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# NATIONAL WOMEN'S HEALTH NETWORK

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September 13, 2002

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Dockets Management Branch  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

**RE: Docket No. 02N-0209**

To whom it may concern:

In response to the request for comments regarding the FDA's regulations, guidances, policies and practices and compliance with First Amendment case law, the National Women's Health Network and Prevention First are submitting the following comments.

The National Women's Health Network is a nonprofit organization that advocates for national policies that protect and promote all women's health and provides evidence-based, independent information to empower women to make fully informed health decisions. Prevention First is a coalition of independent health organizations that challenges the overwhelming emphasis that has been placed on long-term use of prescription drugs for disease prevention. Prevention First works to counter direct to consumer advertising of prescription drugs, especially advertisements that are false or misleading. The founding members of Prevention First are the Boston Women's Health Book Collective (Boston, MA), Breast Cancer Action (San Francisco, CA), the Center for Medical Consumers (New York, NY), DES Action (Oakland, CA), the Massachusetts Breast Cancer Coalition (Massachusetts), the National Women's Health Network (Washington, DC), and the Women's Community Cancer Project (Cambridge, MA).

The First Amendment is essential to our freedom, but it was never intended to protect the exploitation of the public's health for corporate profit. FDA's oversight of advertising and other promotional activities by companies marketing drugs and devices is of critical importance in protecting the public's health. The need for this oversight was illustrated plainly this summer in the case of hormone replacement therapy (HRT).

In July of this year, women were confronted with the news that the risks of the hormone regimens that have been prescribed for decades outweigh the benefits for healthy women. Millions of women have been taking these drugs, persuaded – by drug company ads and health care providers who had in turn been persuaded by drug company promotional campaigns – that it would protect them from age-related illnesses and concerns. Yet the research to support these claims had never been done. And when the studies were conducted, science showed that the theories about HRT's benefits which had served as the basis for the drug ads were not just

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unsupported but actually counter to the truth. HRT increased risk for heart disease, rather than preventing it as drug company materials had suggested.

The massive misinformation campaign that companies selling HRT products successfully conducted for more than 30 years has been a triumph of marketing over science. The experience with HRT is but one of many examples showing that there is a need to strengthen FDA's authority to regulate advertising and promotion of drugs and other health products.

### **Advertising to Consumers**

Since 1997 when FDA issued a guidance clarifying the regulations for drug ads, there has been a dramatic increase in direct-to-consumer advertising of prescription drug products. Spending on this form of product promotion went from less than \$800 million in 1996 to more than \$2.6 billion in 2001.<sup>1</sup> In the face of this expansion, the regulations and policies that FDA has in place regarding such ads are falling short of the goal of ensuring that consumers get adequate and truthful information about advertised products, a key responsibility of FDA.

Research shows that the ads are effective for their intended purpose which is not to educate but rather to increase sales of the products they promote. Corporate investment in direct-to-consumer promotion is having a demonstrable effect on patient behavior and attitudes as well as on spending on prescription drugs. 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 44 percent of them received a prescription.<sup>2</sup> It should be no surprise, therefore, that retail spending on prescription drugs was \$155 billion in 2001, almost double what it was in 1997.<sup>3</sup> And drug companies are reaping huge benefits from these sales. In 2001, pharmaceutical industry profits were 18.5% of revenues, significantly outperforming all other industries in the country.<sup>4</sup>

It is clear that direct-to-consumer advertising is effective at generating profits for drug companies. The next question to consider is whether it might also be effective in educating the public and improving the public health. Unfortunately, the research shows that this is not the case, and the public is on the losing end of direct-to-consumer advertising. Drug ads do little to improve public understanding of the risks and benefits of the products they promote. A study conducted by the AARP Public Policy Institute of the impact of direct-to-consumer printed advertising as a source of information for consumers about medications found that less than half of consumers age 60 and older say that the ads usually contain enough information about risks and possible side effects.<sup>5</sup> Another study found that after viewing television prescription drug ads, almost 60 percent of people said they knew little or nothing more about the medicine advertised, and 70 percent said that they knew little or nothing more about the condition the advertised product was intended to treat.<sup>6</sup>

Not only are the ads not improving public health by educating consumers, they are having a negative effect on public health by leading to unnecessary and potentially inappropriate prescription of drugs. A study of doctors found that physicians who are asked for prescriptions are more likely to give them even when they express ambivalence about whether it is the appropriate medical decision.<sup>7</sup> These doctors may be responding to real economic pressure in making their decisions. Another study found that 15 percent of patients would consider switching physicians if their doctor refused a request for a prescription medication that they had seen advertised.<sup>8</sup>

### **Pushing Drugs to Doctors**

The advertising of drugs to consumers is only a small piece of the promotional campaigns conducted by pharmaceutical companies. Health care providers are under daily assault by drug promoters who visit them in their offices and exercise influence over virtually every stage of medical education and every piece of information that prescribers receive about drug products. Drug companies spent more than \$16 billion in 2001 on efforts to influence physicians.<sup>9</sup>

Promotional campaigns to health care providers are also regulated, although more loosely, by FDA. But just as they do with direct-to-consumer advertising, FDA's regulations, policies and practices for oversight of promotional materials to health care providers are falling short in protecting the public. Well-meaning doctors are misled by advertising messages carefully crafted to look like unbiased, scientific information. And the ads that companies target to prescribers are not the only source of influence. Through drug company-sponsored continuing medical education seminars and programs at teaching hospitals, drug companies gain influence over almost all the information that health care providers receive. FDA is responsible for ensuring that these efforts don't harm the public by spreading false, misleading and confusing information, and the agency is failing in this duty.

The example of HRT is once again useful for understanding how existing regulations and policies are deficient.

For decades, drug companies spent millions of dollars on campaigns which distorted available scientific evidence about HRT, successfully convincing health care providers that hormones would solve the menopause complaints and age-related concerns of their patients. Wyeth Ayerst ran ads in a publication for primary care physicians in 1998 with the headline "If your menopausal patients have new questions about menopause...consider the entire body of evidence." This ad was illustrated with a drawing of a woman's body with lines pointing to the various body parts that HRT was alleged to help.<sup>10</sup> The company was blurring the facts about the science, and giving doctors the impression that "the body of evidence" supported HRT use. But because the company carefully walked the line of existing FDA policy, the ad didn't rise to the level of an enforcement action against Wyeth by FDA. On top of misleading ads like that one, manufacturers of HRT products also paid for research that would make their drugs look good and

then paid to disseminate the results to doctors. They published paid supplements in medical journals that looked just like the peer-reviewed studies in the journals themselves. The companies spent millions of dollars every year on their efforts to make doctors believe that the theories about all the good things that HRT might do, were supported by science. All of this is allowable under current FDA regulations.

Another example of the inadequacy of existing regulations, policies and practices is provided by the repeated violations by Eli Lilly, manufacturer of the drug raloxifene. Raloxifene has been approved for treatment and prevention of osteoporosis, but Lilly has been promoting it with physicians for prevention of breast cancer. FDA enforcement was apparently inadequate to prevent this violation since a Lilly competitor sued the company in federal court in 1999 for improper promotion, and there is an ongoing investigation by the Justice Department's Office of Consumer Litigation into the marketing of the drug.<sup>11</sup>

#### **Less Enforcement When More is Needed**

While promotional campaigns for prescription drugs have proliferated, FDA's oversight has withered. For example, in the area of direct-to-consumer drug advertising, enforcement actions have dropped off even while spending has exploded. In 1997, FDA issued 139 warning letters and notices of violation. In 2000, it issued only 79, and in 2001, only 73.<sup>12</sup> Even when the FDA does issue a warning letter, the action is inadequate to address the problems created by misleading ads. Once a bad ad has aired, the genie is out of the bottle. There is no way to ensure that consumers who received the misleading or incomplete information will get corrected and complete information about the drug. As the law stands now, companies have little incentive to produce accurate advertisements.

In fact, companies are starting to directly defy even those limited and weak enforcement actions that FDA does attempt. Earlier this month, *The Wall Street Journal* reported that Allergan Inc., the manufacturer of Botox Cosmetic wrinkle injections, has told the FDA that it will not pull ads for its product despite the fact that the agency has cited the company for making misleading statements in its ads and patient materials and for providing confusing information to physicians.<sup>13</sup> If the company continues to disregard FDA, the agency has the power to send a more formal warning letter and, if necessary, to take the company to court. But it is as yet unclear if FDA will do either of those things, and in the meantime Allergan can continue its misleading and confusing advertising campaign.

#### **Recommendations for Stronger, Stricter Oversight**

FDA's current regulations, policies and practices governing promotion of products are not sufficient to ensure industry's compliance with the intent of existing those regulations, or more importantly, to ensure that consumers receive full and correct information about promoted products. Given the prevalence of advertising and promotional campaigns to both health care providers and consumers, the evidence that direct-to-consumer advertising does not educate the public or improve the public health and the widespread abuses by companies in promoting their

products, the National Women's Health Network and Prevention First urge FDA to enact new and stronger regulations in this area.

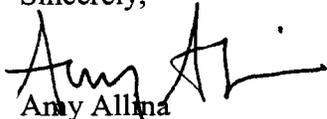
\* FDA should issue regulations specifically for direct-to-consumer advertising, to establish clear rules for what is and is not permitted.

\* FDA should require pre-view of ads; the current system relying on self-restraint by drug manufacturers and an underfunded system of FDA warning letters, sent after offending advertisements are aired or published, is inadequate.

\* FDA should take stronger action against violators including routinely requiring corrective ads and should take a strict line with repeat violators including imposing monetary penalties and instituting a three strikes policy which prohibits advertising by companies which repeatedly air inaccurate or imbalanced ads.

\* FDA should provide consumers with useful information. This should be provided by FDA on the Internet, in inserts included with products and elsewhere. The information should be written in easy-to-understand language, and include information on success rates, and comparative efficacy and pricing data. This is how consumers' right to know should be satisfied, not through promotional advertisements that are designed to sell products.

Sincerely,



Amy Allina  
Program Director  
National Women's Health Network

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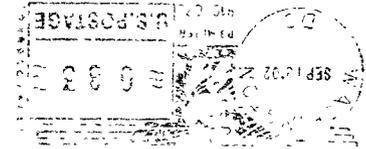
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