 1992 to 10.4 in 2000.³ Along with this increase in usage, Americans are also using more expensive prescriptions which are, not coincidentally, the most advertised drugs.⁴ Between 1999 and 2000 prescriptions for the 50 most advertised drugs rose six times faster than prescriptions for all other drugs.⁵

Americans do not necessarily have to pay so much for their prescription drugs. One method for keeping the costs of prescription drugs down is for doctors to prescribe

¹ Dani Veracity, *The great direct-to-consumer prescription drug advertising con: how patients and doctors alike are easily influenced to demand dangerous drugs*, News Target, at <http://www.newstarget.com/z010315.html> (last visited Nov. 25, 2005).

² *Id.*

³ *Id.*

⁴ *Id.*

⁵ *Id.*

less expensive alternative treatments. Currently, if you walk into a doctor's office and request a prescription, chances are you are going to get exactly what you asked for. However, if you simply walked into the doctor's office complaining of particular symptoms, it would be up to your doctor to decide the best way to treat those symptoms; and more likely than not, the best treatment for your symptoms would not be the most expensive.

The other method for keeping the costs of prescription drugs down for patients is to reduce the amount of money pharmaceutical companies spend on advertising of prescription drugs. In 2003, pharmaceutical companies spent over \$3 billion on DTC prescription drug advertisements.⁶ In fact, drug companies spend more on advertising campaigns than they do on the research and development of new products.⁷ In 2004, Merck spent \$160.8 million to promote Vioxx; more than any other single drug.⁸ It was also more than PepsiCo spent to advertise Pepsi or Budweiser spent to advertise its beer.⁹ As a result, the pharmaceutical industry is the most profitable industry in the world.¹⁰ Drug companies make more money than oil companies, banks, Ford, and GM.¹¹ Simply by reducing what drug companies spend on advertising, perhaps through the type of advertising the company engages in, the cost of even the newest prescription drug would decrease.

In addition to being over-medicated, Americans are improperly medicated. A result of the current scheme of DTC advertisements is that consumers only want the drug that they saw in the advertisement not an alternative that is different but perhaps safer or more effective. The problem with this is that the most commonly advertised drugs are new drugs.¹² However, when a drug is new little is known about its long-term effects.¹³ For example, consider the recent downfall of Vioxx. After Merck, the producer of Vioxx, conducted studies on the long-term effects of the drug, it voluntarily withdrew the drug from the market because of indications that it caused serious cardiovascular events, such as heart attacks and strokes.¹⁴

A new approach to DTC advertisements that would improve the usefulness of the information for consumers would be ads that alert patients to the existence of a disease and to the availability of treatment for that disease and then encourages patients to see

⁶ *Id.*

⁷ *Id.*

⁸ *Id.*

⁹ *Id.*

¹⁰ *Id.*

¹¹ *Id.*

¹² *Id.*

¹³ Erica Johnson, *Direct-to-consumer Advertising*, CBC News, at <http://www.cbc.ca/consumers/market/files/health/directads/> (last visited Nov. 25, 2005).

¹⁴ U.S. Food and Drug Administration, *FDA Issues Public Health Advisory on Vioxx as its Manufacturer Voluntarily Withdraws the Product*, FDA News, at <http://www.fda.gov/bbs/topics/news/2004/NEW01122.html> (last visited Nov. 25, 2005).

their physicians to discuss possibilities for treatment.¹⁵ Such advertisements would allow patients who did not know that they had a disease but recognized the symptoms in themselves, to seek advice from their physicians.¹⁶ Another advantage to this alternative approach to DTC advertisements is that rather than presenting a patient with a drug as a solution to their symptoms, the advertisements leave doctors the opportunity to treat the patient in the safest, most cost-effective, efficient way.

One common argument in favor of the present scheme of DTC advertisements is that the ads promote doctor-patient communication. However, the proposed alternative can achieve this same goal. When an advertisement presents a consumer with a list of symptoms of a disease and states that treatments are available, the consumer will talk with their doctor if they think they have that disease. It is not necessary to present a consumer with a particular drug in order to get them to seek help from their doctor. Most of the time, the patient visits her doctor because of the symptoms in the drug ad, not because of the drug being advertised. The only reason she specifically asks for the advertised drug is because the advertisement led her to believe that it was the only viable option available for treating her disease.

One proponent of the current scheme of DTC advertising claimed that it would be impossible for doctors to keep on top of all of the new treatments becoming available every day.¹⁷ He went as far as to propose that the patient actually knows best.¹⁸ This claim is absurd. First, it is a doctor's responsibility to keep aware of the best treatments for his patients. Second, the patient cannot possibly know what is best when she is only presented with a few options herself; the options of the highest advertised drugs.

Currently, the United States and New Zealand are the only two countries in the world that allow virtually unregulated DTC advertising of prescription drugs.¹⁹ In Canada, drug companies can advertise the name of a product or say what it treats, but cannot do both in one ad.²⁰ Adopting a similar scheme would be beneficial to the United States.

¹⁵ Michie Hunt, *Direct-to-Consumer Advertising of Prescription Drugs*, The George Washington University National Health Policy Forum 8 (April 1998), available at http://www.nhpf.org/pdfs_bp/BP_DTC_4-98.pdf, (last visited Nov. 25, 2005).

¹⁶ *Id.*

¹⁷ Johnson, *supra* note 13.

¹⁸ *Id.*

¹⁹ Barbara Mintzes et al., *How does direct-to-consumer advertising (DTCA) affect prescribing? A survey in primary care environments with and without legal DTCA*, Canadian Medical Association Journal, at <http://www.cmaj.ca/cgi/content/full/169/5/405> (last visited Nov. 25, 2005).

²⁰ Johnson, *supra* note 13.

Current DTC Promotion Does Not Present the Benefits and Risks of Using Prescription Drugs in an Accurate, Non-Misleading, Balanced, and Understandable Way

Only one in four consumers who have seen or heard DTC advertisements of prescription drugs find them to be understandable.²¹ The confusion most likely stems from the fact that the ads contain the wrong kind of information.²² The most common complaint about DTC advertisements is their shortage or complete lack of risk and side-effect information.²³ Additionally, consumers have complained that DTC ads also lack information on the potential for misuse of the drug and directions for proper use.²⁴

Although DTC television ads do present potential harmful side effects, the ads gloss over them so fast that the consumer gets the impression that the dangers are nothing to worry about.²⁵ Additionally, television ads do not list all of the potential side effects, just the most common.²⁶ Therefore, most consumers are not properly educated about the drug they are requesting. Current DTC advertisements trivialize medical treatment.²⁷ One author went as far as to claim that DTC advertisements make consumers think that buying prescription drugs is as inconsequential as buying a candy bar.²⁸

Obviously, it is not possible to effectively list every side effect of a drug in a 30-second television spot. The solution is to adopt the DTC advertising scheme proposed above. If an advertisement presented symptoms of a disease and not a drug, side effects would not be an issue. Patients would see the ad, visit their doctor, and their doctor would present them with the treatment options as well as with the benefits and risks of those options.

One author aptly summed up the issue when he said “education is not the same as advertising.”²⁹ Sixty-eight percent of Americans prefer to get their drug information from doctors.³⁰ Similarly, while watching television, Americans turn off DTC advertisements more than any other type of advertisement.³¹ Information from health professionals and consumer groups carry a different message from a company trying to

²¹ Hunt, *supra* note 15, at 7.

²² *Id.*

²³ *Id.*

²⁴ *Id.*

²⁵ Veracity, *supra* note 1.

²⁶ *Id.*

²⁷ Johnson, *supra* note 13.

²⁸ *Id.*

²⁹ Les Toop et al., *Direct to Consumer Advertising of Prescription Drugs in New Zealand: For Health or for Profit?*, Report to the Minister of Health supporting the case for a ban on DTCA 10 (Feb. 2003), available at <http://www.haiweb.org/campaign/DTCA/DTCAinNZcaseforaban2003.pdf> (last visited Nov. 25, 2005).

³⁰ *Id.*

³¹ *Id.*

sell a product.³² Additionally, a patient suffering from a disease is vulnerable to advertising that uses emotional appeal to promise relief.³³

Conclusion

DTC advertisements of prescription drugs do not properly present the risks of using prescription drugs in an understandable way. The FDA should promulgate regulations that restrict prescription drug advertisements from presenting any information beyond the symptoms of a disease. If I had seen an advertisement that presented symptoms of severe mood swings and informed me that I had a treatable condition, I would have discussed the issue with my doctor but would not have questioned her treatment method. However, because I was bombarded with Zoloft advertisements that misled me into thinking Zoloft was only for treating depression, I delayed starting treatment that ultimately helped my condition. Of course I was not faced with a life or death situation, but someone else may be. For that reason I believe the FDA needs to rehaul its current regulation of DTC advertisements to prevent any further miscommunication.

I thank the FDA for the opportunity to comment on this topic and respectfully request that it take my suggestions into consideration when deciding whether to increase or decrease the regulations on DTC advertisements. If you have any further questions please feel free to contact me at the above e-mail address.

³² *Id.*

³³ *Id.*