

99N-1174

**AARP TESTIMONY FOR FDA HEARING ON DIETARY SUPPLEMENTS**  
**June 9, 1999**

4260 '99 IN 21 10:20

Good afternoon. My name is Richard Johnson, and I am the AARP Delaware State President. AARP is interested in the regulation of dietary supplements because so many of our members, and older persons in general, use supplement products. In recent years, we have commented on FDA proposals regarding general regulation of supplements and of claims made on product labels.

At the outset, we'd like to commend FDA's work in standardizing the labels of supplements. Clear, readable information on product labels about the nutrient content of supplements and supplement ingredients, as well as uniform standards for claims made about these products, provide consumers with the information they need when choosing supplement products to improve their health.

Ironically, what consumers are not getting is assurance that the products they are using are safe. Without proof that these products are safe, the supplements that people are taking to improve their health may make them sick, or in some rare instances, even kill them.

We believe that the agency's number one priority in the area of supplement regulation should be to ensure the safety of these products. We understand that the Dietary Supplement Health and Education Act significantly hampers FDA's ability to remove dangerous supplements from the market. We also recognize that the agency has limited resources to dedicate to this issue. However, we urge the agency to think creatively about what it can do to address supplement safety.

99N-1174

183

One of the major obstacles in this area is the lack of scientifically sound research on supplement safety. There has been some research conducted on the safety of certain dietary ingredients -- in particular vitamins and minerals. In addition, other substances have a long history of safe use. However, research is needed on many other dietary ingredients. Without a requirement that FDA review and approve supplements before they are marketed, there is no reason for manufacturers to conduct this research. Further, since so many dietary ingredients cannot be patented, there is no guarantee that a manufacturer can recoup the costs of any safety research.

Given the limited research funds that FDA currently has at its disposal, it should consider some other ways to raise the necessary research funds. One possible source could be a user fee program; every manufacturer of dietary supplements could be assessed an annual fee based on annual sales or some other appropriate criterion. The monies collected would be distributed as research grants.

Under such a program, the agency could establish an advisory council to develop research priorities. One issue of concern to our members is the possibility of serious interactions between certain supplement products and prescription medicines.

Implementing a user-fee safety research program may be challenging however. Some interests may believe it more appropriate to implement such research through the National Institutes of Health (NIH). AARP urges the agency to work with other entities within the Department of Health and Human Services, like NIH, and with Congress, the supplement industry, and interested consumer groups like AARP, to develop and implement a supplement safety research program.

A second issue of concern to us is the problem of product classification. A product's labeling standards and safety requirements depend on whether it is classified as a "drug", a "food," or a "dietary supplement." The lines between these classifications are blurry to begin with, and are made even more unclear by products that cross the lines of definition. For example, "Benecol" and "Take Charge," are two margarine products that contain an added substance which lowers cholesterol. Calling these products something else -- "functional foods" or "nutriceuticals"-- only confounds the confusion. We are concerned that manufacturers may be classifying their products to ensure that they are subject to the least burdensome regulatory requirements. AARP believes that FDA must examine this issue and develop an approach to ensure that products are appropriately classified and conform to proper standards for that assigned classification.

Finally, we would like to mention our concerns about the efficacy of supplement products. If sufficient funds were available, we would like both the safety and efficacy of supplement products to be researched. Some of this research is already being done. For example, the Office of Complementary and Alternative Medicine at NIH is currently funding research, in conjunction with the National Institute on Aging, on the effect of ginkgo on memory. Clearly, more of this research needs to be conducted.

At the same time, we believe that the agency could be doing a better job of reviewing the claims about a product's efficacy that appear on supplement labels to determine if there is sufficient scientific support for them. Of particular interest to AARP members are the claims made about products marketed to older persons -- such as those that

claim to improve memory, promote prostate health, and reverse the aging process. Our concern is not just that these products may be worthless, but also, that they may not be harmless. Such claims may lead a person to forego proven treatments and select alternative remedies that are based on unsubstantiated promises.

AARP appreciates the opportunity to present our views on an FDA approach to supplement regulation. We would welcome an opportunity to participate in the development of a sound regulatory system that protects consumer health and safety in this rapidly expanding area of health promotion products.