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Joan Claybrook, President

August 31, 1998

Jane Axelrad
Associate Director for Policy
Food and Drug Administration
Center for Drug Evaluation and Research
1451 Rockville Pike, Rm. 6027
Rockville, MD 20852

Dear Ms. Axelrad:

We are writing in regard to our recent discussions concerning consumer representation on the Pharmacy Compounding Advisory Committee and, more specifically, the distinction between a representative from a consumer organization and a consumer representative nominated by the FDA's Consumer Consortium.

As discussed in more detail below, the Food and Drug Administration Modernization Act of 1997 (FDAMA) requires that one member of the Pharmacy Compounding Advisory Committee be a representative from a consumer organization. We believe that the person selected by the FDA from the nominees put forward by the Consumer Consortium does not qualify as a representative of a consumer organization. Although you said, when we spoke, that the person selected was a representative of the Consumer Consortium, the Consortium is an advisory body to the FDA that helps the agency evaluate consumer representatives. The Consumer Consortium is not a "consumer organization."

1. Background

Each FDA advisory committee or scientific advisory panel has as a member a "consumer representative." For many years, the FDA has filled that position by seeking nominations from the Consumer Consortium.

In regard to the Pharmacy Compounding Advisory Committee, the Consumer Consortium put forth to the FDA three people for consideration as "consumer representative." The FDA chose one of the people. This scenario is typical of how a

Ralph Nader, Founder
1600 20th Street NW • Washington, DC 20009-1001 • (202) 588-1000

"consumer representative" to other FDA advisory committees is chosen.

Section 127 of FDAMA requires that the Pharmacy Compounding Advisory Committee include a representative from consumer organizations. The language is as follows:

> The advisory committee shall include representatives from the National Association of Boards of Pharmacy, the United States Pharmacopeia, pharmacy, physician, and consumer organizations, and other experts selected by the Secretary.

The person chosen as the consumer representative to the Pharmacy Compounding Advisory Committee is a nurse who has no apparent connection to any "consumer organization."

2. FDAMA Differentiates Between a Representative from Consumer Organizations and a Consumer Representative

The language of FDAMA clearly distinguishes between a "consumer representative" and a "representative[s] from. . . a consumer organization."

First, Section 120, which establishes the requirements for scientific advisory panels, requires that each panel include "a representative of consumer interests." The fact that Congress required in Section 120 that every scientific advisory committee have a "consumer representative" and in Section 127 required that the Pharmacy Compounding Advisory Committee have a "representative . . . from a consumer organization" strongly suggests that Congress intended the two terms to have two different definitions.

Similarly, Section 120 also states that "consumer organizations [along with other groups] shall be afforded an opportunity to nominate individuals for appointment to the panels." The fact that Congress used both the term "consumer representative" and the term "consumer organizations" in the same section again suggests that the two terms are not synonymous.

Accordingly, the requirement that the Pharmacy Compounding Advisory Committee have a representative of a "consumer organization" does not merely repeat the general requirement that each committee have a "consumer representative."

3. The FDA Consumer Consortium is not a Consumer Organization

The FDA Consumer Consortium is a coalition of groups that consists of individuals from national and community-based organizations. The Consortium is not a "consumer organization" for a number of reasons.

First, the FDA's Office of Consumer Affairs manages and convenes Consumer Consortium meetings. The Consortium is thus a quasi FDA advisory body.

Second, the current roster of the Consumer Consortium includes not only representatives of consumer organizations but also representatives of professional trade organizations that are not and do not purport to be consumer organizations.

Third, the Consumer Consortium's only function is to assist the FDA in evaluating potential consumer representatives.

Accordingly, the person chosen as the consumer representative to the Pharmacy Compounding Advisory Committee does not represent a consumer organization, simply because she is considered to represent the Consumer Consortium.

4. Conclusion

We recognize that Section 127 is a highly charged issue and that the Agency is under tremendous pressure to meet a number of legislated deadlines contained in FDAMA. One the other hand, we hope that the FDA is aware that consumer organizations with their limited resources have also been under pressure to comment on numerous aspects of FDAMA. We know that you have finalized your selections for members of the advisory committee, and we regret that we did not focus earlier on Section 127's clear requirement of a representative from consumer organizations. Nonetheless, we believe that the statute mandates that such a representative be placed on the committee.

Moreover, we are concerned that the consumer perspective be adequately represented on this committee for two reasons. First, there is little public awareness that pharmacists can produce, in unregulated manufacturing facilities, products that have not been shown to be safe and effective. Second, consumers are the only group whose safety is at risk from products that are manufactured and sold by pharmacists that have not been shown to be safe and effective and are produced in unregulated facilities. For these reasons, FDA's compliance with this statutory requirement is very important.

Although, as you know, we have consulted our lawyers on this matter, it is our preference not to litigate. Rather than proceeding through the courts, we urge the FDA voluntarily and immediately to correct this situation. We believe that this situation arose inadvertently, but, now that the matter had been brought to the FDA's attention, FDAMA requires that it be corrected.

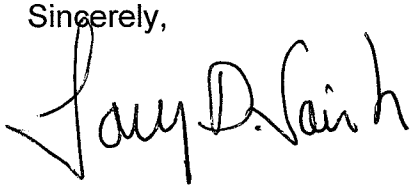
This matter also raises the broader issue of the role of the Consumer Consortium and membership on FDA advisory committees for representatives of consumer

organizations. The FDA is under tremendous pressure to approve new drugs and medical devices, and because of the potential for these products to have a negative impact on the public's health -- if wrongly approved -- it is of utmost importance that consumers are truly represented on advisory committees. Unfortunately, the current roster of the Consumer Consortium and the current process do not guarantee this result. Rather, "consumer representatives" are not infrequently health professionals or other individuals without a connection to, or history of, representing consumer interests, but were nominated as a result of the composition of the Consumer Consortium. Although such individuals may make useful contributions to the committees on which they serve, the title "consumer representative" is meaningless if almost anyone can be deemed to fill that role.

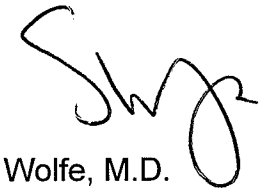
We ask that FDA policies and procedures clearly articulate that the role of Consumer Consortium is to select consumer representatives for advisory committees and that consumer representatives must have a connection to consumer organizations or a history of consumer advocacy.

We hope that both these matters can be resolved amicably and look forward to your response.

Sincerely,



Larry D. Sasich, Pharm.D., M.P.H., FASHP
Public Citizen's Health Research Group



Sidney M. Wolfe, M.D.
Director
Public Citizen's Health Research Group

cc: Michael A. Friedman, M.D.
Janet Woodcock, M.D.
Ronald Wycoff, M.D.
David Horowitz
Charles Gaylord