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September 13, 2002

**National Center for
Policy Research for
Women & Families**

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Food and Drug Administration
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Re: First Amendment Issues

To Whom It May Concern:

In response to the request for comments regarding whether the FDA's regulation of consumer advertisements violates the First Amendment and the effects of free speech on public health, the National Center for Policy Research for Women & Families is submitting the following comments.

The National Center for Policy Research for Women & Families (CPR) is a nonprofit, nonpartisan organization dedicated to providing researched-based information that can be used to improve programs and policies affecting women and families. We are concerned that consumers will be hurt if the FDA fails to adequately regulate drug advertising.

Advertising to Consumers

Direct-to-consumer advertising has increased greatly since 1997 when the FDA issued a guidance clarifying the regulations for these types of ads. Spending on direct-to-consumer advertising has trebled since that time. Obviously, a lot of money is being spent to try to influence consumers' medical treatment. Regulation of advertising to consumers is important because ads are often the major source of information consumers have about a particular product. Most consumers do not have either the time or expertise to evaluate products on their own, and so rely on the government to ensure that advertisements provide them with truthful and non-misleading information. Consumers also rely on the government to ensure that products that reach the market will be safe. Therefore, the FDA should not underestimate the importance of the need for government regulation of drug advertisements. The experience with hormone replacement therapy is one of many examples showing consumers are harmed when ads and promotional efforts provide inaccurate or misleading information.

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Studies have demonstrated that ads directed at consumers affect medical treatment. One study found that a third of consumers who had seen direct-to-consumer advertisements had gone on to speak with their doctors about the medicine advertised and of that number, 44 percent received a prescription. Retail spending on prescription drugs has doubled from 1997 to 2001. Given the extent to which advertisements can influence consumers to seek drug treatment, inaccurate advertisements could have disastrous effects on public health.

Drug companies are clearly benefiting from their increased drug sales: in 2000, profits for the pharmaceutical industry were 16 percent higher than any other major American industry and about two and a half times higher than the average profit margin for all U.S. industries. It is therefore clear that direct-to-consumer advertising is effective at generating profits for drug companies.

Unfortunately, studies also show that these ads are not effective at educating the public. Studies of older Americans have found that less than half of them believe drug ads have enough information about risks and side effects. Other studies have found that most older Americans believe that the ads failed to give them any additional information about the drug advertised or about the condition the drug treated.

Advertisements directed at consumers have also affected the practice of medicine, and not in a way that benefits consumers. Physicians who are asked for prescriptions are more likely to give them even when it is not clear that the drug is the appropriate treatment (Mintzes, 2002). The fact that patients are requesting, and receiving, potentially harmful drugs when it is not necessary or appropriate is a clear danger to public health.

Enforcement

Because consumers are influenced by ads, and physicians want to please their patients, consumers must rely on the government to ensure that the information they are getting is accurate. Unfortunately, the FDA has become increasingly inactive even while the number of drug promotional campaigns has increased. For example, enforcement actions have dropped in recent years while promotional spending rose. The FDA issued 139 warning letters in 1997, compared to 79 in 2000 and 73 in 2001.

Even when warning letters are issued, there is no way to ensure that consumers who received the misleading or incomplete information will subsequently receive accurate information. Therefore, because ads are so influential, consumers are harmed when the government fails to proactively regulate drug advertising before it influences any consumers.

Stronger regulations and enforcement are needed. For example, the *Wall Street Journal* recently reported that Allergan Inc. has told the FDA that it will not pull ads for its product, Botox, despite the fact that the agency has cited the company for making misleading statements in ads and patient materials and for providing confusing information to physicians. The agency could take the company to court, but meanwhile Allergan has continued its misleading advertising activities despite FDA criticism.

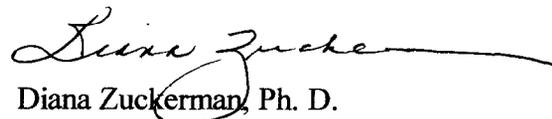
Based on available research, CPR believes that stronger regulation of drug advertisements is necessary. Given that drug advertisements have increased exponentially and that consumers rely heavily on them to provide information, and that millions of Americans are exposed to misleading ads before such ads are halted, the FDA's regulation of drug advertisements should be strengthened rather than weakened.

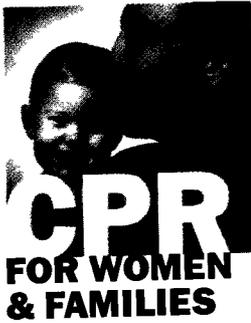
The FDA can improve its regulations regarding direct-to-consumer advertising by clearly delineating what information an advertisement must contain. Required information should include potential risks, success rates and whether any long-term safety studies were conducted. Companies should not be permitted to make claims that are not supported by conclusive research evidence. Risk information in written ads should be easy to read and in large fonts. All advertisements should be previewed by the FDA to ensure that they comply with the regulations, because once misleading information has been disseminated, it is impossible to ensure that all persons exposed to the original information receive the corrected information.

The FDA should have the authority and resources to take faster and stronger actions against companies that violate any advertising regulations. This would create a clear disincentive to make inaccurate promotions. Actions that the FDA should consider include severe monetary penalties and criminal penalties. We agree with the recommendation of the National Women's Health Network that companies that repeatedly air inaccurate or misleading ads should be prohibited from advertising.

Finally, the FDA should provide consumers with access to unbiased, understandable information about the drug on its website and in consumer guides, so that consumers have information from a source without a financial interest in promoting the product.

Sincerely,


Diana Zuckerman, Ph. D.



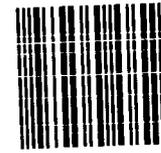
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