

June 27, 2001

Dear Dr. Barrett,

As Director of Clinical Services for Ideal Health, I have received a copy of an email, dated May 8, 2001, written by you to the wife of a new member. Evidently, your comments in this email were such that they needed a response from us as rebuttal of your negative recommendations. I also understand that you are in the process of gathering information on our PrivaTest to post on your website. These two points are the primary reason for this letter.

First of all, I'd like to say that I applaud your concern for the American public and your intent to provide guidance through the often-confusing maze of healthcare options. That is our intent as well. However, we obviously disagree on the method of that guidance.

It is curious to me that you have already posted our PrivaTest under "Dubious Laboratory Tests" before, apparently, completing your information gathering. It appears that you subscribe to the notion that all "non-traditional" health concepts are "guilty" until proven innocent. In evaluating any test or company with which you are unfamiliar, it would seem a logical part of your due diligence to contact the company directly for information. And since it appears that you are primarily concerned with the scientific validity of our testing, your request for information would be correctly directed to me.

To date, I have not received any type of inquiry from you or from anyone on your staff.

I am therefore taking this opportunity to clarify the purpose and application of our PrivaTest for you.

It occurs to me that your statement in the email that "the whole concept is absurd" may be partly based on a misconception about our testing. That misconception may be that we are measuring vitamin and mineral levels in the urine. If that were, indeed, what we were doing, I would also agree that *that* approach is problematic. *However, if you read our literature carefully, you will see that we are not measuring the level of any nutrient at all.* We are measuring metabolic pathway end products, which are markers that reflect pathway function. A brief discussion of the concepts behind this approach is found below. However, there is a point that must be made here before I proceed.

A review of your website quickly reveals that your opinions and the opinions of our scientific staff (as well as many other nutritional researchers) are immediately at odds with each other. It is clear that you are not a fan of the concept of "functional medicine," (or, for that matter, network marketing). After reviewing your website frequently over the last several months, I am aware of your negative position on most anything that is considered "non-traditional" medicine. I am not writing here to enter into a debate on the pros and cons of functional medicine. A Food and Resource Economics professor of mine (with whom I had many lively debates) once wrote on one of my exams, "You use your prejudices very well." I now extend that comment to you. You, too, use your prejudices well and my concern over *that* is the purpose of this letter. Since your website clearly indicates the depth of your opinions, it is unlikely that anything I write here will have a great impact on your mindset. Therefore, we'll just have to "agree to disagree" from the outset concerning functional medicine.

That being said and realizing that you are reading this with bias, here is the rationale behind our PrivaTest, excerpted from a document currently under development at Ideal Health. No one goes to the level that we do to take care of the individual and make sure that our tests are scientifically valid.

**Q: Are these three areas in the PrivaTest really indicators of nutritional status?**

A: These lab tests are indicators of nutritional status in so far as they are markers of biochemical function related to nutritional usage or repletion, and thus can also be controlled (more accurately, influenced) by the sufficiency or insufficiency of essential nutrients. Our three tests indicate nutritional status as follows:

- Urinary lipid peroxides can reflect the state of oxidative stress by measuring the level of harmful compounds (peroxides) that have, simply put, escaped the “trap” of a person’s antioxidant-quenching system and thus are showing up in the urine. Oxidation of fat cells produces residues called ThioBarbituric Acid Reactive Substances (TBARS), such as malondialdehyde. The measurement of TBARS is a research tool used by those who are doing antioxidant and physiological research and who are publishing in peer-reviewed journals such as the *Journal of Applied Physiology, Medicine and Science in Sports and Exercise*, and *Free Radical Biology & Medicine*. The test is not intended to provide direct measurement of the amount of vitamin E or other antioxidants in the person’s body, but it does provide a strong marker of how effectively those antioxidants are *functioning* by measuring how much lipid peroxide “escapes” into the urine.

- The urinary sulfate level is a marker for the level of sulfur reserves, one of the key compounds used by the liver for changing toxic substances into water-soluble compounds, which are then cleared from the body by the kidneys. Dietary deficiencies of sulfur-containing amino acids can reduce liver sulfation systems. If you are showing a higher level of sulfate in the urine, this generally correlates with a good sulfur reserve for liver detoxification processes. Conversely, a lowered sulfate level can indicate the body’s attempt to conserve its sulfur because (1) it is running low on supply or (2) reserves are being rapidly used for increased detoxification demands. Again, this is not a direct measurement of liver detoxification, but a marker for nutrient function.

- The research on nitric oxide has exploded in the last few years, providing new insight into this molecule, which appears to be an important regulatory molecule in many systems in the body, particularly in the immune and vascular systems. The nitrate level measured in the urine (following a period of dietary-nitrate restriction, as directed in our testing instructions) has been recognized as a marker for endogenously produced (made inside the body) nitric oxide. Once again, this is not a direct measurement of nitric oxide, but a marker for the up- or down-regulation of its production.

**Q: Can supplementation really affect these pathways?**

A: Yes. For instance:

In a study done on 21 males, it was found that urinary lipid peroxide excretion levels were significantly decreased in the vitamin-E supplemented group compared to the unsupplemented group after an eccentric exercise session at 75% of their maximum heart rate (exercise being a known oxidative-damage inducer). Meydani, M. et al., *Am. J. Physiol.* 264 (Regulatory Integrative Comp. Physio.33) R992-R998, 1993 Human Nutrition Research Center on Aging at Tufts University.

Studies on failure -to-thrive children with leaky gut show low urinary sulfate levels and an “increased requirement for dietary sulphur amino acids . . . for hepatic detoxification of xenobiotics (toxins) . . .” Michie C., Obinna F, Thomas A, et al. Intestinal permeability, diet, and growth. Letters, *Lancet*, 1991; 338; 1403.

Researchers have found that “. . .abundant in vitro and in vivo data demonstrate that availability of arginine for NOS (nitric oxide synthase) can control the synthesis of nitric oxide with major physiological and in many cases pathological consequences.” Larrick, JW. Metabolism of Arginine to Nitric Oxide: An Area for Nutritional Manipulation of Human disease? *J Optimal Nutr* 1994; 3(1): 22-31.

**Q: Since you aren’t measuring specific nutrient levels, how do you determine what goes into my Custom Essentials?**

A: Your Custom Essentials is customized as follows:

First, a foundation formulation of all the traditionally known essential vitamins and minerals is selected for you based on your gender and age. These dosages are determined by using data for persons

of your sex and age group, derived from peer-reviewed research studies evaluated by our staff of PhD's, clinical nutritionists, and other experts.

Next, your test results are evaluated. Each test result category has several sets of nutrients associated with it, which are known to influence the specific biochemical pathways described by that test result. Depending on your results, those nutrients are then added to your foundation formulation in specific amounts, one set of nutrients for lipid peroxides, one set for sulfates, and one set for nitrates.

The total mixture is then homogeneously blended in a stepped blending process under carefully controlled conditions to produce your Custom Essentials product. This special blend is the single, best-fitting combination for you out of 48 possible combinations of 55 essential nutrients and accessory ingredients.

**Q: How would you describe Custom Essentials?**

A: Custom Essentials is a cutting-edge, pharmaceutical grade, multivitamin/mineral supplement, providing all of the known essential nutrients customized to the needs of age and gender, *with targeted nutrition based on the three vital metabolic areas evaluated in the PrivaTest.*

**Q: Do your tests look at sensitivity or specificity?**

A: Most clinical healthcare practitioners have been trained to assess laboratory results in terms of disease or absence thereof. In fact, the terms "specificity" and "sensitivity" are defined as such, with "specificity" being those persons deemed free of disease *as identified by a test* and "sensitivity" being those persons having a disease *as identified by a test*.

However, when it comes to metabolic and nutritional medicine, we cannot apply the same black-and-white terminology to nutritional laboratory evaluation because we are not diagnosing disease; we are evaluating *function*.

For example, in the PrivaTest, the decision point of concern for urinary sulfate (a marker for sulfur reserves) is 180 mg/Liter. (We have established that decision point based on several factors including peer-reviewed literature studies, clinical observations, reference range comparisons from other metabolic laboratories, and in-house data collection.) Below this point, we reasonably suspect that body sulfur reserves are being compromised for some reason. Now, the corollary to that supposition is that, with low sulfur reserves, Phase II detoxification ability may *also* be compromised due to the important roles that sulfur-containing compounds play in detoxification.

Suppose that 1000 individuals take the urinary sulfate test. Out of that 1000, let's say there are 200 people below 180 mg/Liter. In other words, based on our criteria, there are 200 "positives." Are we able to say with precision that all 200 people with less than 180 mg of urinary sulfate are experiencing compromised detoxification ability? No. We are simply saying that a marker for sulfur reserves is showing that possibility.

Now, here's the crux of the matter. Because these clinical markers can sometimes be affected long before clinical symptoms appear AND because our therapies are based on low to moderate doses of nutritional substances, we are willing to accept more false positives.

In other words, in nutritional medicine, it is more important to have sensitivity than specificity. We will assume that *everyone* with a certain set of markers is heading down the road to eventual overt clinical symptomatology, even though *all* of them might not be. We would prefer to offer all "suspect" individuals a safe, nutritional "insurance" package *now*, rather than wait for a definitive differentiation through future clinical diagnosis after function is compromised to the extent that disease has developed. That is preventive medicine.

According to the researchers at MetaMetrix Laboratory, this concept is at the very heart of what metabolic testing labs do and is exactly what differentiates them from traditional reference

laboratories. We are examining functional biochemical markers and using nutritional therapy to support, improve or even correct pathway function.

Like you, Dr. Barrett, I have been traditionally trained, as have all the PhD's and MD's who were involved in the development of the PrivaTest. Collectively, our research staff and Board members represent educational and/or professional affiliations with the finest institutions in the country, including: Harvard Medical School, Boston University, Brown University, Hahnemann Medical College, University of Florida College of Medicine, University of Texas at Austin, and Beth-Israel Deaconess Medical Center in Boston.

I, myself, graduated from a fully accredited nursing program in 1972 and have been a registered nurse for almost 30 years. My clinical background includes Coronary Intensive Care, Cardiac Catheterization, Surgical Intensive Care, Renal Dialysis, and Neonatal Intensive Care. However, since my very first nursing school nutrition courses, I have been intrigued with nutrition and biochemistry and have pursued further education on these subjects over these 30 years as well.

Eight years ago, I was fortunate enough to gain employment with a clinical laboratory and medical clinic specializing in functional medicine testing and nutritional therapy. During my years of work with that laboratory, I saw many people respond to the functional medicine approach where the traditional medical model had failed. You might state, "Placebo effect." Possibly, but why was there no "placebo effect" when the patient was using the more traditional approaches? The belief in our traditional medical model can certainly be just as strong in a patient seeking help from conventional medicine, at least initially. If the patient was "susceptible" to the placebo effect, surely it would have been equally operative in the two modalities. Additionally, improvements persisted. Anecdotal? Yes, certainly. Individual results are unfortunately given this label, which somehow implies that the individual results must be invalid. But for those people who gained increased function and quality of life, this "anecdotal" response changed their existence for the better.

As a long-time frequenter of health food stores, I have been appalled at some of the well intended, but alarming nutritional advice I have overhead that is being daily dispensed to the American public. Ideal Health is attempting to bring consistency and logic to the supplementation question, based on science and individual needs. Is our approach perfect? What is? Is it subject to future change through further research? What isn't? In fact, our goal *is* to improve through on-going research.

Like you, Dr. Barrett, we at Ideal Health are concerned about the consumer who is perhaps megadosing on large amounts of unnecessary supplementation. In fact, we are proponents of the "less is more" concept when it comes to nutritional supplementation.

Our research supports much more moderate levels of nutrients than is common in the industry. For instance, some studies show that 500 mg of vitamin C increased liver glutathione stores by 50%. Increasing the dose to 2000 mg raised stores only another 5%. Therefore, the maximum effect was achieved with the smaller dose. Absorption studies show that the body can handle just 20 mg of riboflavin and about 50 mg of pyridoxine in one dose. There is a limit to the amount of enzyme that the body can make in a day and throwing more vitamins into the mix does not necessarily increase activity. There is also evidence that greater than 100 mg of B6 per day can actually reduce sulfation in Phase 2 liver detoxification. Of course, due to biochemical individuality, there are exceptions to these situations but, generally speaking, Americans may be using costly and unnecessary supplementation. We regularly present educational information of this kind to our consumers in our monthly newsletter. We *prefer* an educated consumer. We are attempting to bridge traditional and non-traditional approaches to health. In fact, the term "complementary medicine," describes our goals perfectly; the two approaches *can* complement each other. To do that, we are using methods familiar to the traditional medical mind, laboratory testing and peer-reviewed studies. Familiar methods, used in a new application. That is the way progress is made; opening minds to a new way of looking at things.

Unfortunately, traditional science and medicine have a long history of being the "last to know" when it comes to accepting new approaches over a long-entrenched way of doing things. The scientific community

is also infamous for persistently embracing erroneous information as official dogma. We have only to consult the nearest history book to read example after example of this fact.

- (1) The “ebb and flow” theory of blood circulation persisted among medical experts from Galen’s days in the 2<sup>nd</sup> century AD until William Harvey disproved this theory in 1628.
- (2) The 1513 Copernican theory that the Earth revolved around the Sun, was considered implausible by the vast majority of Copernicus’ contemporaries and by most astronomers and natural philosophers. Acceptance of this theory was not achieved until 1687.
- (3) The concept of “spontaneous generation” (the idea that living organisms could develop from non-living materials; e.g. maggots were “created” from rotting meat) was accepted as fact by “mainstream” scientists from Aristotle’s time of 322 BC until 1688 AD.
- (4) Semmelweiss, a physician at a maternity hospital in Vienna, observed in 1845 that there was increased maternal mortality from puerperal fever in the maternity wards where *physicians* delivered the babies, compared to the wards where *midwives* delivered the babies. In that time, it was common practice for doctors to come straight from the autopsy room and enter the maternity ward to perform deliveries, wearing their bloody clothes and without washing their hands. Back then, the more prominent the surgeon, the filthier the lab coat; a symbol of how hard he was working. Remember, these were the medical authorities of the time. Semmelweiss proved that these very doctors were actually causing the puerperal fever problem when they examined the laboring mothers without washing their hands. Over resistance, Semmelweiss instituted hand-washing protocols, which reduced the mortality rate from 18% to less than 1%. His reward for this? He was fired. The established physicians, especially those who were proud of the “hospital odor” of their hands, resented being told that they were causing disease. It would take almost 20 years before the germ theory was accepted by mainstream medicine. Think how many women died unnecessarily during those 20 years.
- (5) More recently, we can examine the issue of trans-fatty acids. For over 30 years, those in the “non-traditional” arena have been stating the dangers of these types of altered fats found in partially hydrogenated products, especially margarines. Margarines were pushed on the American public during that time as being “safer” than butter. In recent years, “traditional” medicine is now finding merit to our position that trans-fats are extremely damaging.
- (6) In this week’s (June 26, 2001) issue of *Circulation: Journal of the American Heart Association*, researchers found that albumin measurement in the urine is a marker of cardiovascular disease in postmenopausal women. *Ideal Health’s FitTest has been measuring microalbumin in the urine of our customers for almost two years now!*

Max Planck, the winner of the 1918 Nobel Prize in physics, once stated:

“An important scientific innovation rarely makes its way by gradually winning over and converting its opponents; it rarely happens that Saul becomes Paul. What does happen is that its opponents gradually die out, and that the growing generation is familiarized with the ideas from the beginning.”

Unfortunately, this is too often true. Traditional medicine has a history of “circling its wagons” whenever challenging ideas are presented.

Dr. Barrett, again, I applaud your efforts in the education of the public. I know the desperation that people have for health and as we baby boomers age, that is only going to become more of a national issue. This creates fertile ground for scam artists. The healthcare scene is definitely a place to cry, “Caveat emptor!” Your website is a laudable effort to protect the public and has wide influence due to your impressive Curriculum Vitae.

However, with that influence comes a great responsibility that your “prejudices” don’t close the door on methods that are considered “non-traditional,” but are, nevertheless, complementary to “traditional” medicine and are effective and often much safer.

FDA document #FS 01-9 published in May of 2001, states that adverse drug events “may cost the lives of up to 100,000 Americans, account for more than 3 million hospital admissions, and increase the nation’s hospitalization bill by up to \$17 billion *each year.*” (Emphasis mine.)

These are statistics describing FDA approved prescription drugs. The comparatively small number of adverse events reported to the FDA regarding nutritional supplements is an enviable record when compared to the number of adverse events from “approved” prescription drugs.

However, even this safety record for supplements can be improved. We are working to make nutritional supplementation even safer through individualization *and* more cost-effective by cutting out unnecessary supplementation. It is unfortunate that those who are strict “traditionalists” have decided to label our efforts and our scientific methods as “dubious.”

That may also be unfortunate for those who view your website as the “last word” in “quackwatchery.” Through your website, they may be persuaded to close their minds against information that has potential benefit for them and then do no further investigation on their own.

Those with your kind of responsibility must guard against becoming too attached to a “dirty lab coat” and the smell of “hospital odor” on the hands. New ideas that don’t fit with your current model *must* be considered. Otherwise, no progress will be made OR it will be made too slowly to make a difference in the lives of those who need it now. *Fortunately, an increasing number of savvy healthcare professionals are beginning to use functional medicine in their practices.*

I thank you for reading this somewhat lengthy letter. I also request that you use it in its entirety if you decide to use any of it at all for your website. We will be posting it on our website.

Again, I don’t expect my comments to significantly change what you think or what you write about us. I just want to make sure that our position is presented fairly on your website so that consumers can decide *for themselves* what is appropriate for their health needs.

We are actually on the same side, but our different clinical experiences give us different opinions. As the Dave Mason song says, “There ain’t no good guys, there ain’t no bad guys. There’s only you and me and we just disagree.” But that’s America, isn’t it?

Respectfully,

Denise Autry, RN, CCN  
Director of Clinical Services, Ideal Health