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May 21, 2007

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

Re: Docket 2007D-0021

The National Health Council is pleased to present comments on the Food and Drug Administration's draft guidance entitled, "Guidance for the Public, FDA Advisory Committee Members, and FDA Staff: Procedures for Determining Conflict of Interest and Eligibility for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," dated March 2007.

The Council commends FDA for taking steps to more fully address concerns regarding potential conflicts of interest for advisory committee members.

In every aspect of the FDA's broad mandate, from human and veterinary drugs, biological products, medical devices and food, advisory committees play a vital role. Maintaining credibility with the public is crucial to the agency's effectiveness. The integrity of advisory committee recommendations to the FDA should in no way be undermined by real or perceived conflicts of interest of individual committee members. This guidance helps clarify the steps and criteria FDA will apply to future advisory committee participation, and provides the public with a better understanding of how such participation is determined.

Often times, the advisory committee hearings are the most public aspect of the FDA's regulatory decision making. Patients in particular and consumers in general should trust that individuals serving as special government employees have been nominated and fully vetted based upon their expertise and their unbiased, independent point of view regarding the product and sponsor before the committee.

While the National Health Council welcomes stricter guidelines for determining participation in FDA advisory committees and the issuance of waivers, we are concerned that imputing the financial interest criteria to "an officer, director, trustee, employee or general partner" of nonprofit organizations—such as the patient groups we represent—potentially may prohibit well-qualified individuals from service. We believe advisory committee participation should be based on the individual's financial interest and not the organization or institution with which he or she is affiliated.

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The National Health Council's membership includes many advocacy organizations such as the Epilepsy Foundation and the Alpha-1 Foundation. These organizations range in size with respect to their membership, staff, and overall budget. Often times, nonprofit groups representing smaller patient communities have fewer scientific and medical experts from which to draw upon for leadership positions. Imputing the financial interests of the organization upon any current or prospective office holders for the organizations could not only bar many well-qualified experts from serving on FDA advisory committees, but it could also have a chilling effect upon our members ability to engage such physicians and researchers in their respective patient advocacy organizations.

Furthermore, the Council recommends that for advisory committees in which the patient perspective is important for deliberations and decision-making, the patient representative be deemed a special government employee subject to the new conflict of interest criteria, and serve as a voting member of the committee. The Council recognizes that the roles of representative members and special government employees serving on advisory committees are viewed differently. Special government employees are appointed to provide advice on the basis of their best judgment while representatives are considered to "present the views of a private interest."¹

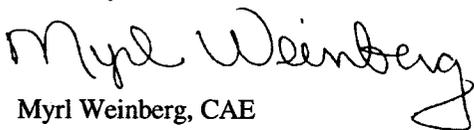
Many people living with chronic conditions or disabilities are forced to become experts in their own right, navigating the health care system and advocating for their own care and treatment. To relegate patients to a nonvoting status on advisory committees convened to address the approval of new treatments or new indications impacting their personal health and that of their patient community is imprudent. Their perspective and best judgment should be fully considered and valued in the context of advisory committee deliberations, recommendations and votes.

Finally, the Council commends the FDA for posting on its website a consolidated list of vacancies on the current advisory committees. This makes it easier for individuals and nonprofit health groups to more easily identify the openings for which qualified people could be nominated. Ensuring that these positions are filled in a timely manner expands the pool of potential members eligible to serve and further instills integrity and independence in the FDA's decision making process.

The National Health Council encourages the FDA to reconsider its guidance to reflect these recommendations and welcomes the opportunity to continue working with FDA on these regulations. We would be happy to meet with you regarding any of these comments.

You may reach me on my direct, private line (202) 973-0546 or via e-mail at mweinberg@nhcouncil.org.

Sincerely,



Myrl Weinberg, CAE

¹ *Federal Advisory Committees: Additional Guidance Could Help Agencies Better Ensure Independence and Balance*; GAO-04-328, page 18; Available at: www.gao.gov/cgi-bin/getrpt?GAO-04-328.