

**CHAPTER VI: COMPLEMENTARY AND ALTERNATIVE MEDICINE AND
AGING**

Studies Related to Aging

Many Federal agencies, the U.S. Food and Drug Administration and other Federal agencies, the Department of Health and Human Services and its various components, one of which is the National Institutes of Health, are paying a lot of attention to trying to rectify some of these concerns related to health risk. Of course, outside the domain of health agencies, are more regulatory-oriented agencies related to economic risk and so forth. We at the National Center for Complementary and Alternative Medicine have a large mandate to try to create new and useful knowledge for people and to disseminate the information in clear and meaningful ways to everybody, which is really our job—and of course, to train other people to do the same. So when we prioritize how we're going to address and how we're going to look at this, that, and the other phenomena that are out there in the world of CAM, given that there are so many, we use several criteria. They include those that are listed here. First, we want to address major public health issues. Second, we want to be sure that there is sufficient evidence to warrant an investment either in laboratory-based studies, or as they progress, to studies in people or in experimental animals and then in people. As I just mentioned, we want to pay really good attention that the products we use, whether they be biological products or unbiological products, like acupuncture needles or magnets, are good-quality products. We want to make sure that we don't design the perfect experiment that can never be done. We want to make sure that our studies are possible, if feasible. Driving it all is our concern, as yours, we share this concern, for safety first. I was brought up from my first day at medical school, having been trained in Latin in an earlier part of my life, with the dictum "primum non nocere," which means first do no harm. That, of course, is embedded within a health care provider's mind, and it's embedded within all of our minds. Whatever it is that we do, first you should do no harm to ourselves or to others. So these studies have to be ethical.

This is a snapshot of some of NCCAM's, that is the National Center for Complementary and Alternative Medicine's, large multicenter, what we call phase III trials. It's a big multicenter site with hundreds and usually thousands of patients. You'll notice that conditions on the left are conditions that are disproportionately affecting middle-aged and older people. Dementia, whether it be Alzheimer's disease or vascular dementia, for example, that occurs after a person has sustained a stroke. Osteoarthritis, a disease, again, principally of middle-aged and older people. Prostate cancer—clearly so. Depression, which increases with advancing age. Heart disease. Benign prostatic hypertrophy. We're going to talk a little bit more about each of these as we progress.

Many of you may know that St. John's wort has been around in many countries for a long time and has been tooted and touted for many different things, including treatment, it has been said—based upon some not well-done studies—for people who have what we refer to in psychiatry as major depression of mild-to-moderate degree. Not major depression of major degree, which really requires more intensive antipsychotic drugs or antidepressant drugs. But the National Center for Complementary and Alternative Medicine, in partnership with the National Institute of Mental Health, sponsored a wonderfully designed and well-done and well-interpreted study. No single study is foolproof and this one isn't bullet proof either. But it's the best extant study on people who have major depression of mild-to-moderate degree. This study was examining whether St. John's wort did better than a standard antidepressant medicine or a placebo. The bottom line, literally and figuratively, was that this was, as shown in red, ineffective in this particular study. Another study was published in a very prestigious journal, the *Journal of the American Medical Association*, just about a year ago last spring. If you notice, I'll flip back one slide for a moment, we're now a large multicenter study in people with a different kind of depression, minor depression, to see if they might benefit from this agent. Because that study is just getting going, it's a little too soon to say. It will take several years.

As many people only semi-joke, "Did you take your ginkgo?" The usual response, semi-jokingly, is, "No, I forgot to." Now ginkgo has a huge amount of scientific information,

based on laboratory studies, that suggest, in the laboratory perspective, that it may have some uses to protect against adverse aging, including, potentially, the loss of memory function, such as occurs in people with dementia, whether it be of the Alzheimer's type or the closely related kind we call vascular dementia. At the moment, the largest, best, and most rigorously designed study, again this one has more than 3,000 people, between 3,000 and 3,100 people, is being conducted right now at multiple centers, under the sponsorship of this very renowned neurobiologist, to determine whether ginkgo will decrease the incidence of dementia, particularly in Alzheimer's disease, which is the focus, which we're all concerned about, as a phenomenon that is just waiting to increase given the global aging and U.S. aging that we talked about in the beginning. Whether it can forestall downward changes in cognitive function, and whether, in addition, it might have some other effects related to cardiovascular or overall well-being and mortality. This study is ongoing now and will take a little while before it's completed and evaluated thoroughly. The results, of course, will be immediately available to everybody.

A lot of you have heard about DHEA because that's another really hot topic. DHEA is a hormone. It's actually a weak hormone that basically is a precursor. It comes from the adrenal gland, these little glands that sit on top of each kidney, which produces a whole bunch of hormones, one of which is DHEA. So DHEA is a weak adrenal androgen. What does that mean? It means that it acts like a male sex hormone. As it turns out, it can also be converted to a female sex hormone, so it's actually a precursor for the male and female sex hormone. It's the most abundant chemical of that class, which we call steroids, that occurs in the body of people. Now it's been known for 30 or 40 years that its levels start to decrease in the 20s and just go inexorably downhill, so that by the time healthy people are in their 70s and 80s, the levels have decreased 80% to 90% compared with what they were when those same people were 20 or 30 years of age. It's also been postulated by a number of investigators, including our own group, that this may contribute to some age-related changes, such as loss of the amount and strength of muscle, thinness of bones and a tendency to osteoporosis, and increase in body fatness, especially belly fat. In animal models, not human studies, it's been shown that giving back DHEA to old animals does wonderful things. It makes their muscles stronger, their

bones stronger, it protects them against cancer, it protects them against heart disease, makes rats live longer—who wants old rats? I don't know. But in any event, it makes them do that. However, the efficacy and safety, as a so-called anti-aging intervention in people, I can assure you is 100% unproved. In contrast, this is used by an increasing number of middle-aged and older people. However, the efficacy is unproven and the safety is unclear—these are reasons to be concerned that perhaps this weak female hormone or weak male hormone may possibly do bad things to people. For example, women who have had breast cancer— you might want to give them a weak estrogen given all that we've learned. Or you might not want to give men who have had prostate cancer a male hormone. That might not be a good thing to do. So there's a need to get more information about those questions.