

**BREAST
CANCER
ACTION**

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April 27, 2004

Division of Dockets Management (HFA 305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket Number 2004D-0042

“Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertising” and “Help-Seeking’ and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms”

To public health organizations like Breast Cancer Action, the FDA’s proposed guidelines leave the distinct impression of Isaac Stern playing a Stradivarius while the capitol of Italy goes up in flames. The premise of the guidelines seems to be that advertising of drugs to consumers is a good thing, and the mission of the FDA is simply to make it better. Despite that premise, the guidelines call for assistance in helping the FDA learn what works and what does not in drug advertising. The FDA should know the answer to that question before it issues guidelines on what is acceptable advertising. As far as Breast Cancer Action can tell, drug advertising does not work for consumers.

Particularly striking are statements in the guidelines that suggest that the best source of comprehensive drug information is the drug companies. (See lines 118 to through 121 of the Print Advertisement guideline and lines 156 through 169 of the “Help-Seeking” Guidelines.) The failure of these companies to provide clear, balanced information on the benefits and risks of their products has led to calls in other countries to either ban direct-to-consumer advertising altogether or to more stringently enforce existing bans.

Moreover, the guidelines seem designed to encourage drug and device firms to engage in more adventurous advertising to consumers, while ignoring the painful reality of the lack of sufficient FDA resources to effectively monitor such ads.

Under the proposed guidelines, the public would be subject to ads that fail to convey meaningful information about the effectiveness of the promoted drugs. While the guidelines fail to address effectiveness, consumers cannot understand a drug’s benefits and risk unless the issue of effectiveness is addressed in a standard way with reference both to pre-approval clinical trials and absolute (as opposed to relative) risk and benefit information. Where proof of efficacy exists solely for surrogate endpoints, such as a drug proven solely to produce tumor regression, the manufacturers should be required to explain in their ads that tumor regression is not the same as proof of the drug’s ability to extend the life of a cancer patient.

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The needs of consumers also dictate that the worst and most common side effects for all drugs should be listed in the body of the ads.

Where help-seeking ads are concerned, the FDA should prohibit any advertising that promotes testing for health conditions, since such ads inevitably encourage drug interventions even when the test's effectiveness is, at best, marginal.

Respectfully submitted,

A handwritten signature in cursive script that reads "Barbara A. Brenner". The signature is written in black ink and includes a long, sweeping horizontal line at the end.

Barbara A. Brenner
Executive Director

Breast Cancer Action is national grassroots education and advocacy organization whose mission is to inspire and compel the changes necessary to end the breast cancer epidemic. As a matter of policy, in order to avoid the fact or appearance of a conflict of interest, Breast Cancer Action does not accept funding from any pharmaceutical or biotech company.