

May 21, 2007

Documents Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket 2007D-0101

The Academy of Managed Care Pharmacy (AMCP) is pleased to provide comments to the Food and Drug Administration (FDA) on the March 2007 draft guidance titled "Guidance for the Public, FDA Advisory Committee Members, and FDA Staff: Procedures for Determining Conflict of Interest and Eligibility for Participation in FDA Advisory Committees." This draft guidance describes the factors and analyses that should be used in considering whether an advisory committee member has a potential conflict of interest and whether participation in a meeting is appropriate.

AMCP is a national professional association of pharmacists and other health care practitioners who serve society by the application of sound medication management principles and strategies to achieve positive patient outcomes. The Academy's 5,300 members develop and provide a diversified range of clinical, educational and business management services and strategies on behalf of the more than 200 million Americans covered by a managed care pharmacy benefit.

The Academy understands that the FDA relies on the independent expert advice to the agency on scientific, technical, and policy matters related to the development and evaluation of FDA-regulated products. The Academy further understands that the FDA is committed to adhering to the laws and regulations governing the process for selecting advisory committee members. As described in the notice concerning the draft guidance, FDA staff has found it difficult to achieve consistent results that the public could readily understand because of the complexity and discretionary elements in the current system.

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As explained in the draft guidance, advisory committee members will be considered under a more stringent policy.

First, if an individual has qualifying financial interests whose combined value exceeds \$50,000, she generally would not participate in the meeting, regardless of the need for her expertise. Second, if the disqualifying financial interests are \$50,000 or less, the individual would be eligible to participate only if she met the applicable statutory standard for participation; e.g., the need for her services outweighs the potential conflict. Third, even where the standard for participation is met, the individual's participation would be limited to non-voting. Fourth, FDA intends to generally limit participation in certain cases where there may be a perception of a conflict of interest, even though full participation would be permitted under the applicable statutes.

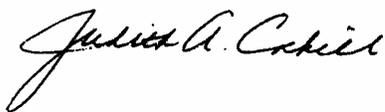
The Academy commends the FDA for issuing a guidance that greatly simplifies the process of defining conflict of interest as it relates to FDA advisory committee members. In addition, as stated in the draft guidance, this policy will reduce variability in determining who may participate in FDA advisory committee meetings and promote consistency in the advisory committee process. AMCP agrees that the simplified approach is a step toward enhancing the public's understanding of the selection process.

AMCP has two specific areas in which it will comment. The first is regarding the financial interests of Advisory Committee members. The Appendix specifies that any financial interest in the preceding 12 months if presently held would be a disqualifying financial interest. The Academy suggests that this criterion should use a look-forward perspective as well, to include possible or anticipated future research grants, consulting or other work for hire.

The second area is the importance assigned to financial interests. There is no differentiation of the importance of financial interests in the guidance; for example, \$20,000 in direct consulting/speaking fees could be worth more to an individual than \$100,000 in a research grant in which the person is a co-investigator or researcher. The Academy believes the FDA should account for both the source of the financial interest as well as the amount.

AMCP appreciates the opportunity to comment on this extremely important issue. If you have any questions, please contact me at (703) 683-8416 or at jcahill@amcp.org.

Sincerely,

A handwritten signature in cursive script that reads "Judith A. Cahill". The signature is written in black ink and is positioned above the typed name and title.

Judith A. Cahill, CEBS
Executive Director