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University of California, Berkeley Wellness Letter**

I would like to thank the members of this Committee for inviting me to participate in this investigation into the marketing of nutritional supplements to the elderly. This is a topic which is extremely important to us at the University of California, Berkeley Wellness Letter as we seek to provide the public with an independent, reliable summary of available scientific information regarding all aspects of health promotion and disease prevention. Our criteria for evaluating such information include clinical trials with adequate numbers, double-blind controls and good statistical techniques for analyzing the data, followed by publication in an independent peer-reviewed scientific journal.

When we began the Wellness Letter in 1984, our focus was largely on standard nutrition, fitness and stress management. Ten years later, in 1994 when what we consider to be the ill-conceived DSHEA legislation was passed (after unprecedented lobbying by the supplement industry) the floodgates opened to allow anyone to market almost anything as a dietary supplement. By that time our readers had already begun turning to us for clarification of the seemingly unbelievable claims being made for these products. If the claims were true, dietary supplements were surely the magic bullet everybody was seeking. If they weren't true - as many of our readers already suspected - and the supplements were just a waste of money, were the products at least safe?

As the years passed, a significant portion of our efforts and print space has been devoted to carefully examining the claims, debunking the ones that could not be substantiated and helping our readers navigate through the slick and mostly misleading advertising for dietary supplements. One of the very first that we tackled (in 1992) was Gero Vita. At that time they were only marketing GH3 as an anti-aging formula and we were extremely forceful in recommending that our readers disregard all the claims made for this product. Later we went on to warn our readers not to believe **any** of the claims made in Gero Vita's Journal of Longevity. Today Gero Vita's website features no less than 12 products which claim to have anti-aging properties. (Figure 1) They have names like TMG Force: An Anti Aging Breakthrough and ACF 223: A Patented Anti-Aging Formula. Not one of these 12 so-called anti-aging preparations has ever been tested and proven to be effective.

Although the ingredients in dietary supplements are required to be listed on the label, the amounts of individual ingredients in so-called "proprietary blends" is not required. The lack of a system of Good Manufacturing Practices and more stringent ingredient labeling regulations makes it impossible to know how much, if any of the purported active ingredient is actually in the products and perhaps more importantly, whether it is uncontaminated. The Wellness Letter has now carefully reviewed more than 70 dietary supplements, including conventional vitamins and minerals. Our complete supplement review is available on our website (www.wellnessletter.com) and a print out of this material has been made available to the Committee.

While we have acknowledged that some of these supplements appear to be useful in certain situations (e.g. St. John's Wort, Glucosamine), the only supplements we currently recommend to our readers are Vitamin C (if dietary sources are insufficient), Vitamin E, Folic Acid and a multivitamin for older adults. Our reasoning for this is that whereas vitamin preparations are standardized and regulated, other dietary supplements reside in a murky netherworld somewhere between drugs and food. Exempt from all but the most minor of labeling regulations (yet again thanks to DSHEA) the manufacturers of these products have nonetheless been allowed to make claims in their advertisements that are almost completely unsupportable by scientific review. They are not required to prove efficacy **or** safety before they bring a product to market. DSHEA has put the burden of proof on the FDA to show that something is **not** safe and the FDA must rely on the reporting of adverse events, which in this case turns out to be a

voluntary, inefficient and unwieldy system. The end result is a juggernaut industry that now approaches 17 billion dollars a year in sales.

While dietary supplements are legally precluded from making health claims on their labels - they cannot say they cure cancer, heart disease or even acne - they are nonetheless being marketed as cure-all "drugs" and medical miracles. It is a historical fact that many of today's most important drugs have botanical origins. It is not unreasonable to assume that some of the herbal and other botanical preparations now being sold as dietary supplements may one day be shown to have predictable therapeutic outcomes. If, in fact these products have drug like properties, they are drugs and they should be regulated and controlled like drugs. However, the common perception that the so-called natural products used in dietary supplements are always safe, is completely unfounded and dangerously misguided.

The rigorous scientific research that needs to be done in this area is certainly doable, but it is expensive. The manufacturers have very little incentive to carry it out. The government cannot allocate enough money to NIH to evaluate the multitude of ingredients currently on the market. The industry has grown exponentially without this kind of testing and without any standardization of ingredients, so it continues to rely on practically nothing but anecdotal information to support its claims. By and large, most young, healthy people who take dietary supplements do so without adverse consequences, except to their pocketbook. But the ill and the elderly are a different issue.

Perhaps the most insidious aspect of marketing dietary supplements to the elderly under the terms of DSHEA is that companies like Gero Vita can knowingly exploit the hopes and fears of a population for whom safety issues are extremely complicated and which, by and large, has more reasons to be concerned about the economic impact of useless substances. When you promise older people (either explicitly or implicitly) that by taking your product they will slow down the aging process, live longer, have more energy, have fewer wrinkles, remember more and perform better sexually, you have touched a raw nerve.

According to the latest statistics compiled by AARP, over one-third of older persons reported they were limited by chronic ailments and most had multiple conditions. One of the likely outcomes of aging is a slowing down of the renal and hepatic systems, which means that drugs of any kind, whether prescription or botanical, are not cleared as quickly through the kidneys and not metabolized as efficiently by the liver. This makes the elderly more susceptible to the effects and side effects of any drugs. Because older people typically take many forms of medication for chronic conditions, the likelihood of adverse interaction is also greatly heightened.

As you can see from Figure 2, some of the most common dietary supplements have known adverse effects in the presence of certain conditions, many of which are common in the elderly. One example of this is ginkgo biloba which is heavily marketed to improve memory and has a potent inhibitory effect on the platelet activating factor. This could lead to excessive bleeding and is especially troublesome for anybody already taking blood thinning medications or aspirin.

Another troubling example is a dietary supplement which claims to be DHEA, a powerful hormone manufactured in the human adrenal gland. This substance is being marketed as an anti-aging formula that enhances mood, energy and memory, boosts sex drive, reduces osteoporosis, improves fat loss, increases muscle mass, improves the immune system, reduces autoimmune disorders and reduces heart disease. (Figure 3) In its natural state the effects of this hormone on the body are not well understood and as a supplement it is potentially very dangerous. DHEA is not a "natural medicine" and most certainly not a dietary supplement and should never have been classified as such.

But even for those supplements which do not have adverse effects, the amount of money spent on worthless products is of great concern. Again, according to AARP, of the 31.7 million older persons reporting income in 1998, 36% reported less than \$10,000. The median income reported was \$13,768. About 3.4 million elderly persons were below the poverty level in 1998. It is particularly disturbing to think that older people might choose to spend money on dietary supplements instead of prescription drugs which are known to be efficacious and safe.

Obviously the subject of dietary supplements could be discussed and debated almost indefinitely. The existence of a law like DSHEA makes it nearly impossible to change a situation which is complex and confusing and with issues that range from medical to economic to ethical. As long as the FDA and FTC are precluded from doing for dietary supplements what they have been able to do for food, prescription and over the counter drugs, we will never bring reason to this unreasonable and untenable situation. To this end we make the following recommendation. (Figure 4)

- **Repeal or amend DSHEA to give the FDA the power to regulate nutritional supplements as they now do OTC drugs and thus require scientific proof of efficacy and safety.**

While we recognize that this is the most important step forward that could be taken, we also acknowledge that it is unlikely to happen any time soon. In the meantime, we recommend the following:

- **Make adequate resources available to the FDA and the FTC to enforce existing rules covering claims made on labels and claims made in other advertising.**
- **Require the FDA to finalize the Current Good Manufacturing Practices which should include quality control, standardization and accurate labeling.**
- **Require that the labels of dietary supplements instruct consumers to report adverse events directly to the FDA and provide a toll free phone number and website.**

Thank you for your time.