

Collaborating with Stakeholders
Safe Use of Products -- Risk Management
Presentation to the FDA
Thursday, March 23, 2000

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Thank you for the opportunity to address you again, this time on risk management as it relates to patient/consumer education on the safe use of products. As the representative of an education and advocacy organization that focuses on breast cancer, I am well aware of the challenges of educating the public about risk. In the context of safe product use, the greatest challenge that we now face in this arena is direct-to-consumer advertising of pharmaceuticals. The example of tamoxifen is telling for what it indicates we should – and should not – be doing to educate the public about both the risk of illness and the safety of drugs.

As you know, I am the Executive Director of Breast Cancer Action. We have been following tamoxifen since the organization was founded in 1990, and have been concerned about the use of the drug in healthy women since that use first began to be studied in the National Cancer Institute's Breast Cancer Prevention Trial. We opposed the FDA's approval of a new label permitting the marketing of tamoxifen to healthy women, and our fears are being borne out with every passing day.

AstraZeneca, the manufacturer of tamoxifen, is engaged in a huge marketing campaign to get women to ask their doctors about Nolvadex. This direct-to-consumer advertising is largely in print, though some television advertising has been done. The first print ad, which appeared in women's health magazines, was the subject of a detailed cease and desist letter from the FDA in January, 1999. Since then, the company has developed both new print ads and television ads that are equally problematic, but more subtle.

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The print ads for Nolvadex are misleading, but not so Jane Doe consumer would notice. They generally feature a young woman, though young women are at considerably lower risk of developing breast cancer than older women. The ads encourages women to know their risk assessment number, though the risk assessment test is one that has been seriously criticized because it omits key information. And the ads heavily imply that a risk score of 1.7 makes you a good candidate for Nolvadex, even though, in the study sited in the ad and on which the new label was based, less than one quarter of the participants had risk scores lower than 2.0. The numerous dangers of the drug appear mostly in fine print.

In the face of this advertising, educating the public about the true risks and benefits of tamoxifen takes far more resources than any one non-profit organization can muster. This is particularly so because so many cancer organizations receive funding from AstraZeneca and are consequently unwilling to put all the facts on the table. Some of them, in fact, help the manufacturer by promoting tamoxifen, without any attempt to balance the one-sided information that AstraZeneca provides.

The public's health requires that the FDA take whatever measures are necessary to stop the direct-to-consumer marketing of powerful pharmaceuticals. Risk management will be a meaningless phrase so long as drug manufacturers can promote their products directly to the public. Breast Cancer Action believes that until direct marketing ends, the FDA should require pharmaceutical companies to submit all advertisements for approval *prior* to their dissemination. To do otherwise leaves the public in the untenable and hopeless position of informing itself about the benefits and risks of powerful drugs.

Collaborations between the FDA and the pharmaceutical industry will not advance the cause of safe product use. In the area of risk management, the FDA must find and work with organizations that are independent of the profit motive that drives drug marketing.

Thank you for your attention.