Which Road to Superior Quality?

Rick Liva, ND, RPh

I recently read 2 viewpoints regarding the state of the dietary supplement industry. My recent experiences with either false representation or poor quality of raw materials would support the first opinion and relegate the second to wishful thinking. The second opinion tries to polish a tarnished kettle, but no matter what kind of polish is used or how hard one polishes, the kettle remains dull.

I'll share the second opinion first, which was published in the April 2007 issue of *Nutritional Outlook*.[1] It is an open letter to the dietary supplement industry (DSI) written by a man who started a popular retail line of dietary supplements. He laments that the media has been bashing the DSI for the past several years. The stats he presents show that nearly 12,000 articles on supplements were published, with 2.7 billion readers, from December 2005 to November 2006. Of these, 30% were negative and only 23% were positive (47% were neutral). Interestingly, some 78% of all the 12,000 articles were published about safety, quality control, and efficacy.

He writes, "Regularly published stories about our products not meeting label claims further erodes consumer confidence." He also lists 8 industry problems. The first is the assertion that the industry has developed a serious credibility gap that must be reversed. The next 7 are about poor communication, concerns with drug interactions, upset over a few supplement categories (eg, weight loss), and the fact that the industry has not put enough money into Washington lobbying. And yes, he makes the claim that every one of these problems can be fixed with time, money, and commitment. The stated goal is for the industry to "get its house in order" (I assume he means improve quality control and quality assurance industry wide, but he does not state this specifically). In the meantime, he suggests we spread the good news about who we are and what we have to offer.

Commentary on the Second Opinion

Although the above sentiment to get our "house in order" is a thought in the right direction, unfortunately the inferior and the deficient parts of the industry will continue to overshadow the good. The quality piece needs to be dealt with in specific terms and resolved as soon as possible. I believe that poor quality is a huge problem in this industry and that it will not go away until someone sets a standard, enforces it, and drives out the players who are not willing to step up to the plate. Until this happens there will be an uneven playing field and significant deficiencies will exist. This man's lament is valid, but his approach too closely matches the industry's overarching focus on maximizing dollars rather than improving product and promotional integrity.

The First Opinion

The first opinion was an anonymous posting to John Week's *The Integrator Blog* (www.theintegratorblog.com).[2] It is simple, to the point, and easily understood. Too bad no one is heeding this person's advice. And too bad most clinicians do not take the time to make sure professional product companies prove their quality claims.

The posting states,

> *"Regarding this constant whining about how the press doesn't like the supplement industry. Is there thickheaded stupidity in mainstream media coverage of alternative medicine? Of course. Do the drug companies control our thinking about health and illness to a depth we don't even want to consider? Absolutely. But know what? The supplement industry is so damned sloppy with its sourcing, its manufacture, it's ridiculously lame promo/marketing, that it deserves pretty much all of the flack that it gets. If the DSEA (Dietary Supplement Education Alliance) would spend half as much time and money focusing on developing real quality initiatives as they do on producing stupid-ass PSAs for network television, the industry wouldn't have an image problem to begin with. If all these kvetchers would put some energy behind positioning the industry as part of the solution to the healthcare crisis, and do what they need to do to clean up their acts, they might actually get somewhere."*

Commentary on the First Opinion

Well said, whoever you are. This is the focus the industry needs to take if it is going to prosper with credibility and be of utmost value to people.

Recent Quality Assurance Challenges

Is there proof of poor quality in natural products? As readers of this column know by now, the answer is absolutely. Consumer Lab recently tested chondroitin sulfate in products and found that 73% failed label claim. My company routinely tests all raw materials that come to us. Because of this we get exposed to lots and lots of quality assurance data. Following are the problems we found most recently (and this list could be greatly expanded if I went back for years).

Ashwagandha (*Withania somnifera*) extract that flunked identity testing (Thin Layer Chromatography, TLC) for genus and species verification and was hugely subpotent by High Performance Liquid Chromatography testing. This material was supplied by a European botanical supplier with a good reputation for quality.

Astragalus (*Astragalus membranaceous*) that flunked identity testing (TLC) for genus and species verification.

Borage oil capsules that list a 4-year expiration date but went rancid within 24 months. This product was bought from one of the largest supplement manufacturers in the world. When I asked for data to support the expiration date, the manufacturer sent gamma-linolenic acid assays that back up the 48-month dating. However, in my testing of this product for stability, I repeatedly, found that it goes rancid between 18 and 24 months. I can only assume they do not do any rancidity testing in their 48-month

stability program. Surely if they did, they would find what I found—a rancid product way before 48 months. I am sure they sell a lot of this product to many suppliers that use their 48-month dating without doing any verification testing of their own. How many people are out there consuming this product with rancid oil in it?

L-Arginine that was substituted with L-Arginine HCL but was labeled L-Arginine. (L-Arginine HCL is only 80% arginine, whereas L-Arginine is 100% arginine.)

Myrrh gum (*Commiphora myrrha*) powder that flunked identity testing (TLC) for genus and species verification. When confronted, the supplier admitted that they sent the wrong product labeled as the right product.

Panax ginseng that claimed to be 15% ginsenosides but that tested at 11.4%—a 24% subpotency. This material was supplied by a European botanical supplier with a good reputation for quality.

Pyridoxine HCL that claimed to be 98-100% but tested at 90% and required a 10% subpotency adjustment to use it.

Riboflavin 5 Phosphate that claimed to be 98-100% but tested at 90% and required a 10% subpotency adjustment to use it.

Xylitol powder that flunked purity testing because it was adulterated with sorbitol.

Besides bringing to light the many issues abounding in quality, I also wish to make the point that problems are found because a company takes the time and spends the money to look.

Along these lines, I had one practitioner contact me who had sent *IMCJ*'s Manufacturer Quality Assurance Self-Audit Form (see below) to 30 manufacturers. He received back only 2—a 7% response. Of these, 1 provided no proof and said if this person wanted proof, he would have to come visit the manufacturing facility itself to see it. The other openly admitted they don't do much with quality assurance—although, if you look at their advertising and marketing materials, they promote their "superior quality."

I ask again: Are the supplement companies you buy from turning the proverbial blind eye and using whatever they get without verification? How would you know? Do you ask for proof? If not, why not? Does it matter to you? Are you using subpotent, superpotent, or contaminated products?

What to do?

So, what is the road to superior quality? It is very uncomplicated and straightforward. Proof of routine testing of each batch of raw material for identity, potency, and purity (testing for an array of contaminants), as well as finished-product-potency testing to verify label claims, are simply the right things to do. That said, I suspect and fear that most manufacturers are just not doing this testing. Why? No one makes them have to do so and it saves them a boatload of money. Should we rejoice that they get to buy lots of toys with the extra profits?

With the examples given above, it is all too obvious that the old adage of "garbage in, garbage out" applies to the retail and professional branches of the dietary supplement industry. But this garbage is hidden in pretty packaging and slick marketing. What you see is not necessarily what you get. Widespread lack of quality assurance proof creates a "buyer-beware" scenario. As a clinician, when you procure supplements to pass along to your clients, you need to be able to judiciously obtain and interpret a company's QA information and find the truth.

The goal of all of my articles on quality assurance is to impress on you the urgent need for quality standards. To help you do this, I developed and wrote a questionnaire for clinicians to question manufacturers and/or suppliers about their quality assurance practices. It is available at *IMCJ*'s website, **www.imjournal.com**. In the menu bar on the left, click on "**Quality Assurance**" (located near the end), then click on **"Manufacturer Quality Assurance Self-Audit Form**."

Please send this form to each of your natural products manufacturers and/or suppliers and see what comes back. It directs them to answer a series of questions, but also asks for documentation that helps provide verification that they are, in fact, doing what they claim they are doing. The questionnaire asks for proof as well as yes-or-no answers. It is easy to answer yes to a question on a form; it is more difficult to provide proof.

When the Self-Audit Form is returned, you also can then use some of the answers to calculate the daily toxicity load that will result from ingesting a manufacturer's product. Again go to the *IMCJ* website, click on "Quality Assurance," then click on "**Toxicity Calculator**." Contamination is a serious quality assurance problem and needs to be considered when taking or prescribing dietary supplements. It is critical to assess the toxic load of various contaminants based on the highest-possible daily dose of a particular manufacturer's product, ie, the amount a person would take as a normal dose in a day. By using the Toxicity Calculator you are to able to determine this.

It is also important to note, since I do not list names, that some supplement-manufacturing companies do take most or all of the QA measures I have detailed in this and other issues of *IMCJ*. I commend them for their diligence and commitment. It is important for clinicians to know who they are. The only way to find out is to send them the QA form and question them.

Ask, ask, ask, and ask again for proof. Never stop asking for proof of quality assurance testing. If you are not asking, you are burying your head in the sand and risk using inauthentic, subpotent, or contaminated product. The manufacturers that supply you with independent proof are testing, and the manufacturers that give you double speak and supply nothing are not testing.

If you are unfamiliar with quality-assurance issues or need further clarification, I am available to answer your questions and provide information. Please contact me at rickliva@center4health.com.

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References

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2. Weeks J. Study finds "dismal news" on media reports on dietary supplements. *The Integrator Blog.* April 18, 2007. Available at: http://www.theintegratorblog.com/site/index.php?option=com_content&task=view&id=275&Itemid=93.Accessed June 26, 2007.