

# National Organization for Rare Disorders, Inc.®

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...out of the darkness,  
into the light...®

## Member Organizations:

Alliance of Genetic Support Groups  
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Williams Syndrome Association  
Wilson's Disease Association

## Achieving Effective Regulation of Dietary Supplements Under the Dietary Supplement Health and Education Act

Statement of  
Michael S. Langan  
Health Policy Advisor

National Organization for Rare Disorders, Inc.

Before the

Center for Food Safety and Applied Nutrition  
U.S. Food and Drug Administration

July 20, 1999  
Oakland, California

## Associate Members

Aicardi Syndrome Newsletter, Inc.	Arc of Ohio	Family Caregiver Alliance	National Coalition for Research in Neurological & Communicative Disorders	Recurrent Respiratory Papillomatosis Foundation	Washington State Parents for Vocational Education (PAVE)
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99N-1174

Dedicated to Helping People with Orphan Diseases

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Good morning, my name is Michael Langan. I serve as the health policy advisor to the National Organization for Rare Disorders, known by many simply as "NORD." Thank you for allowing us this opportunity to assist the FDA in developing an overall strategy for achieving effective regulation of dietary supplements under the Dietary Supplement Health and Education Act of 1994.

NORD is the consumer federation of more than 140 voluntary health agencies and thousands of individuals dedicated to the identification, treatment, and cure of rare "orphan diseases." We are the coalition that worked for the passage of the Orphan Drug Act of 1993. On behalf of over 20 million Americans suffering from any one of more than 6,000 rare diseases, we continue to advocate for and monitor the development of treatments that would not be developed without the incentives of this landmark legislation.

Many Americans afflicted with serious and often life-threatening rare disorders have valid medical need for products that are not available for sale as pharmaceuticals, but are only available as nutritional supplements. Because nutritional supplements are unregulated, we are very concerned about the lack of quality of these products and the absence of uniform standards promising that every pill or tablet contains the exact amount of active ingredients specified on the label.

One hundred years ago patent medicines sold in the United States claimed to cure every malady known to man from arthritis to cancer, syphilis, liver and kidney diseases, tuberculosis, etc. It was only after several public health crises and needless deaths from unregulated medicines that the United States government required proof of safety before medications could be marketed. During the 1960's, the law was changed to also require proof of efficacy. Today, as the century comes to a close, this nation has reverted one hundred years to an era of unregulated medicines that are advertised as effective against health problems without any scientific proof, and without any assurance of safety. As a consequence of DSHEA, consumers have become convinced that "natural" dietary supplements are safe. And, the FDA is taking action only after the public health consequences of unregulated products maim or kill people who were given no warning about unsafe and dangerous nutritional supplements.

The FDA has not moved fast enough to remove dangerous nutritional supplements from the market, and supplement manufacturers do not hesitate to market products with known public health risks. Even after the agency calls for withdrawal of unsafe supplements, retail stores continue to sell them. We urge the FDA to increase enforcement actions to prevent further public health tragedies, and to require manufacturers to test these products before they are sold to an unwitting public.

In addition to assuring consumers access to safe dietary supplements that are truthfully labeled, the FDA should assure that the products are bioequivalent, meet uniform dissolution standards, and are labeled for contraindications, side effects, etc.

The FDA should require manufacturers' conformance to Good Manufacturing Practices (GMPs), and assure that the ingredient labeling on a supplement bottle indicates the exact content of each tablet or capsule. 100 mg. of Vitamin C should contain 100 mg. no matter which brand a consumer buys. There is no other group of consumer products that is allowed to be sold in the United States unregulated. Many tests have shown that supplements often do not contain the exact ingredients claimed on the label, some supplements are sub-potent, some are super-potent, and some contain no active ingredients at all. Even pills within the same bottle can vary as to contents. This is a "buyer-beware" market because of the absence of government regulation. FDA's inability to test the contents of supplements has put the public at the mercy of dishonest vendors. There are people with rare diseases who have valid medical need for supplements, but they cannot rely on the quality of these products without government regulation.

We suggest that nutritional supplement companies should conform to the same quality regulations as generic drugs and over-the-counter pharmaceuticals. They should be required to submit proof of bioequivalence and dissolution testing. Bottles of supplements should be required to post an expiration date and side effect warnings meeting the same standards as over-the-counter drugs.

Many consumers are not aware that supplements may have side effects, that they should not be taken with other drugs or foods, and as a consequence there have been many critical and even life-threatening events arising out of use of some of these products because adequate warnings have not been provided to consumers. When the FDA issues press releases to inform the public about side effects or supplement interactions, the agency's education efforts are totally inadequate. Warnings should be posted on product containers, not a ten-second announcement on the nightly news.

We advise the FDA, because its primary mission should be a consumer protection agency, that safety should be the highest priority in the dietary supplement strategy. For example, despite documented reports that the supplement 5HTP contained the same flawed tryptophan that killed or maimed several thousand Americans a few years ago, 5HTP continues to be sold over-the-counter as a nutritional supplement. The FDA "asks" for "voluntary" recalls of dangerous products whereas it should require recalls of products with evidence of imminent public health hazards. Such products should be ordered off the market without delay. The FDA should aggressively express its need to Congress for statutory authority to withdraw dangerous supplements before people are harmed, not after. Similarly, a "voluntary" recall of GHB and related products represents insufficient protection of public health by the agency. If the government can recall thousands of cars because of an automobile defect, it is incredulous that the FDA cannot recall nutritional supplements that have caused critical health problems and deaths.

There are many other safety, labeling, and marketplace issues that the FDA should address without further delay. There are too many supplements labeled "USP," which is supposed to indicate that they conform to the U.S. Pharmacopoeia standards, but they

do not in fact live up to those standards. Apparently USP is aware of the violations, but it is not a government agency and has no enforcement authority. FDA does have enforcement authority against untruthful labeling, and it should do something to stop this dishonest practice by violative supplement companies.

Similarly, the FDA should issue GMP regulations for nutritional supplements; require expiration dates on all bottles; require manufacturers proof of testing for dissolution and bioequivalence; list warnings and side effects clearly on all labels; and require a stronger statement on labels that each product has not been tested for safety nor effectiveness and is not approved by the FDA. The public is under the impression that the FDA will not allow any unsafe or ineffective product to be sold; therefore they believe that nutritional supplements are approved by the agency for sale in the United States.

Consumers should know by reading the labels on nutritional supplements that they are taking personal responsibility for ingesting untested and unproven products that may or may not have health implications, both good or bad. They should be able to read understandable warnings about known side effects, just like they read on an aspirin bottle. They should learn via the label whether to take the supplement with or without food and which medications they should avoid. Finally, the FDA should vigorously monitor and regulate the outrageous print and television advertisements that are misleading and untruthful. By allowing these ads to continue, the FDA has allowed the snake oil salesmen of the beginning of this century to roll back the consumer protection clock by 100 years.

Again, thank you for the opportunity to assist the FDA in developing an overall strategy for achieving effective regulation of dietary supplements under the Dietary Supplement Health and Education Act of 1994.