

May 21, 2007

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

**Re: Docket No. 2007D-0101, OC 200782.**

Dear Sir/Madam:

Eli Lilly and Company (“Lilly”) appreciates the opportunity to comment on the “Draft Guidance for the Public, FDA Advisory Committee Members, and FDA Staff of Procedures for Determining Conflict of Interest Eligibility for Participation in FDA Advisory Committees (“Draft Guidance”). Lilly supports the comments submitted by the Pharmaceutical Research and Manufacturers of America (PhRMA) on the Draft Guidance. In addition, we offer the following comments:

- Lilly agrees with FDA’s stated goals of simplifying the eligibility assessment criteria for advisory committee participation, increasing the transparency, clarity, and consistency of the advisory committee process and enhancing public trust in this process. However, we believe an equally important goal should be to facilitate participation by an adequate pool of scientific experts to support the critical public health function of these committees. In this regard, Lilly is concerned that the Draft Guidance may prove excessively rigid in its application, restricting the participation of those most qualified to serve. This result also would be directly contrary to the Agency’s explicit desire to foster effective collaboration among government, academia, and the private sector via programs such as the Critical Path Initiative.
- The need for advisory committee members with specialized expertise will likely increase given trends in pharmaceutical development such as pharmacogenomics and tailored therapy. These trends make it even more important that the Draft Guidance avoid unduly restricting participation of potential advisory committee members.
- The Draft Guidance provides for certain advisory committee members who would “participate but not vote.” On this point, the Draft Guidance should clarify that such members are entitled to fully participate (other than voting) in the advisory

committee meeting. In other words, their non-voting status should not disqualify them from offering their opinion during the deliberation process prior to the vote.

- In addition to the above comments on the Draft Guidance, we believe it would be important for FDA to consider ways of objectively monitoring the advisory committee process and its effectiveness. A simple accounting of rosters might be collected and maintained, enabling an assessment of committee readiness via the proportion with a full complement of qualified members. The number of vacant positions could be monitored, along with the time taken to fill them. An assessment, through periodic surveys, of the qualifications of advisory committee members and of the quality of decision-making, would be useful. While such surveys would be challenging to design and conduct, their results would enable the impact of the Draft Guidance and future modifications to the advisory committee process to be assessed based on tangible evidence rather than on perceived or presumed needs.
- The FDA should consider what measures beyond simplified conflict of interest guidance might strengthen the advisory committee process. For instance, increased rigor in training of advisory committee members would be welcome, particularly training in the fundamentals of drug regulation.

In summary, Lilly offers these comments on the Draft Guidance to help ensure that the advisory committee process maintains the scientific capability necessary to provide expert advice to FDA on increasingly complex and specialized matters of science and policy. We appreciate your consideration of these comments.

Sincerely,



ELI LILLY AND COMPANY

Jennifer L. Stotka, M.D.  
Vice President, U.S. Regulatory Affairs