

Sunday, May 20, 2007

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD20852

**RE: Docket No. 2007D-0101**

**Comments submitted by Breast Cancer Action and FDA Patient Representative Natalie Compagni Portis regarding proposed guidance on Procedures for Determining Conflict of Interest and Eligibility for Participation in FDA Advisory Committees**

FDA's proposed guidance on procedures for determining conflict of interest and eligibility for participation in the agency's advisory committees represents a welcome strengthening of measures to assure the public's faith in the FDA's decision-making process. Given the need -- recognized in the draft -- to bolster public faith in the FDA's function, Breast Cancer Action strongly believes that the guidance should be binding on the agency.

The comments that follow about the contents of the guidance focus on the need to make the rules function to address the concerns posted by conflicts of interest among advisory committee members. The proposed guidelines appropriately state the intent to limit participation when there is even the appearance of a conflict of interest. We believe that the draft guidance needs to be changed to give meaningful impact to this intention.

The goals and principles of the guidance as drafted are undermined by the high level set for the amount of a disqualifying financial interest. If the FDA's purpose is to avoid having financial conflicts of interest influence or appear to influence committee recommendations, the \$50,000 minimum disqualification level is too high. The disqualifying level of financial interest should be \$1000. And if an individual has a level of financial interest that is sufficiently high to create an apparent or actual conflict of interest, that fact should disqualify the individual from committee participation. The fact of a conflict -- not its degree -- should be disqualifying.

If the financial interest is sufficient to disqualify someone from active participation in a committee meeting, then non-voting participation should also be prohibited, since comments by committee members also have the potential to influence decision-making, even when the person making the comment is barred from voting.

The algorithm developed for evaluating the existence and extent of a conflict of interest appropriately looks at financial interests held by an individual in the preceding 12 months, not just currently. However, the proposed exemption from the financial interest calculation of securities interests not in excess of \$15,000 effectively makes the already-too-high \$50,000 minimum disqualification level \$65,000. This exemption should be eliminated.

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The need to assure that the FDA's decision-making process is free of actual or perceived conflicts-of-interest has become more pressing as the companies whose products are subject to agency approval become increasingly responsible for the FDA's funding. Breast Cancer Action's comments on the proposed guidelines are intended to make the guidelines reflect the agency's commitment to decisions uninfluenced by the financial interest of those who appear before it.

Respectfully submitted,

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*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 companies.*