

**FDA Stakeholders Meeting on Dietary Supplements
Food and Drug Administration, San Francisco District
Oakland Federal Building
July 20, 1999**

Comments Made by:

Ed Blonz, Ph.D., M.S.

139 Purdue Avenue, Kensington, CA 94708
510 525-6925 (phone/fax) ed@blonz.com

I am a university-trained scientist and former academic, now self-employed. I have a number of publications in peer review journals and have written seven popular books on foods and nutrition. My efforts during the past 10 years have been focused on bridging the wide gap between scientific research and public understanding. In addition to responding to consumer questions online, I have a weekly newspaper column that goes to more than 600 newspapers around the U.S. I deal with a wide range of issues concerning nutrition, foods, food science, health and alternative medicine. I receive more questions that I could ever hope to answer and I am grateful for being given an opportunity to share some of my experiences.

First, I applaud the efforts to enhance FDA effectiveness in the regulation of dietary supplements. In my experience, one of the greatest dilemmas is the uneasy balance between the regulatory imperative to establish safety and reliability, and people who want their "cures" now.

Our treasured societal freedoms open the door for a never-ending variety of scientific shenanigans. Those grounded in rational thinking would agree that there has to be a mechanism to control unsubstantiated claims. Science should be the final arbiter of what gets told to the consumer under the aegis of authority, but I have observed that many so-called "experts" find a great deal of flex with the facts - especially when commercial interests are concerned. Indeed, companies that take the high road where science is concerned may find themselves at a competitive disadvantage to others that play fast-and-loose with their science.

Typical strategies involve a reliance on anecdotal evidence coupled with a pitch that "it worked for them, so why not for you?" Factor in the support of a good salesperson with pseudo-credentials, and you can end up with impressive marketing clout.

There is also an incessant parade of infomercials bleating their endless tirade of testimonials, each offering framed with the trite sounding statement "finally a product that really works."

Another conduit for questionable products is the burgeoning field of multilevel marketing. This marketing technique has neighbor selling to neighbor, oftentimes trying to recruit them into their sales force. I've found that when health-related products are being offered, the facts tend to take a back seat. In many cases the dealer has no real training in the health-related field.

As the average age in this country continues to rise, we have the reality that more and more people suffer from, or are at risk for, chronic ailments. They are often told to grin and bear it by a managed health establishment made ever the more impersonal by a myopic focus on the bottom line.

These are the realities, and they don't lend themselves to simplistic solutions.

As food for thought, I would like to suggest the following.

1. Testing for safety and effectiveness continues to be a thorny issue. Manufacturers complain that there is little economic incentive for them to fund the research needed to prove their health claims. Besides, once done, the results could be used by anyone. Despite this argument, though, the burden of testing must fall on the industry that stands to profit from supplement sales - not on the FDA. Tax incentives might be made available to coax the industry into action.
2. Congress should consider giving the supplement industry a defined period to get its house in order. During this period a self-policing policy would be established, safety testing could be started, and a nonpartisan panel could be empowered to decide the type and amount of proof needed to establish health claims. A triage approach would be utilized to assure that the most critical issues are handled in an expeditious manner.
3. The FDA in cooperation with other Government agencies, perhaps making use of the Cooperative Extension Service, would be charged with providing provide a series of warning labels or inserts to inform consumers about side effects, minimum toxic doses and potentially dangerous interactions with other nutrients or herbs. Similar information would be made available to health professionals. This would have an additional benefit of helping to open the doors of communication between patients and health professionals regarding the use of alternative health modalities.
4. Advertising campaigns would be instituted to alert the consumer to look for products that carry the product inserts. In tandem with this, an industry or government sponsored "seal of approval" might be instituted to help consumers identify and patronize the companies that take part in the process.

We all can recall how a massive effort was instituted to develop tamper-proof seals as a consumer protection measure. We can do it again.

In conclusion, we must be ever cognizant that what is speculative and unproven is not necessarily false. It simply means that the requisite tests have yet to be done. Much of what is now mainstream science was once considered irrational at one time. If regulations end up overly conservative, it will lead to an inevitable consumer backlash and a black market, with proponents elevated to the status of martyrdom. Not only would this tarnish the image of the FDA, the enforcement implication of such a development would be staggering both politically and in terms of funding realities.

The onus must be put on the industry, but an industry working together with the regulatory agencies charged with enforcement. The bottom line is to strike a common ground where the consumer is the ultimate beneficiary.