

CHAPTER II: HERBS AND OTHER DIETARY SUPPLEMENTS

Research on the Efficacy and Safety of Dietary Supplements

In the Office of Dietary Supplements, we try to help to understand, first of all, from the needs of consumers, “What are the important questions that need to be answered?” We learn a lot by holding conferences that deal with the issues that we think or we’re told are important to consumers. So over the last 2 or 3 years, we and our partners at the NIH have held a series of 3 conferences about dietary supplement use across the lifespan. In 2001, we held one on kids, and in 2002, one on women. Just recently, there was one on dietary supplement use by the elderly. The goal behind these and all of the other conferences that we work on with our partners is to try to identify the research needs. What are the next questions that need to be asked? We then try to seek ways to answer them. What we know is that consumers take herbal products for a number of purposes. This gave me the excuse to put up the lovely pictures that were provided by my friend, Stephen Foster, who is probably one of the best botanical photographers in the world. Echinacea is used to enhance immune function. There are a lot of reasons why people might be interested in that. Likewise, St. John’s wort, or *hypericum perforatum*, is used, as we noted earlier, for mood elevation, and there has been some very active research in this area. It has not always led to a unified set of conclusions. And ginkgo, one of the prettiest and oldest plants in archeology, is used by people who are interested in maintaining their level of cognition to perhaps allay the decline in mental status that for some attends the aging process.

There are a lot of reasons why people take these things, but the plain fact is that solid research about the efficacy and the safety of dietary supplements, and this is particularly true of herbal supplements, is variable. It’s variable in quality, in quantity, and in conclusions. It is stronger for some kinds of supplements than for others. There is a longer history of active research when it comes to those supplements that are usually thought of as nutrient supplements—vitamins and minerals. The fact that there is such a diversity, so many choices in the marketplace, of botanical supplements—and I’m using

the term herbal and botanical pretty much interchangeably here—makes the task much more difficult, particularly when you realize that not all of those products have gone through any kind of efficacy, safety, or quality testing before they were put on the market. I do believe that situation is changing, but as of today, you would be hard pressed to know precisely what it is you were buying.

In terms of safety, because of the way in which adverse events are reported about dietary supplements, it's essentially passive. There's no requirement, for example, that a manufacturer must provide data to the FDA about any adverse events that their customers have reported. They might report those to the FDA, but they're not obliged to. So it's a variable quantity and quality event. There's a lot of research that really is needed at a number of levels. We need to better understand how and why people use dietary supplements, and there are many organizations, including some in government, that are trying to get a better handle on this, in part to then help us to understand what the most important research needs are. I think it's fair to say that basic research is still required for many supplements. For some, botanical supplements being an example, we think it's important to have a better understanding of how they work, as well as whether or not they work. There needs to be a greater investment in studies that actually look at them as intervention tools. Clinical trials are appropriate, as are real world, efficacy studies that essentially examine the way people are using dietary supplements as they're marketed in the U.S.