On March 18, 2012, Dateline NBC weaved their way through a report beginning with the results of an improperly mixed dietary supplement (DS), which led to disastrous consequences. The episode ended with the exposure of a major problem in the DS industry – fraudulent laboratory analysis by “independent laboratories.” This is the very same problem reported in Alternative Medicine Review (AMR) eight years ago (Volume 9, Number 4, 2004) in my editorial entitled “Bursting the Analytical Bubble.” Having authored more than a dozen editorials on DS quality control problems rampant in the industry, I know the problem has not gone away and has been consistently ignored by the DS industry for years. Perhaps this news story will be a kick in the pants.

The Dateline episode began with the life changing consequences of mistakenly putting toxic levels of selenium in a product. This mistake was due to an improper level of selenium called for in the master formula for the product in question. The interviews with the victims, complete with documented hair and fingernail loss and medical nightmares, are heartbreaking. The rest of the episode documents how the analytical quality-control standards, which should have been in place, failed.

The liquid vitamin product, Total Body Formula purchased from General Nutrition Center (GNC), was eventually subject to a recall effort after consumer symptoms caused alarm. The raw material supplier of the selenium, Wright Enrichment, upon learning about the problem, allegedly produced a false certificate of analysis showing acceptable selenium levels, without having an actual laboratory test run. TexAmerican Food Blending was responsible for the blending of the final liquid product. Interviews on camera by the production manager reveal that upon finding “black specks” in the liquid product, the employees strained the product through “women’s panty hose” into buckets to try and remove the contamination.

“Dateline set up a sting operation for the laboratory director, Dinesh Patel, who also did the fraudulent analysis mentioned in my AMR editorial (Bursting the Analytical Bubble)”

BUT, what if the raw material supplier, the blender, and the final retail sales giant had submitted the ingredient, the in-process product, and the final product to an independent laboratory for analysis? The problem would have been solved, correct? Well, not necessarily. As the Dateline investigation continued, they carefully set up a sting operation for the laboratory director, Dinesh Patel (Patel), who did the fraudulent analysis mentioned in my AMR editorial (Bursting the Analytical Bubble), albeit under the guise of a new company, now Atlas Bioscience.

Atlas Shrugged (Kind Of)

Her husband was abusing their daughter, or, perhaps an axe murderer was a nephew, or an embezzler was a brother. When you see one of those stories on television news, the mother “couldn’t believe her husband would do that to her daughter”, the uncle never saw the axe fetish, and the sibling did not relate the brother’s funds, which were well beyond his means, to embezzlement. Sometimes it is the truth; many times it is someone turning a blind eye to something they are intimately aware of.
Two carefully constructed powder samples were prepared for submission to Atlas for analysis. Unknown to the smiling Patel, there were ingredients for which analysis was requested that were not even in the product and which should have come up with no detectable results. Moreover, both samples had been laced with materials that were not only toxic, but also which were present in high enough levels that no legitimate analytical laboratory on earth could possibly miss them. One sample was spiked with high levels of selenium and the drug sibutramine; the other with high levels of arsenic and lead. Atlas reported analytical results suspiciously close to the levels provided by Dateline on a “suppliers analysis” (i.e., the initial fabricated certificate of analysis) for the two products, even though those levels were fictitious. This was the same thing that Patel did in the “analysis” he provided for the AMR product sting eight years ago, only this time he was missing levels of materials by almost a thousand-fold: toxic levels as it turned out, and he missed the sibutramine entirely, even though it was part of the analytical request.

Imagine yourself now listening to a political speech on television. Close your eyes and pretend it is not the statement Patel used in his defense to Dateline:

“When given misleading information regarding a samples make-up, we would not be aware that the data being observed is being compromised due to the matrix parameters we are not cognizant towards.”

In something imaginable only as the Heisenberg Uncertainty Principle being interpreted by a reincarnated William F. Buckley in the throes of an LSD meltdown, Patel has reduced analytical laboratory science to an internet social standard.

And now for the fun part. Since I have mentioned the internet, let’s do a little searching. If you Google “Atlas Bioscience” one of the things you will see are links with (PDF) in front of them. Many of these links once would have taken you to PDFs of Atlas’ “analytical reports,” for products submitted by DS product companies (who shall go unnamed in this particular editorial, but which you can readily see for yourself in the URLs). At one time certain DS companies were proud to display these links from their company websites as a testament to their “product quality.” Many of the links no longer work when you click on them. However, if you move your cursor to the right of each link a double arrow appears and to the right of that a copy of the unlinked PDF will appear, albeit this copy is a little harder to read. Take a bit of time to view these: You will find it an interesting way to spend an hour.
Now for the part that keeps me in the running for the most disliked person in the DS industry: what to do when you have to take your child to the parent-teacher conference knowing full well that the teacher should be fired...

Trade associations that count ingredient suppliers, supplement manufacturers, and retailers, as dues-paying members are often reluctant to step on the toes of those that contribute to their coffers. At no time does this become more obvious than when a negative story about supplements comes out in the national media. Just like Captain Renault in *Casablanca*, commanding his police force to “round up the usual suspects,” the stomach churning line from some trade associations has always been that “the problem is only caused by a few bad actors.” While Lieutenant Colonel Kilgore, in *Apocalypse Now*, loved “the smell of napalm in the morning,” I prefer the sound of member toes crunching when stepped upon.

Press releases in response to the *Dateline* episode (edited for space) included:

**The American Herbal Products Association (AHPA):**

“Laboratories such as the one depicted on the *Dateline NBC* show do not represent the mainstream of laboratories that service the food, dietary supplement, drug, and allied industries. ... The specific situation of a laboratory’s failings covered by *Dateline NBC* is not representative of the responsible supplement industry. The show failed to recognize the expertise found in hundreds of supplement companies that understand how to properly qualify a third-party testing laboratory. Knowledgeable manufacturers know how to choose a lab and to verify results.”

**The Natural Products Alliance (NPA):**

“Consumers can trust what they read on the labels of dietary supplements. We share the concern about the issue of ensuring that products contain what the label claims and are not contaminated... Fortunately, consumers are smart enough to understand that a few or occasional lapses in quality assurance should not translate into suspicion of an entire category of products, especially one with a strong history of safety. ... Products that contain undeclared drug ingredients are not dietary supplements. These products are illegal drugs, and they have no place in the legitimate marketplace.”

**The Council for Responsible Nutrition (CRN):**

“We are concerned, as any industry would be, when a few companies engaging in fraudulent and criminal activity overshadow the legitimate products sold by responsible companies. ... Responsible companies follow the Good Manufacturing Practices (GMPs) regulations that became fully effective in 2010. These rules prescribe step-by-step requirements for the manufacturing and testing of dietary supplements—from the raw ingredients coming into a plant to the finished products headed for consumers—and place absolute responsibility on the manufacturers and distributors, including the actions of any testing labs they hire. We call on FDA to take strong enforcement action against both the companies and the testing labs who do not make safety their top priority...”

“Meatloaf sang ‘Two Out of Three Ain’t Bad.’ In the case of trade associations one would hope that it was more than ‘One Out of Four Ain’t Bad’”

**United Natural Products Alliance (UNPA):**

The UNPA has not issued a press release on the *Dateline* segment as of the writing of this editorial. One interview with Loren Israelson, UNPA Executive Director, had him stating that the segment was “sobering and distressing and that this issue will hopefully be dealt with.” UNPA has operated an analytical group for its membership and has held analytical lab competence training events for the past eight years. UNPA has maintained a position that:

“FDA (Food and Drug Administration) is set to begin Section 111 GMP inspections of contract analytical laboratories who are seen by FDA as an extension of the manufacturer and thus within the scope of Section 111 inspection... It has become increasingly clear that the large majority of DS manufacturers have no benchmark data to judge whether their spend on inside/outside analytical testing is appropriate based on industry best practices. We believe this should be remedied and have been in discussions with Ole Miss [University
of Mississippi, editor] and FDA to provide key benchmark data education for company executives with regard to costs for analytical testing, personnel training, analytical equipment, investments, etc. We believe this will be a critical tool to help companies judge their performance against best practices.”

Meatloaf sang “Two Out of Three Ain’t Bad.” In the case of trade associations one would hope that it was more than “One Out of Four Ain’t Bad.”

Every time that I have attended industry trade events I have heard the “industry leaders” complaining about the problems in the industry, and quality problems in the industry have been at the top of the list over the past 10-15 years. There have always been complaints about how to fix this big, amorphous quality issue in the DS market, the same one the media has been beating the industry over the head with for more than 10 years now. If we just keep telling the press that DS products are great and there are only a handful of bad actors, they will probably just go away. It is obvious that this strategy has been working well thus far...

If the industry keeps wanting to make this a problem too big to fix, nothing will ever get fixed. We need to compartmentalize this into manageable, smaller tasks in order to get to the ultimate goal.

I have some suggestions for the “Three Out of Four” whose responses were a far cry from the accurate and to the point response of UNPA (i.e., that this issue is “sobering and distressing”).

1. Until you have a program in place that, through reliable independent analysis of your members’ products, has shown the quality of said products to be beyond reproach, quit issuing press releases defending those members as “responsible.” You don’t know what is behind door number three unless you walk around backstage and look.

2. Quit pretending that putting some quality assurance program logo from your association on various members’ labels amounts to real quality control review and assurance. Insist that your members be inspected by and trained in quality control by a qualified, independent organization such as NSF or NSF-DBA. And that those members subject themselves to random, unannounced audits by such an organization.

3. Insist that members attend training seminars in conjunction with FDA and/or personnel such as NSF-DBA. These are not just one-hour talks on quality control at an annual trade show by someone who is not qualified and who is affiliated with either a member company or the trade organization.

“if the industry keeps wanting to make this a problem too big to fix, nothing will ever get fixed”

4. Start issuing press releases whenever there is a bad inspection, detailing what should be done, and I mean really done, to correct the problem.

5. Stop issuing the same press release with only a few words changed whenever there is a bad media story about the DS industry. A third grader might do that in English class. Trade associations and the DS industry, in general, need to be better. Again, detail what should be done, no matter whose toes you step on, to correct the problem.

6. Knock out the dry labs, and you stop the ability of bogus companies to "legitimize" bogus products or ingredients. (See following guest editorial by Frank Jaksch, Founder and Chief Scientific Officer of Chromadex, who was instrumental in the Dateline story).

Don’t shrug it off. Atlas might have shrugged, but the DS industry can no longer afford to.