

Council for Responsible Nutrition
The Workshop: CRN's Day of Science
Hyatt Regency Crystal City
May 3, 2007

Steve Mister's Opening Remarks at *The Workshop*

Good morning and welcome to CRN's The Workshop - A Day of Science.

We are very pleased you have chosen to join us today for our conversation on *Dietary Supplements and Evidence Based Medicine*.

At its core, evidence based medicine is simply an attempt to apply more uniformly the standards of evidence gained from the scientific method to certain aspects of medical practice. Specifically, it seeks to apply judgments about the quality of evidence to those aspects of medicine that depend on rational assessments of risks and benefits of treatments. And over time, science has developed a hierarchy of investigations to aid those who practice healthcare to assess the validity of various courses of action. So as long as your context for "medicine" is treatments, cures, mitigation of diseases, and the objects of study are unique chemical entities that are introduced to your patients with the singular intent of addressing specific problems, that works pretty well. After all, the Hippocratic oath says "physician, do no harm." Before you start experimenting with a patient who has already suffered some deviation from good health by exposing them to new chemical entities, one should have reproducible evidence to support the course of therapy or treatment.

But now enter the focus of 21st century healthcare into that model. Consider that today we recognize that health is more than the absence of disease. Consider that an active state of wellness can be practiced everyday and that daily nutrition can play

a vital role in maintaining good health. It's no longer get sick; see a doctor; get treatment; get better. Consumers want to play an active and continuous role in studying staying well.

Now further introduce dietary supplements into that model – compounds that are mostly natural; that we ingest in varying degrees depending on our diets; that can confer health benefits over years and may very well help to prevent a variety of chronic diseases as well as fill in nutrition gaps. Further complicate that with a regulatory system for these products that doesn't even permit supplements to make label claims about treating, curing or mitigating disease; a framework that does not incentivize clinical research on these products in the way that it rewards pharmaceuticals with patent protection on the chemical entity and exclusivity on the marketing of products. And then add in a medical community that is skeptical of these products because they don't even require a consultation with a physician to administer.

The hierarchy of the evidence based medicine is even less appealing when purists demand randomized controlled trials as proof, but randomized controlled trials maybe neither practical, affordable or perhaps even appropriate. Would you really deny a study participant calcium and vitamin D in order to be in the control group? Who would pay for a 20-year randomized controlled trial for multi-vitamins for disease prevention?

So you can see the difficulties of fitting dietary supplements into the evidence based medicine paradigm of the 20th century. It's the proverbial square peg in a round hole. But that's not to suggest evidence based medicine has no connection

to our products. If supplement manufacturers are going to gain acceptance from mainstream medicine, we must adapt the evidence based medicine paradigm to accommodate our unique challenges.

We shouldn't reject the pinnacle of the hierarchy, the randomized controlled trial, just because it is hard to do. But we can demand that randomized controlled trials be developed and adopted to appropriately evaluate what our products are designed and capable of doing. And when we suggest alternatives, like observational research, those methods should be just as rigorous and open to peer review.

What I fear is happening is that on the one hand evidence based medicine is evolving into a rigid dogma that instead of classifying kinds of research within a hierarchy for their expected validity, has instead it is becoming a way to reject anything – and everything – that is less than the gold standard. And conversely, it has become a defense for uncritically promoting the results of Randomized Clinical Trials regardless of whether they were well conceived, rigorously executed or even properly designed to answer the questions being asked.

I would challenge us today to consider whether the evolving paradigm for scientific research —relying strictly on randomized clinical trials (RCTs)—is appropriately the sole tool for demonstrating the benefits of nutrients, including nutritional supplements. Are there other, equally valid ways to demonstrate benefits from our products?

We recognize the scientific rigor of randomized controlled trials, and they are certainly an important piece of the research puzzle. But we cannot ignore all the other research—case-control and cohort studies, and other epidemiological data—as

these studies often point us in the direction indicating where further research should be focused and may be just as rigorous for proving hypotheses as well as developing them. If observational studies show a benefit which is not confirmed by a clinical trial, that does not discount the importance of the initial studies. The totality of the evidence should not be dismissed. Perhaps the conclusions of the observational study were wrong; but perhaps the clinical trial or the meta-analysis based on those trials was studying the wrong population, or seeking to validate treatment rather than prevention, or wasn't studying the right dose to begin with.

These are some of the questions that I hope we will have an opportunity to grapple with today.

The research community needs to re-evaluate how to most efficiently and productively conduct nutrition research. Members of industry and other stakeholders need to support scientific research in all of its valid forms in order to further the broadest and best knowledge about how dietary supplements can help people live healthier lives.

That is our challenge. At CRN, we call ourselves “the science behind the supplements,” so it's appropriate that we raise these issues and that we lead the research community to begin to answer these questions.

So thank you for all being here.