

## Beyond “Belief”: Moving Away From Dietary Supplements’ Reliance on Consumer’s Good Faith

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The New York Attorney General’s recent actions [1] against dietary supplement retailers and brand marketers has gone well beyond the borders of the state as well as beyond affecting only the brand marketers specifically targeted in its ongoing investigation. In essence, Attorney General Schneiderman has called into question the quality and compliance of the product category as a whole. One of the greatest concerns from the industry point of view is the potential, substantive shaking of consumer confidence in dietary supplements—and from the approximately thirty billion dollar and growing industry’s side of the fence, is what the whole hullabaloo is truly all about: Consumer confidence—or more accurately in the case of supplements—faith.

Industry has responded proactively against the NYAG’s ongoing activities, which have expanded from the initial Cease & Desist letters [2] sent to four major retailers including Target, Walgreen, Walmart, and GNC. The action was based on the results of testing conducted by DNA analysis (and much derided by industry and other experts), to requests for additional information substantiating allowable claims on these products. Going even further, Schneiderman’s office has sent requests to additional supplement brands [3] available in New York including Pharmavite, NBTY, Nutraceutical Corp., and others, for specific manufacturing and related information on their products.

One has to surmise from the highly public manner in which events have occurred that the NYAG is looking to raise awareness beyond simply conducting an investigation into the potential fleecing of the citizens of the state of New York. Major, national media outlets quickly and broadly picked up the story. Given the analytical methodology used on products in the investigation, DNA barcoding, as mentioned prior, was deemed inadequate by industry and many experts on botanical analysis, it would likely seem on first blush that that NYAG is conducting what could be construed as more of a smear campaign against the supplement industry than an exercise in consumer protection. Certainly, industry supporters and its trade associations are pushing that message to consumers, using words and phrases like “lack of transparency” and questioning why the NYAG would spend taxpayers’ money on these efforts when the federal government, via the Food & Drug Administration (FDA), handles enforcement over the category already.

The facts, however, are that no matter how much the trade

might wish it were so - the industry isn’t so squeaky clean, and the NYAG’s investigation may not end favorably for the industry. Though there are more than a few businesses producing quality products in compliance with applicable regulations (yes, the dietary supplement industry is regulated by the FDA contrary to what is often stated in media reports), there are definitely those who are not. It’s been estimated that approximately seventy percent of dietary supplement manufacturers are not in compliance with various, significant elements of the applicable good manufacturing practice (GMP) and regulations, which are in place to ensure the quality and safety of products.

And beyond that there are “bad players” and businesses in the supplement industry who are blatantly “cheating”—not putting the ingredients on the label in the products, intentionally substituting other ingredients (deeming these products to be “adulterated” and “misbranded” by the FDA when caught), making illegal claims on products, the “good guys” in the industry as a whole may in many ways be shooting themselves in the foot with regards to consumer confidence and that aforementioned consumer faith.

And, it may have been doing so well before, and since, congress passed the Dietary Supplement Health & Education Act (DSHEA) in 1994. DSHEA is the law that made supplement products a legal category as a subset of foods. As such, and on the basis that foods are considered inherently safer than pharmaceuticals, the products aren’t subject to the same rigorous requirements of FDA premarket approval as drugs, making entry into the supplement market much easier overall.

Before leaving the topic of “cheaters” and fraud, and moving into the history of the supplement industry and ways in which the industry may itself be providing ammunition for the oft heard phrase, caveat emptor (“buyer beware”), let me say this: the supplement industry isn’t alone when it comes to counterfeiting, by any means.

Interpol’s Operation Opson has been going on for the past four years, and now with over forty-seven countries involved, has reported results annually against fraudulent purveyors of food and related consumer categories—such as dietary supplements. The most recent, Opson IV [4], reported the seizure of over two thousand five hundred tons of illicit and counterfeit food,

with examples that should frighten even those with the most iron of stomachs—including everything from alcohol, meat, and strawberries to wine and mozzarella cheese. There’s also the University of California, Davis, Olive Center study [5], which demonstrated that only thirty percent of the extra virgin olive oil sold in US/California actually met international standards—citing major, national brands including Bertolli, Colavita, and others among the fraudulent providers.

While not being the only industry to experience fraud doesn’t excuse it, it should provide some perspective. It’s clearly not just a US issue, and it’s probably fair to say it’s somewhat rampant - looking at the most recent Opson IV list, counterfeiting in the food realm is happening in a lot of countries around the world. It’s going to take consumers demanding better products, and frankly, not buying lesser products/from those brands that aren’t willing to demonstrate their products are what they say they are in addition to industry stepping up and being compliant with applicable regulations and providing transparency that demonstrates that compliance, that will help change things, and move away from relying on the good faith of consumers.

This paper seeks to examine those areas in which the supplement industry is and has been relying, and in some cases one could go so far as to say preying, on that consumer good faith. Also offered are possible ideas for how the industry (and consumers) can move away from that belief-dependent system and towards educating users of supplements/consumers educating themselves to make more informed choices as well as building more substantiated consumer trust.

### **Dietary Supplements: A (Kind of) History Lesson**

The “birth” of the dietary supplement industry and it’s more recent, explosive growth, is widely attributed to the passage of the Dietary Supplements Health & Education Act (DSHEA), which amended the Food, Drug & Cosmetic Act (FD&C Act) in October of 1994 to create a separate definition and rules for claims for supplements, among other things. However, supplements existed and were regulated by FDA prior to the passage of DSHEA, and much of that history is worth noting as it helps to understand the current climate. But, enough research and well-written reports have been produced on this topic, and as such it seems better to focus here on the highlights and recommend reading those other, detailed accounts in full.

Before DSHEA, FDA regulated supplements as foods, drugs, or both, using its authority over drugs and food additives for enforcement. The agency often used food additive regulations as means of declaring a supplement to be unsafe under the FD&C Act, which would burden the manufacturer with the onus to prove the supplement was exempt from any such requirements.

*Kordel v. United States* [6] was also a landmark case and decision in 1948 that upheld the FDA’s power to regulate supplements. The Supreme Court decision concluded that FDA could invoke its authority over drugs against dietary supplements if information accompanying a supplement product included claims of treatment or prevention of a disease or a use that affects body structure or function. As a result of these enforcement tactics, most supplements were marketed by brands as foods, seeking shelter in the less strenuous regulatory environment.

Food products are and were authorized to make structure-function claims without FDA approval, because as indicated in the statute, foods inherently have these effects on the body’s structure and function—though supplements were only able to have the food classification applied if claims were related to aroma, taste, or nutrition.

In 1973, following a rise in products marketed as foods containing high dosages of vitamins and in what were deemed unnecessary combinations by the FDA, the National Nutritional Foods Association (NNFA) challenged new FDA draft regulations in federal court [7,8]. The draft regulations prohibited those combinations of vitamins and minerals when sold as foods, as well as setting maximum and minimum potency levels for nutrients. Though the court held that FDA was able to establish limits for vitamin and mineral doses with regards to eliminating consumer confusion over therapeutic effects, it also ruled that the mere fact that a nutrient is sold in high dosages would not automatically subject it to regulation as an unapproved drug—which the FDA had originally intended. This decision weakened the agency’s usage of drug authority as a means to regulate dietary supplements because the FDA would now have to establish proof that a manufacturer intended consumers to use its product as a drug therapy.

The effect of the above was, via subsequent lobbying efforts, the passage of the Proxmire Amendment by Congress, which codified the above decision in industry’s favor and further nullified the FDA’s authority over vitamins and minerals. *Fmali Herb, Inc. v. Heckler* [9] is another case in which the FDA’s authority continued to be diminished, centering around the FDA argument that the grandfather exemption for commonly used food additives in existence prior to 1958 exempted only those additives that were present and in commerce in the US, and was seeking to exclude various herbs and substances used in Traditional Chinese Medicine and other cultures. The courts ruled in favor of Fmali Herb and the industry, and the decisions allowed for ingredients used broadly outside the US to be exempted under the “grandfather clause”.

From 1983 until the early 1990’s, the supplement market boomed under the somewhat more forcibly relaxed enforcement options available to the FDA. Products practically flooded the market until 1993, when L-tryptophan, an amino acid being used by millions of Americans as an anti-depressant and bodybuilding aid, was attributed to thirty-eight deaths and fifteen hundred adverse events. In response, the agency assembled a Task Force that looked for options not only for the L-tryptophan issue, but also for all dietary supplements. The results of the Task Forces’ recommendations signaled to industry that FDA was seeking to regulate industry much in the way it had prior to the passage of the Proxmire Amendment, and in response, the industry turned to raising awareness with the general public for support.

In broadly distributed messaging, industry indicated to consumers that as a result of FDA’s approach many products, including vitamins and minerals, would be removed from the market. In addition, the FDA’s interpretation of the Nutrition Labeling & Education Act (NLEA, 1990) also contributed to what would eventually be the passage of DSHEA. The FDA’s

interpretation of the NLEA, which allowed conventional foods to make certain health claims meeting a standard of “significant scientific agreement” upon FDA approval, also offered a lower standard of scientific proof for approval. However, FDA, seeing the opportunity for dietary supplements to make health claims that could describe a relationship between those products and a disease, refused to offer [10] the category the lower scientific standard option, and declined to approve health claims for supplements making such claims.

In response to the FDA’s NLEA action, and increased regulatory authority against supplements following the Task Force responses, industry organized a powerful grassroots campaign via various coalitions and through a national “Blackout Day”, in which retailers of supplements covered all products that may be removed by FDA under its active authority with black fabric. All of this prompted the largest congressional public grassroots letter writing campaign in history, estimated at over 2.5 million letters sent to Congress, [11] and eventually led to the drafting and passage of DSHEA.

Perhaps one of the more interesting things to note amongst all of this historical information is this: prior to DSHEA, the primary and most consistent issue, at least from the industry side, was FDA’s overregulation of supplements, and it culminated in consumers, public interest groups, and industry effectively campaigning for, and ultimately getting, DSHEA passed. Flash forward to 2015—and the most often repeated, and erroneous phrase seen in the media is, essentially, “supplements aren’t regulated”.

It’s perplexing how the perception, particularly in the media, has shifted from “too much regulation” to “not at all”. Particularly given the number of regulations put in place in the supplement industry in not even the last 10 years. In 2007, FDA issued the final rule for Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements (21 CFR 111); 2006 saw the passage of the industry promoted Dietary Supplement and Nonprescription Drug Consumer Protection Act [12], which requires the reporting of serious adverse events to FDA; and now with the provisions of the 2011 Food Safety and Modernization Act (FSMA) [13] on the horizon, there will be even more regulation over the industry.

Clearly, supplements are regulated. A more apt statement would perhaps be, “supplements are often found to be non-compliant with applicable regulations”.

Irrespective of that perhaps quizzical, and again erroneous shift, with this somewhat important background on how things have evolved in the dietary supplement industry to DSHEA and where we are today, and having embraced that there are both “good” and “bad” players within it, here are some specific, key points to consider in regards to how the industry may, in fact, be causing some of its own consumer confidence problems (and again, even more importantly, what might be done to address them and ensure consumer confidence is well placed and less susceptible to disruption).

Though it’s likely to be a source of some disagreement within

the industry, in my opinion some of the aspects of DSHEA itself may be part of the problem:

- 1 Greed (The Ephedra Story)
- 2 Undefined label claims/terminology “Natural”, “Healthy”, “Green”, etc.
- 3 Structure/Function claims and “borrowed science”
- 4 Illegal health claims/FTC actions
- 5 Intentionally adulterated & Illegal products (counterfeit products/cheaters)

### **The Mother of All “Bad Player” Motivators: Greed (the Ephedra Story)**

It’s difficult to talk about the dietary supplement industry and issues within it, especially safety, without going all the way back to 1997-2006: the days of ephedra—possibly the biggest black eye the industry ever gave itself. Also known as ma huang, ephedra has been used in Traditional Chinese Medicine for more than 2,000 years for the treatment of asthma, hay fever, and the common cold. Now, it’s often touted begrudgingly as the “ten-thousand pound gorilla (ever present) in the room” by the supplement industry since FDA banned the ingredient in 2004.

The tale of the ingredients removal from use in supplements started in 1997, when FDA proposed a ban on products containing 8mg or more of ephedrine alkaloids, more strict labeling, as well as disclosure of the health risks, which included heart attack, stroke, and death. If the industry had accepted that—or shown safety at another low-dosage—the ingredient would still be available in the marketplace. Greed and the desire to keep large, and what were found to be highly non-standardized dosage products in the hands of consumers, is what drove the ingredient to eventually be banned, as well as have potentially affected the health of a lot of people [14,15].

The industry responded to FDA’s 1997 actions by forming the Ephedra Education Council, and along with Metabolife, a major brand and stakeholder in ephedra products, spent more than four million dollars between 1998-2000 lobbying against the regulation of ephedra. During this time, Metabolife had received over fourteen thousand adverse events associated with its best-selling ephedra product, and had not provided them to the FDA (and for which it’s co-founder was eventually sentenced to six months in prison [16]). In addition, longtime industry congressional allies Orrin Hatch and Tom Harkin questioned the scientific basis for the FDA’s proposed labeling changes. As a result of the industry’s actions, in 2000, the FDA withdrew the proposed labeling changes and restrictions.

Following a New England Journal of Medicine review of ephedra-related adverse reactions in late 2000 [17], as well as pressure from consumer advocacy groups, the Department of Justice compelled Metabolife to turn over the then fifteen thousand reports of adverse events—ranging from insomnia to death—to the FDA. However, it wasn’t until the highly publicized death of Baltimore Oriole’s pitcher Steve Belcher in February 2003, in which the medical examiner found that ephedra toxicity

had played a “significant role” in his death, that the FDA resumed its efforts to regulate ephedra use.

The FDA banned the sale of ephedra-containing supplements in February of 2004, a decision that was upheld in appellate court following a suit filed by manufacturers in 2006. It’s without a doubt the polarizing event in the history of supplements since the passing of DSHEA that is brought up nearly every time there’s a significant, negative issue, particularly when that issue involves safety. Though maybe there were some within the supplement arena who believed the ingredient was truly safe at higher dosages, or who were simply naïve, the end result is industry painted a target on its own back and handed out free bullets to its critics for the unforeseeable future in exchange for immediate profits.

The interesting thing from my view is this: Despite the banning of ephedra, at least fifteen thousand adverse events, and the very public death of Steve Belcher. Despite the banning of DMAA, eighty-six reported adverse events, and the potential death of two US soldiers. Despite OxyElite Pro and the outbreak of at least fifty-six incidents of acute liver failure and hepatitis, including the death of one person, attributed to that products adulteration with an illegal ingredient, Ageline. Despite all five hundred eighty-three and counting of the pharmaceutical-spiked products masquerading as dietary supplements in weight loss, sports nutrition, and sexual enhancement categories, containing potent drugs like sildenafil, tadalafil, sibutramine, and the like. Despite the many, many successful actions against supplements brought by the FTC where businesses are essentially preying on those looking to lose weight or improve their health via unsubstantiated claims.

Despite every incident that’s happened to the supplement industry in a little over twenty years—a huge population of U.S. consumers, nearly seventy percent, report they take supplements. And beyond that, the majority of U.S. adults, eighty-three percent, still express overall confidence in the safety, quality and effectiveness of dietary supplements according to the results of a 2014 industry survey [18].

But for How Much Longer?

### **Undefined Label Claims/Terminology: i.e. “Natural”, “Green”, etc.**

For much of the industry, reliance on consumer belief/trust/faith is prevalent in its use of words on labels and marketing such as “natural”, “green”, etc.—which have no specific definitions or standards for compliance, and are left nearly completely open to consumer interpretation. Thus far, the trend has been a positive one for both the food and supplement industry for the most part (at least at the bottom line)—look at nearly any product and you’re bound to find these words somewhere on the packaging of many products - but for how long before consumers decide that the words have no true, defined meaning?

The FDA has, as of yet, been unwilling to tackle the job—though many believe this will change in the next few years. The closest the agency has gotten to a definition of “natural” is this:

*“From a food science perspective, it is difficult to define a food product that is ‘natural’ because the food has probably been processed and is no longer the product of the earth. That said, FDA has not developed a definition for use of the term natural or its derivatives. However, the agency has not objected to the use of the term if the food does not contain added color, artificial flavors, or synthetic substances [19].*

The organic industry, which does have standardized regulations and definitions in the US (and are well established in many other countries, such as Europe [20] and Canada [21]) via the US Department of Agriculture’s (USDA) National Organic Program (NOP) [22], has attempted to poke fun at the rampant (mis)use of the word “natural” [23], though even it has some problems—ironically, with consumer perception. Many say that consumers have come to associate “organic” with “healthier”, and that perception may be changing given that consumers are learning that the fertilizers organic producers are allowed to use may be just as harmful as their unusable, synthetic counterparts, among other issues.

And fold in the heated debate over Genetically Modified Organisms (GMO)...well, let’s not even go too far into that can of worms. The FDA has waded in the shallow end, supporting voluntary labeling, though it is reviewing two citizen petitions requesting the agency change its position [24].

Industry can help itself by standardizing the definition for words like “natural”, either via industry promotion and self-regulation or petitioning of the federal government, and then brand marketers need to hold themselves accountable for meeting them, including being transparent about it and more importantly, discouraging misinterpretation by consumers. Educating consumers more broadly would also be wise to consider.

Specifically with regards to the term “natural”, industry could ask the federal government/FDA to do this (or ask its friends in Congress to push the FDA to do so)—but reality is the industry will likely be better off creating its own structure for FDA to consider and use as its starting point. Even better, once definitions and standards are in place, require third party certification to verify compliance, adding in an additional layer of security for consumers and building trust.

### **Structure/Function Claims & “Borrowed Science”**

As mentioned prior, labels and advertising often rely on the aforementioned words, “natural”, “organic”, “healthy”, as well as others, and include somewhat vague phrases to describe their intended purpose, such as, “helps promote a healthy immune system”, or “improves digestion”.

Though these are allowable as structure/function claims (S/F claims) [25] as noted above with the passing of DSHEA, the law does not allow brand marketers to link to studies or clinical trials that were done to show an ingredients’ effect on a disease, putting marketers in something of a quandary. If, for example, a botanical ingredient has been clinically shown to have an effect that relates to any kind of disease or treatment thereof, while supplements

are again allowed to use the S/F claims (i.e. “improves respiratory system function”), they are not legally able to say a thing about the disease (i.e. “relieves symptoms of asthma”), and therefore, the study.

This sets up a kind of sneaky, hidden-from-view-but-in-plain-sight system by which the information eventually gets into the hands and eyes of consumers, but in many ways is left open for interpretation due to the indirect nature of delivery. Essentially, it in some ways puts the industry in this somewhat shady light that isn’t what’s intended. Of course, industry doesn’t do itself any favors by fueling the “snake oil salesman” comments when it’s all too often found that products don’t contain ingredients listed on the label or contain other ingredients not on the label.

In addition, more than a few businesses blatantly disregard the regulations and make disease claims anyway (that the product can treat, mitigate, or cure an ailment or ailments). This happens so often that products crop up out the blue to treat the malady of the moment—available most often via the Internet. There were (and still are) supplements being marketed to treat Ebola, [26] H1N1 (Swine flu), [27] and potential radiation poisoning due to the Fukushima Daiichi nuclear disaster, [28] to name some of the more recent offenders. And, of course, there are regularly supplement products available that purportedly cure cancer [29,30], among other maladies. And then there are websites that cite “science” with regards to botanicals and ailments, aiming to look like a viable educational portal, yet are linking to products or blatantly offering to provide links to a vendor of products via email [31].

As a possible answer, first and foremost, consumers need to get smarter, and, again, only purchase products that are compliant with the regulations. The old adage, “If it sounds too good to be true, it probably is”, should regularly be applied when considering supplements marketed for diseases (in fact, these just shouldn’t be bought—period), weight loss, sports nutrition, and sexual enhancement—these last three in particular having had a significant number of fraudulent products in the marketplace. At last count 583 products in these categories had been tested and removed from the market by FDA [32].

I’d be surprised if a conscious consumer reading this didn’t fire back in response to the above with something like, “And how are we supposed to know what products are compliant with the regulations and which aren’t?” Skipping to the end of this paper, I strongly recommend third party certification of supplement products as a requirement by law prior to being able to go to market. Also as noted later, I suggest US citizens mobilize via grassroots campaign and push industry to require that third party certification by law. But more on that later...

Beyond consumers making more informed choices, marketers should consider conducting smaller-scale clinical trials on their products and publishing the results in peer-reviewed publications. Though they still won’t be able to make disease claims against them, having them in direct support of any S/F claims (and any possible safety issues if the study is focused on that), should be impetus enough. Though it happens, industry

challenging the ability to make disease claims is something of a fools errand (many have continued to use the 1<sup>st</sup> amendment as a basis for why they should be allowed to do so—unlikely to happen), and stick with making solid, substantiated S/F claims that are linked directly to the product based on a peer-reviewed clinical trial, and not simply borrowing the science conducted on an ingredient within it.

## **Health Claims/Federal Trade Commission Actions & Pushing the Regulatory Limits**

Beyond the allowable S/F claims, food and supplement brand marketers can utilize other claims—under certain circumstances. In the world of nutritional and supplement labels and claims, the phrase “health claims” or “qualified health claims” have a very specific meaning.

According to the FDA website, a health claim and the difference between a qualified and unqualified health claim are below:

- *A health claim characterizes the relationship between a substance and a disease or health-related condition. Such a claim explains that a food or food component may reduce the risk of a disease or a health-related condition. A health claim must contain the elements of a substance and a disease or health-related condition. Further, health claims are limited to claims about disease risk reduction, and cannot be claims about the diagnosis, cure, mitigation, or treatment of disease. Health claims are required to be reviewed and evaluated by FDA prior to use. An example of an authorized health claim, is: “Diets low in saturated fat and cholesterol may reduce the risk of heart disease.”*
- *Both types of health claims [qualified and unqualified] characterize a relationship between a substance (a specific food component or a specific food) and a disease or health-related condition, and are supported by scientific evidence. All health claims must undergo review by FDA through a petition process. Unqualified health claims (also referred to as “authorized health claims”) must be supported by significant scientific agreement among qualified experts that the claim is supported by the totality of publicly available scientific evidence for a substance/disease relationship (see Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements). In comparison, qualified health claims are supported by scientific evidence, but do not meet the significant scientific agreement standard. As a result, to ensure that they are not false or misleading to consumers, they must be accompanied by a disclaimer or other qualifying language to accurately communicate the level of scientific evidence supporting the claim. Qualified health claims are currently evaluated under FDA’s interim guidance for such claims. Both unqualified and qualified health claims may be used on conventional foods and on dietary supplements [33].*

Issues such as the recently decided POM Wonderful lawsuit in appellate court, [34] in which the Federal Trade Commission (FTC) filed suit against the brand for making illegal health claims

in its national advertising campaigns, are another way a brand and business may be pushing the regulatory boundaries and effectively enriching itself, but harming the category as a whole with regards to consumer perception.

The FTC vs. POM legal battle have been ongoing since 2010, when the FTC filed an administrative complaint against POM seeking to stop it from making health benefit claims without providing independent research to back them up, as well as making statements about disease prevention or treatment without FDA approval. The most recent ruling affirmed a January 2014 FTC decision that POM deceptively advertised that the products could treat, prevent, or reduce the risk of heart disease, prostate cancer, and erectile dysfunction, and were clinically proven to have such benefits. Though the court did not support the FTC’s order requiring two randomized, controlled human clinical trials before making a health claim, it did affirm the FTC’s order requiring at least one, and that there could be a time when two might be warranted.

Another highly publicized case was *FTC v. Weider Nutrition International, Inc.* [35] in 2000, where the FTC alleged that Weider, the marketers of PhenCal and PhenCal 106, a supplement advertised for weight loss, could not substantiate the product’s claims. In the end, the company agreed to enter into a consent order [36], which included paying four hundred thousand dollars in restitution. And there are many, many others: Sensa. L’Occitane. HCG Diet Direct. LeanSpa [37] The list is long...

Some possible considerations for improving this include continued enforcement, less willingness to push the boundaries of the regulations, increased self-regulation, and consumers not purchasing these “too good to be true” products. That said, asking industry not to push the boundaries with health claims is probably akin to shouting at the wind. However, now that the FTC decision has been validated, it’s not as likely others will cross this line so blatantly again. Business owners will certainly take calculated risks and establish or build their brands based on their exposure, resources, etc. If the industry takes a black eye in the interim, the best thing it can do is not stand behind or with those who do, or actively and outwardly denounce and separate themselves from those businesses that are flaunting the rules. And in the case where it’s more gray than black or white—grin and bear it and focus its attention on transparency and compliance—making it all too obvious who the outliers may be.

As an example, industry insiders have affectionately labeled the sports nutrition category as a whole “the wild west”, because similar to that area’s history in the US, there are more than a few brands flaunting the rules and putting out products that contain unlawful, illicit ingredients, or who have figured out how to bend the regulations to support their position with regards to how label claim is calculated—as in the case of protein and nitrogen spiking.

### **Intentionally Adulterated & Illegal Products (Counterfeit products/Cheaters)**

Counterfeit products. As noted in the introduction, it’s happened and is likely happening in every industry—the term d’art for the moment in the supplement industry to describe

the intentional adulteration or misbranding of a product via substitution or usage of an ingredient not on the label is “Economically Motivated Adulteration (EMA)”. In some product areas in the dietary supplement industry, it seems more prevalent—such as the weight loss, sports nutrition, and sexual enhancement categories as mentioned before—and consumers have been warned by FDA [38] and FTC that if it seems to good to be true—then it probably is.

Recent, high profile cases of illegal supplement products—which include cases in which a New Dietary Ingredient (NDI) may be found in a product and where the FDA has not been notified, per the law - include the OxyElite Pro/Aegeline issue [39]—which was linked to a hepatitis outbreak in ninety-seven people in Hawaii; DMAA [40]—which was touted as a “natural” constituent and extract of geranium (often seen spelled as “germanium” on labels, or as 1,3-dimethylamylamine, methylhexanamine), but was actually a pharmaceutical marketed by Eli Lilly and Company as an inhaled nasal decongestant from 1944 until Lilly voluntarily withdrew it from the market in 1983. An investigation into the death of 2 soldiers in Texas finally led to the complete withdrawal of all products via FDA Warning Letters to numerous brand marketers [41] in 2012.

FDA defines NDIs in the below: [42]

*The term “new dietary ingredient” means a dietary ingredient that was not marketed in the United States in a dietary supplement before October 15, 1994. (See section 413(d) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), 21 U.S.C. 350b(d)). There is no authoritative list of dietary ingredients that were marketed in dietary supplements before October 15, 1994. Therefore, manufacturers and distributors (you) are responsible for determining if an ingredient is a “new dietary ingredient” and, if not, for documenting either that a dietary supplement that contained the dietary ingredient was marketed before October 15, 1994, or that the dietary ingredient was marketed for use in dietary supplements before that date.*

*The FD&C Act deems a dietary supplement containing a NDI to be adulterated, unless it meets at least one of the following two requirements:*

- *The dietary supplement contains only dietary ingredients which have been present in the food supply as an article used for food in a form in which the food has not been chemically altered; or*
- *There is a history of use or other evidence of safety establishing that the dietary ingredient when used under the conditions recommended or suggested in the labeling of the dietary supplement will reasonably be expected to be safe and, at least 75 days before being introduced or delivered for introduction into interstate commerce, the manufacturer or distributor of the dietary ingredient or dietary supplement provides the FDA with information, including any citation to published articles, which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe [43].*

The submission of a NDI notification dossier of data to FDA,

the expected contents of which the agency has described and is published on the FDA website, is all that is required under the regulations—to “notify” the agency with a basis for the ingredients safety and not market the ingredient in a supplement for seventy-five (75) days from the date of the notification. FDA does not “approve” or “disapprove” NDIs, instead the agency will either file the notification without comment or raise one or more objections based on any identified concerns. When the agency raises any objections, it informs the submitter that supplements containing the NDI “may be adulterated” under the FD&C Act. Therefore, even if FDA raises an objection to a notification, a manufacturer can still legally market products containing the ingredient on the seventy-sixth day following the notification (that said, it may find itself subject to legal issues in the form of class action suits, etc.).

The rub with NDI's is this: there may be those who legitimately find a constituent within a botanical—but it comes to light that the ingredient being used in products is synthesized and not from a botanical at all—which is another argument currently being fought out by industry within the FDA's Draft NDI Guidance for Industry released in 2011 [44]. Or, there are those who want to argue that because a fish has eaten the algae or crustacean that contains the X or the Y ingredient, and since humans have been eating the fish forever, X or Y have been in the diet, and therefore X or Y isn't a NDI...or, a company blatantly cheats. They find an “old” dietary ingredient—something that was marketed prior to the date of the passing of DSHEA, and say that ingredient is in the product/place it on the label—but intentionally substitute or add in something else—and that something else is often an API (active pharmaceutical ingredient—a drug).

As an example of the latter, Driven Sports, which marketed the award-winning product Craze, received a Warning Letter [45] on the product from FDA in 2014 and was the target of a large scale USA Today investigation that received a significant amount of attention, culminating in an article with the headline, “*Makers of Tainted Supplements Have Criminal Pasts*” [46]. Within the Warning Letter, FDA notes the product was labeled to contain Dendrobex™, purportedly a dendrobium extract, but goes on to cite that no published, credible, peer-reviewed, scientific evidence exists to support the claims that the ingredient contains the numerous constituents listed on the label, and no evidence the ingredient was marketed prior to the passing of DSHEA. In addition, the Warning Letter states there was at least one additional phenylethylamine-type alkaloid (PEA) in the product at a significant level (20mg) that was not on the label.

Though the company voluntarily removed the product, there were apparently plenty of folks, under the guise of comedy even, discussing the potentially contaminated product online as far back as October 2012 [47], which is disturbing for multiple reasons; in particular people were still buying and taking the product until its removal from the marketplace—and not only that—buying it in many cases because it potentially contained amphetamines.

In addition, after the whole incident had long since ended, I was talking with an industry colleague who had worked at another sports nutrition manufacturer. He told me that the staff

there regularly tried out new workout products, and it was clear to everyone who had taken it that it was “spiked with something”. Apparently people in a broad sense more or less know what's going on with these products and, based on the aforementioned example, don't really care and will either buy and use it or not—safety or no safety.

To drive this point home even further, when the news officially came out that the FDA had issued a Warning Letter to Driven Sports and the product was confirmed to contain at least one PEA, it sold out - quickly. And this is the case with other products in which the FDA has issued a recall or public announcement of an API in a product—particularly within the sexual enhancement category as well. When the product Rock Hard Nights was found by FDA to contain sildenafil, the ingredient in Viagra, it also sold out nearly immediately.

What this says to me is that there are at least two, obvious types of dietary supplement consumers: those who are not only willing, but possibly even looking for spiked products, and those who are just looking for products under the tenets of good faith that they contain the ingredients/meet label claims and are seeking to improve their health or similar. Despite the law, regulations, etc. - FDA and responsible industry may be fighting a losing battle to protect at least some consumers who aren't necessarily interested in protecting themselves.

Fortunately in the case of Craze and Rock Hard Nights, no deaths were attributed to the products...but this isn't always the case as noted in the prior examples.

## Going Beyond Belief

It's pretty much a foregone conclusion that in the US, things have gone on too far too long to reverse course and ask or expect Congress and the federal government to make a severe change to something radical like premarket approval for supplements. It just wouldn't work and would essentially put the industry, which isn't entirely “bad” by any means, out of business. This would mean billions of dollars lost for the economy and millions of Americans without incomes. So how can the supplement industry potentially eliminate or reduce the “caveat emptor”, “snake oil salesmen”, and similar consumer mentality, and not only improve the issues that may be causing an erosion in consumer confidence, but also make that image and perception of products more unshakeable, getting away from reliance on consumer faith or belief onto more solid ground?

I've become a proponent of third party certification of late as a possible answer to many of these issues. Having a qualified third party certification program as a requirement by law prior to being able to market a supplement product in the US would eliminate a good number of the concerns on this list, and have the benefits of directly increasing consumer confidence, increasing the market share for legitimate businesses by eliminating illegitimate ones, and offering the potential for a great deal of positive PR to be developed by the industry as a whole.

Such a third party certification program would require product market entry via demonstrated compliance to label

claims as well as other applicable regulations. Facility audits of manufacturers would be conducted and products would be tested to ensure existing GMP regulations were met, including the products identity, purity, strength, composition, and contaminants. Products making explicit or illegal claims—"miracle cures", etc.—would be removed or never make it to market. In fact, all non-compliant products, including those spiked with API's in many cases, would be removed/never make it to market—meaning legitimate businesses would have an increased opportunity for greater market share. Internet sales of illegal and illegally marketed products would be vastly reduced. As a result, consumer safety and confidence would be increased and bolstered, and in the case of the latter, make it much more difficult to wither.

Of course, as demonstrated by the ongoing Interpol efforts, and frankly history (check out the USP Food Fraud Database [48] for details)—there will always be cheaters looking for new ways to cheat. And at some point, somehow, a product with a new, illegal constituent that may not be detected as easily using current analytical methods will make it past the screens. Nothing is foolproof. Regardless, legitimate and responsible ingredient suppliers, contract manufacturers, and brand marketers welcome the idea of third party certification as a requirement by law when I discuss it with them, because they are the ones who are most often suffering at the hands of those who are "cheating", or failing to follow the regulations. In comments to me, they often say they would like to see a real "shake up" within the industry, where a significant action would occur removing many of these "bad players" from the marketplace.

To those businesses in the supplement industry who are acting responsibly, manufacturing and marketing products in compliance with applicable laws and regulations, and consumers looking for quality products, I'd recommend the following: Tell your state and local representatives you want a new law requiring third party certification for compliance with applicable GMP and other regulations for dietary supplements prior to any such product being able to be sold in the US.

As consumers, we need to take our health and rights into our own hands—and not rely on litigious avenues such as class action suits after the fact. Consumers also need to make more educated decisions when it comes to purchasing supplements and avoid those making claims that are not legal or sound too good to be true. Look for and purchase those products that are currently, voluntarily, and legitimately certified by a reliable third party certifier, such as United States Pharmacopeia (USP) or NSF.

Supplement marketers need to demonstrate their products are in compliance and do so transparently, reestablishing that the dietary supplement industry is one with integrity and that consumers can not only have faith that its products are of quality, but see why they should reliably extend that trust. Industry should consider pushing for standardization with regards to key words that currently rely on consumer interpretation, and then demonstrate compliance transparently. Avoid pushing the boundaries with claims, and create reliable, credible science that supports products on an individual basis. And not to sound like

a broken record—but finally, industry should seriously consider promoting and supporting requiring third party certification for products by law prior to marketing supplement products in the U.S.

Perhaps it's time for industry to create its own future via credibility, transparency, and proven compliance using third party certification as a tool, and stop relying on the "good faith" of consumers.

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