Spotlight on Minnesota: Highlighting Innovation in Agriculture, Food and Medicine

Session 2 Developments in Medicine and Health

Q&A

MODERATED BY
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Frank Cerra: How is a consumer to know what works and what doesn't? My frame of reference is this: we have only begun to teach evidence-based practice in the health-professional schools for the critical evaluation of data, and now we have nutraceuticals and medical foods. How is the consumer to deal with that?

Gregory Plotnikoff: Good decisions are always based on informed judgments. The question is: where are people getting their information? At least two surveys exist for which consumers were asked where they get information to make decisions regarding dietary-supplement purchase. At the very bottom of the list were physicians and pharmacists. At the very top of the list was what everyone fears: supermarket tabloids, neighbors and strangers. Surveys have shown that 70% of complementary therapies employed by people are not shared with their physicians. Part of the reason is that consumers fear being ridiculed or shamed by their doctors. The one message I take to physician groups that I address is: every patient encounter is a cross-cultural experience—listen for understanding before trying to be understood. Secondly, good resources are out there for evidence-based practice, and we can talk about those. My sense is: we

need a lot more randomized, controlled, phase-3 trials on these, and we need public sentiment or private industry to provide funds. These are not being funded right now to the degree that is necessary for the public's health.

Cerra: Clarence, I need to ask you to comment. You've had experience with the FDA's system for nutraceuticals and medical foods. Is labeling actually followed through—for instance, is your own product labeled as a medical food? And is the FDA's bar high enough to give comfort to consumers—is it not only something that works, but is the risk low?

Clarence Johnson: Historically, the bar has not been very high. There have been a number of instances in recent years where companies have gotten in trouble with the FDA for promoting medical food products directly to patients, which is not permitted under the guidelines. We are a small company and cannot afford to have too many run-ins with the FDA. So we are careful about that, and perhaps we even go too far the other way. We give our products to patients only through hospitals or other healthcare providers. We can't make health claims or promote our products directly to patients, but, historically, that has not always been the case. And there is no question that food companies and clinical-nutrition companies stretch the limits of the code.

Gary Gardner: We are trying to define problems where we can bring pressure to bear, and we are doing that with focused discussion groups. We are in the process of scheduling one on botanicals and herbals because it's an area that needs research, especially in standardization of pharmacological ingredients. I'm hoping we can define researchable topics and move ahead in that area.

Mark Bolander: From my perspective as an orthopedic surgeon who does mostly joint replacements, it is interesting to compare the experience 10 years ago with DMSO and the experience recently with chondroitin sulfate and glucosamine. I no longer have patients saying that they are using DMSO, yet I, not surprisingly, have a lot of patients who say they are using chondroitin sulfate. I don't know how many say they are not using chondroitin sulfate but actually are, but I suspect it's a lot. It seems to me that there are many reasons for the difference, and it seems like glucosamine and chondroitin sulfate are here to stay. One of the reasons might be that an NIH-funded study showed that they are efficacious. It seems to me that although that doesn't answer everyone's questions, that type of NIH-funded study has value especially from the perspective of small companies that not only cannot afford a run-in with the FDA but also can't afford a major clinical trial. Recently a new NIH institute for alternative medicine was established, and I would think that that is a potentially good source of support for these types of activities. But I don't know how successful or how active it has been.

Plotnikoff: Frank, what is the total budget of NIH for 2002? Is it 22.3 billion?

Cerra: Twenty-three billion dollars, I think.

Plotnikoff: Okay, and approximately $96 million of that is devoted to the National Center for Complementary and Alternative Medicine Research. It has the lowest percent of R21- and R01-funded studies. The interest is overwhelming. It is far more competitive and more difficult to get something funded through there than through other NIH organizations.

Cerra: That is all true. On the other hand, it's amazing that we have such a center at NIH, and that alone means we are heading in the right direction to get the science done to tell us what works and what doesn't.

Audience member: Older people frequently overmedicate themselves with pharmaceuticals—over-the-counter as well as the prescription medications—and now we are talking about introducing pharmacologically active foods. How will we standardize these to prevent cross-reactions and more overmedication? Has that been thought about?

Plotnikoff: That's a very important question. Many things control drug metabolism. Red wine, cigarettes, charbroiled meats, grapefruit juice, *etc.*, can affect very commonly prescribed medications such as calcium channel blockers and anti-cholesterol agents. In fact, we do need to raise consciousness and this is a competency issue for health-science students. Your particular question about the geriatric population I would switch: there are pharmacologically active compounds in food, which, because of their concentrations, would be very hard to overdose on. Should those be the first-line approach rather than the pharmaceutical agents with an associated higher risk of toxicity? In a country such as Japan, I would say that 88% of their OB-GYN, 83% of the cardiologists, and 70% of all physicians incorporate traditional herbal medicines as part of the routine care for common conditions such as arthritis, rheumatism, fatigue, and menopause, and for cancer support. They do so because of reduced toxicity, and because you don't need a very aggressive pharmacologic agent for the elderly. As a society we probably won't be able to afford it either. This is an area of huge interest to this audience in terms of how can non-traditional pharmaceuticals enhance the health of our aging population.

Paul Otten (St. Paul, MN): I am director of a corporate health organization in St. Paul and work directly with about 500 consumers who are self-pay and, therefore, have choices that they would not have if they were third-party payers. First of all a comment. I think that we assume that if it is FDA regulated then

consumers will trust the end-product. I find that that is not necessarily the case. I applaud what Gary Gardner at the University of Minnesota is doing. I also am grateful for the double appointment of the dean in terms of being connected with the medical school. However, I have a problem in trusting our public messages—no matter what the nutritional question is, you should consult with your medical doctor. Yet, until this year, there wasn't a single required course at our own medical school on nutrition. Why am I sent to a medical doctor for nutritional consultation when they have no educational background? When I am sent to the plumber, I don't ask questions about electricity, or *vice versa*. Many of my people say that when they go to the medical doctor and ask about nutrition they are told that nutrition has nothing to do with their cancer or cardiovascular disease. And when they go to the hospital they may be given donuts for breakfast—as happened to my granddaughter. As for getting trustworthy information, I find I have to go to multiple sources and finally may depend on intuition —my fifth or sixth sense—to determine what is right and what is wrong. I also believe that what Dr. Gardner and his staff are doing in terms of finding basic answers makes people trust a lot more than high technology that is over the head, hard to explain and, above all, requires a lot more dollars than simply going back to the basics. Where can someone like myself—responsible for the health of 500 people, on the preventative end as well as on the repair end—where can I go for the best possible reliable information to share with my people?

Plotnikoff: Reliable sources of information are available to help people make informed decisions, such as consumerlab.com, which is a subscription service where independent third-parties provide evaluations of quality of nutritional products. Second, would be the *Pharmacist's Letter*. Again pharmacists and others have come together and prepared very reliable sources. Third, the American Botanical Council has taken a leadership role in herbal issues. In fact, I have been in contact with the Minnesota Board of Medical Practice which is raising the very same question, and so the Center for Spirituality and Healing and the Center for Plants and Human Health at the University of Minnesota are going to take seriously the commitment to be a public resource and to engage in educational activities that are appropriately science-based at the undergraduate, graduate, and professional levels. I would take it as a positive thing if the public would support a move in this area to enhance competence in our graduates to be able to council, from an evidence-based perspective, in both prevention and treatment by low-cost, low-tech, low-toxicity interventions.

Cerra: That last question, in the form of a statement, is correct. There is not enough nutrition in the curriculum of health professionals either in the didactic portion or the applied portion. This is near and dear to my heart. I spent 20 years in research on human nutrition and the situation is slowly changing.

However, I do not think this university has captured the value of its investment in nutrition. We have more resources in nutrition than almost any of the top-five world universities. We have not captured it in an inter-disciplinary approach. But it is getting better. I think this new center is going to help, the Center for Spirituality has helped, the School of Pharmacy is replanting its herb garden, which it gave up in 1930, and so on. So it is just going to take some time. Your point was well made. Last question.

Ilya Raskin (Rutgers University, New Brunswick, NJ): This has been a wonderful meeting. I have attended most of the talks and feel that an important category has been almost completely omitted from the discussions: botanical drugs. The FDA has the guidelines for botanical drugs and is actively pushing them. They include phenylethyl isothiocyanate (PEITC), ribose, and free omega-3 acids that can be developed as drugs. And then there is no issue about where information will be available. They'll be labeled, and physicians will prescribe them. As you know, some pharmaceutical companies—progressive ones, Pfizer for example—are quietly developing botanical drugs as standardized extracts, which are very similar to the products you are discussing. So my question to the panel is: why won't you consider some of those products and put them into the mainstream?

Johnson: Speaking from my own perspective, we have been fairly aggressive in the last few years in looking at the effects of ribose given as a drug intravenously post cardiac surgery or as a diagnostic enhancer for cardio-vascular disease. We have completed phase-2 clinical trials for the use of ribose as a diagnostic, and we are, in fact, taking this product through ethical drug channels to make it available by prescription for post-cardiac surgery, for trauma, and for cardiac diagnosis.

Cerra: Clarence, you might want to comment on what I think goes to the core of this: patentability. I was 10 years into the study of omega-3 fatty acids in signal transduction before we had a standardized source that the NIH finally took over. That's part of the problem. The second part of the problem is omega-3 itself is a GRAS substance, so how does a company protect itself in moving forward to make the investment to get something classified as a drug instead of as a medical food?

Johnson: It is very difficult. Obviously you can't patent the compound because it's naturally occurring. However, you can patent uses for the compound. If you find a compound—in our case it was ribose—that's effective in treating ischemic tissue for recovering function, you can patent that use. And there are certainly composition of matter patents. But when taking technology from a company like ours to Baxter or Abbott or whomever, and trying to partner up

with them—because it is horribly expensive and long-term to bring these products to market—it's difficult to get the classical pharmaceutical companies to understand the value of use patents when they are so traditionally locked into compound patents—after they make a new compound. So we are working very hard to build a patent picket fence around the compound so that when we do take it to someone they will see that, although it isn't as strong as a compound patent, there is so much protection that we have something valuable.