another pithy editorial

Hey kids, it’s time for grand rounds! Let’s check on the patient’s progress and see if he needs to turn his head and cough a little harder!

Ah, Dana Point in July, it must be the Nutrition Business Journal’s (NBJ) annual meeting of hundreds of corporate heads of the dietary supplement (DS) companies and ingredient suppliers – the who’s who of health, as it were, sponsored by a very good publication. I remember the 2010 meeting like it was only yesterday ...

I was invited to a special dinner of the 25 top industry leaders where specific policy issues would be discussed. A major issue of discussion was the aftermath of the Code of Federal Regulations 21, part 111, which called for more stringent FDA inspections of companies and how the industry was doing in the wake of those inspections. Discussion was open as to how to use the lack of any major disasters as a result of these inspections to the advantage of the industry – to counter the negative publicity garnered by some of the morons in the industry. A motion was actually proposed and seconded to initiate a “Mission Accomplished” campaign for dietary supplement quality control. It took two of us, almost being rude, to squelch that idea and convince the group that it would be a disaster in the making. The mission has not yet been accomplished, George. The idea was tabled. That patient seems to be recovering.

Another special meeting, love those private things! This one called by the head of one of the “professional” DS companies to discuss an alliance of the professional brands (pros), to differentiate them from health food store and multi-level marketed brands. In attendance were representatives of a major trade organization with a national presence, including lobbyists. The members of the trade organization included DS manufacturers, food manufactures, and ingredient suppliers, giving them a “voice on the hill.” Personally, I like to think of it as a voice in hell. The idea was that an alliance should be formed and a campaign launched to differentiate the professional companies, most of whom had already had a recent FDA part 111 inspection, from the “other” companies. The “pros” wanted to stand on their reasonable inspection record and tout their quality, their independent lab analysis, etc. Everybody would join the trade organization and it would help the “pros” have a “voice.”

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Living for moments like this, I pointed out that many of the “pros” don’t even make their own products, they are contracted out and, indeed, most do not have analytical laboratories, let alone real quality control measures. There would be no bigger black eye than to have some idiot in the media decide to have products produced by the wonderful “pros” analyzed and find something not to label specification. They would search until they found something, at which point the self-inflicted wound becomes abscessed. To make matters worse, I suggested one way to assure quality was to have a proper independent laboratory do analysis of not only the “pro” manufactures, but of
the other manufacturer members of the trade organization. Neither that suggestion, nor my insistence that the results be available (even if they were detrimental to the “non-pro” members), was met with any warmth. Basically, the organization did not want to upset the cozy relationship with its members, no matter how poor their quality. That patient will never recover.

March 2011, what better place to be than the Natural Products Expo, held in the wonderful Anaheim convention center! Late booking, no problem, I got a room at the Candy Cane Inn, a short walk from the action. Just the name of the hotel leaves the imagination with many jokes better left untold. There were thousands of attendees, perhaps a thousand exhibitors with wares, from natural foods and cosmetics to the aforementioned dietary supplements. Let us find one honest, intelligent person at one booth somewhere selling supplements. Please!!

After being sent reeling by the statements of one raw material supplier that he did not need to do any confirmation or quality analysis on the ingredients he gets from China, because…. drum roll…. he has been buying them for many years and since nobody has complained about quality, he does not intend to start doing analysis now. It will just increase the price.

Quickly sensing psychosis coming on, I decided not to stir the waters too deeply and just pick a discussion topic: Fish oil, since everyone sells it. Let’s look at conformity of labeling among companies and compliance with FDA mandates. I believe I went to every booth and reviewed every label in the room and questioned at least one representative from every company on the labeling of EPA and DHA content and label compliance. If they did not have the answer, I tried to find someone in attendance that did. Some of the questions I asked were:

➧ Why do you have “manufactured by,” instead of “distributed by,” as required when you do not physically make the product?

➧ Why does your company list the amount of EPA and DHA on one label as “triglyceride,” on another label as “ester,” and on another product label there is no listing of form of fatty acid. [This sales person actually stated that they formulated their products based on studies and if the study reported it that way, that was the form that was used. In fact, FDA requires the amount labeled in milligrams of EPA and DHA to be reported as free fatty acid (FFA) amounts. This is the amount of FFA found after subtracting the glycerol backbone of a triglyceride or the ester of a bound fatty acid. Thus, the 300/200 mg label amount may be as triglyceride or ester and actually be significantly less fatty acid than the consumer believes they are getting.]

➧ Why do you not have the source of fish oil, as required by FDA regulation for allergy?

➧ Why do you not have the ending statement “this product contains fish (source of fish)” under the “other ingredients” statement, as required by FDA regulation for allergy?

Not one company had any analysis available at the booth, either for labeled levels or contamination levels. Not one person had the ability to answer assuredly the levels of free fatty acids in the product. This patient has died, since this portion of the industry seems more intent on profit and sales than quality control.

Minneapolis in April – springtime in a beautiful city and the first iMosaic conference bringing together four physicians groups in one setting for the first time. This is where the “pros” will be, so obviously they will have all the answers to simple questions on that silly subject, quality control. Right...

“All that stuff above about labels and oil from dead fish, etc., we’ll just put an ibid here and save you the eyestrain – lots of incorrect labels and very little knowledge.

Then there was the guy from a Texas company that has been around for about thirty years who stated that the company had products made by a contract manufacturer but they never did any finished product analysis. However, he was proud...
that his company did analyze all the raw materials used in those finished products of unknown quality. He stated with all sincerity that “when you mix all those ingredients, it’s hard to get all the right levels.” What a comforting thought. Don’t validate that you might have it all wrong, much like politics. This patient is ill, but can recover.

As I spend time at conferences and talk to practitioners whom I have known for years, every single one decries the state of the industry and their own lack of knowledge, but they still buy those products. Everyone wants to know how to distinguish good from bad, but has lacked a credible resource to teach them the difference. At conventions and seminars there will be a one-hour talk from a company affiliated person on quality control, usually ranting about contaminant analysis. Their herbal extracts may be contaminant free, but it might not even be the herb they think it is if they follow faulty identification procedures.

What is needed is an education program for practitioners, by independent, qualified personnel. Every organization should set aside one full day of accredited time for proper education on what practitioners are putting in their patients’ mouths and staking their reputations on. This cannot be done properly by manufacturers, distributors (with or without quality assessment programs), unqualified companies, or unqualified agencies that “certify” manufacturers with GMP stickers. It needs to be done by unbiased, experienced, qualified personnel who can address not only manufacturing and regulatory issues, but also analytical and technical issues.

The organizations that sponsor seminars and conventions need to set standards, after they receive enough education to establish proper standards, for all exhibitors and personnel exhibiting. Companies wanting to sell their products should have at their booth (and representatives should be knowledgeable about):

- GMP, a copy should be required.
- Representative SOPs
- Raw material analysis for identification of representative ingredients. These must come from an acceptable laboratory.
- Finished product analysis for representative products, which also must come from an acceptable laboratory.
- A database of technical information on source of ingredients and manufacturing.
- A copy of their last FDA inspection record, including any 483 comments.
- A copy of a complete production record, unsanitized, for a representative product.

We cannot ask companies to bring the kitchen sink, but it becomes quickly evident which companies have in place at least reasonable quality control procedures. At some point each organization, be it educational, national or regional, will have to come to grips with this problem. Make the patient cough a little harder or the media will do it for you – I guarantee it.

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