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At Your Peril: Quality Control Failures can Lead to Disaster

By Rick Collins, Esq.

No reputable sports dietary supplement company wants to be associated with reports of a contaminated product. In some cases, tainted supplements can lead to arrest and criminal prosecution; in others, the bad press alone can have a devastating effect upon consumer confidence and a company's bottom line – sometimes even before the alleged contamination is confirmed. Even if the reports of supposed contamination are ultimately found to be unsupported in whole or in part, the damage done may be disastrous. If the contamination involves a substance banned in competitive sports, a lawsuit may be filed if an athlete fails a doping test after using the product.

How prevalent are tainted supplements? Research conducted at an Olympic-accredited testing lab in 2002 found 94 of 634 supplement samples contained substances not listed on the label that would trigger positive drug tests, and a 2007 report found that about 25% of supplement samples contained low levels of steroid and/or stimulant contamination. U.S. bobsledder Pavle Jovanovic and NFL running back Mike Cloud blamed doping positives on tainted protein powders. World-class swimmer Kicker Vencill and Austrian skier Hans Knauss got big bucks when they sued supplement manufacturers for their flunked doping tests.

Why would banned substances be present in supplement products, even when quality control safeguards are in place? First, there's the possibility that somebody at the manufacturing facility is *intentionally* spiking the product with an illegal drug to enhance the effects. That was the case not too long ago when the unapproved drug clenbuterol showed up in a supplement product, and it might be the case regarding an energy and fat loss supplement recently reported to contain undeclared sibutramine, a *controlled substance* appetite suppressant. The FDA issued a public warning that unsuspecting consumers could be injured because sibutramine can substantially increase blood pressure and heart rate – quite risky for anyone with heart problems. According to the FDA, the manufacturer claimed on its Web site that only "trace amounts" were found but FDA lab tests showed that the product contained "a significant amount of sibutramine per dosage unit."

Second, some manufacturers, in a misguided effort to keep their proprietary ingredients a secret, may be unclear or indifferent as to their labeling obligations under the law. Some manufacturers of sexual enhancement dietary supplements have come under heavy fire for the undeclared presence of "analogs" of prescription erectile dysfunction drugs. While the legal definition of an analog may be debatable, the requirements about listing a product's ingredients are not. The FDA has issued health alerts that these products threaten public health especially "because consumers may not know that these ingredients can interact with medications and dangerously lower their blood pressure."

Third, and the most common explanation for tainted supplements, is accidental "cross-contamination" at the raw materials stage. Supplement raw ingredients, like many pharmaceutical ingredients today, often originate in China, where quality control may be hit-or-miss. Some bad apples among U.S. supplement *(Continued on p.2)*

Clinical Studies For Dietary Supplements:

An Interview with Dr. Darryn Willoughby

By Rick Collins, Esq.

Dr. Willoughby holds BS and MEd degrees in Exercise Science from Tarleton State University and a PhD in Neuromuscular Physiology and Biochemistry with a sub-emphasis in Nutritional Biochemistry from Texas A&M University. He is a Fellow of the American College of Sports Medicine and the International Society of Sport Nutrition (ISSN). He is also the current President of the ISSN, and is a Certified Strength and Conditioning Specialist from the National Strength and Conditioning Association (NSCA) and a certified exercise and sport nutritionist from the ISSN.

RC: What is your title and what kind of research and studies do you conduct at Baylor University?

DW: I am a tenured, associate professor of exercise/nutritional biochemistry and molecular physiology in the department of health, human performance, and recreation. I conduct studies investigating the impact of resistance exercise, with or without nutritional intervention, on skeletal muscle growth by studying the expression behavior of various genes critical to muscle growth.

RC: Describe some of the studies you've conducted at Baylor, and your findings.

DW: I have done many studies involving some of the most popular sports nutrition products. My studies involving the aromatase inhibiting dietary supplements Novedex XT and 6-OXO showed that both of these supplements were effective at elevating endogenous levels of testosterone. I did a study involving a dietary supplement protein product where we found that supplementing with whey and casein protein combined with additional amino acids during resistance training was more effective at improving muscle strength, mass, and other training adaptations than training with carbohydrate supplementation alone. I have done studies on the functional thermogenic coffee JavaFit and showed it to be more effective than regular coffee at increasing *(Continued on p.2)*

Darryn Willoughby, Ph.D., FISSN
Associate Professor, Health, Human Performance, and Recreation Director
Exercise and Biochemical Nutrition Laboratory

"CLINICAL STUDIES"

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Baylor University, Waco, Texas

resting energy expenditure and anaerobic exercise performance. I have done a study on the thermogenic supplement Meltdown and showed that it was effective at increasing resting energy expenditure and fat oxidation. I have done a study with the supplement product NO-Shotgun and showed that when combined with resistance training it was more effective at increasing muscle strength, mass, and markers of myogenesis than resistance training alone. I have done a study with creatine ethyl ester and showed that seven weeks of supplementation in conjunction with resistance training was not more effective than creatine monohydrate at increasing muscle creatine uptake or muscle strength and mass, however, it was shown to degrade into creatinine in circulation to a much greater extent than creatine monohydrate.

"What sets Baylor apart is our laboratories and equipment, along with the wealth of knowledge and expertise of key faculty members."

RC: What role do clinical studies generally play in the dietary supplement industry?

DW: Valid, clinically-controlled studies involving nutritional supplements are critical because the industry is not, or rather is poorly, regulated relative to manufacturer's ability to substantiate their products' claims and efficacy. These studies help shed light on alleged effectiveness, safety, etc. along with possible mechanisms of action of which a supplement is claimed to operate.

"Valid, clinically-controlled studies involving nutritional supplements are critical..."

RC: What sets Baylor University apart from other research facilities and why do so many sports nutrition and dietary supplement companies choose Baylor to conduct their clinical studies?

DW: What sets Baylor apart is our laboratories and equipment, along with the wealth of knowledge and expertise of key faculty members. Our quality research efforts and the publications that have been produced as a result, speak for themselves. Companies choose Baylor for this reason, along with it being a major research university. In addition, companies know that the studies will get done in a timely fashion with a very meticulous and controlled approach.

RC: How does a company go about hiring you and Baylor University to design, conduct and publish a clinical study?

DW: They will need to contact me and discuss what it is they have in mind relative to the supplement and the purpose/goals of the project. I must have an active role in designing the study and making sure the study is appropriately controlled, and is not biased. I will then develop a proposal with a budget. Once we have come to an agreement relative to the parameters of the study, the time frame, and the budget, then I move forward and seek the appropriate permission for the university. Baylor and the sponsor will execute a clinical research agreement that gives me as the investigator some rights to the data, relative to publishing or presenting. Once the study is completed, a final report is provided to the sponsor. Prior to publishing or presenting, the sponsor will need to provide their permission for me to do so.

RC: Darryn, on behalf of my firm I would like to thank you for your time. We hope this interview will inspire more dietary supplement companies to arrange clinical studies for their supplement products.

Dr. Willoughby is an internationally recognized scholar and one of the top leaders in the field where his primary research focuses on the molecular mechanisms regulating muscle hypertrophy and atrophy and the efficacy of nutritional supplements. He can be reached by phone at his office at (254) 710-3504 or by email at Darryn_Willoughby@baylor.edu. ■

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"At Your Peril"

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manufacturers have not scrutinized the raw ingredients to the extent that they should; it's time for them to upgrade their quality control protocols immediately. But even companies committed to high quality can inadvertently market tainted products when trace impurities – including banned substances – escape detection during standard quality control review. The result can be products with too *little* contamination to have any physiological effect – either good or bad – but just *enough* to cause a flunked drug test. Recognizing that "certificates of analysis" accompanying foreign raw ingredients may not be reliable guarantees of purity, some supplement companies have begun using explicit warning labels to *stop* drug-tested individuals, including athletes, from using certain products at all. It's hard to have sympathy for a drug-tested athlete who cries foul if he uses a product with a label that explicitly warns tested athletes like him *not* to use it.

At Collins, McDonald & Gann, we've personally witnessed *all* three scenarios in our years as legal counsel within the sports nutrition industry. We've seen federal criminal prosecutions for intentional spiking and, sometimes, for mislabeling. As for inadvertent contamination, critics of the supplement industry, including Major League Baseball, are calling for stricter federal regulation of dietary supplements. It could happen. But it's important to remember that *most* supplements are *not* contaminated, and that those that are often only have trace amounts. Besides, stricter quality control and labeling

is *already* on the way as the FDA-issued new Rule for "good manufacturing practices" is phased in requiring industry to test the purity, strength and composition of their supplements. The rule, with limited exceptions, applies to all domestic and foreign companies that manufacture, package, or hold dietary supplements intended for sale in U.S. commerce, including those involved with the activities of testing, quality control, packaging, labeling, and distributing (*all* companies must comply by June, 2010). We are working hard to help our clients meet the new standards. Hopefully, reports of tainted supplements will become fewer and farther between, to the great benefit of both industry and consumers ■

Endorsement Contracts: By Alan Feldstein, Esq.

There is More to Them than Meets the Eye

In this day and age of advertising and marketing there are so many different methods to try to convey your message through the noise and clutter of magazine ads, web sites and the like. Different ways to market your product and get your message across are only limited by your creativity – and what rights you have acquired.

This is particularly true in endorsement agreements and athlete contracts. There is a broad variety of issues to consider and what might not seem important now could be very important in the future. That is why it is essential that you have some forward-thinking lawyers who have helped clients deal with their past debacles to anticipate issues which, if overlooked, could be the cause of a very rude awakening in the future.

It is important to specifically describe the services that the endorser is going to perform. How will they promote your company, brand or products? How many photo shoots? Are they going to write articles? Will they appear at trade shows? Will they appear at corporate conventions? What if they don't? What happens if they do something that puts them in the headlines – but not in a good way? Think of Michael Phelps with a bong and what that incident has cost him and his sponsors.

How can you use the "results and proceeds" of the services they are providing and in what mediums? It is important to get as broad an array of rights as possible for as long as possible. Can you use it just in print ads? The Internet? What about at trade shows, on YouTube, corporate conventions, flyers, product labels, or posters? We have even negotiated endorsers doing the "on-hold" greeting when people call the corporate offices.

How and when you can terminate the agreement is important. This is especially true if your endorser does something that shines an unfavorable light on them. Also, for how long can you use the materials? What happens after termination – do you have a right for an extended period to run through your inventory?

In addition you want to make sure you control the use and not give the endorser too much power to decide how their likeness can be used. Also, you want to be clear that this is a "work for hire" agreement and that they retain no rights. You also want to be sure that they are an independent contractor and responsible for taxes, insurance and the like.

When a relationship between an endorser and company first starts out it is like a budding romance where everyone is happy and trusts each other. Like many relationships it can sour quickly. That is why it is so important to have a well drafted agreement which addresses all of the issues that may arise in what is hopefully a long and fruitful relationship.■

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Topical, Transdermal, Sublingual… INGESTION?: By Mike DiMaggio, Esq.

What are acceptable means of ingesting a dietary supplement?

Dietary supplements are governed by the Federal Food, Drug and Cosmetic Act (FD&CA). Within the FD&CA, we find the Dietary Supplement Health and Education Act ("DSHEA"), which provides specific guidelines for what constitutes a dietary supplement. As counsel to many sports nutrition companies, over the years we have seen this segment of the industry push the envelope of innovation, striving to bring new and more effective products to market. For example, esterification of vitamin supplements and modified versions of creatine have been introduced in order to make good products better by improving absorption efficiency. However, products that are developed to use transdermal, topical or sublingual delivery are a wholly different matter.

The sports supplement industry has seen a number of products introduced to the market that are intended to be sprayed or rubbed on the skin. Some of these products have been for a "topical" or localized effect on the affected area, while others are meant to have a systemic effect through absorption by the capillaries. This transdermal effect is one way the ingredients can bypass the metabolic process and more directly make their way into the bloodstream. This delivery method is commonly seen in transdermal "prohormone" products or in weight loss products touted to provide targeted fat loss. While this can be a very efficient way to accomplish the goal of getting active ingredients into the bloodstream, it is also considered by FDA to be a drug delivery method. In fact, prescription drugs such as Androgel®, which is used for testosterone replacement therapy (TRT) in men, or drugs developed for pain management often use some of the same "carriers" that you might find in the aforementioned sports nutrition products, such as ethanol (ethyl alcohol), isopropyl myristate, and Dimethyl sulfoxide (DMSO).

Another delivery method that has been inappropriately used in sports nutrition products is sublingual delivery. Using this method, the product is placed under the tongue where it dissolves, bypassing the "first pass" of oral metabolism, and diffusing the active ingredient(s) directly into the bloodstream through the tissues under the tongue. This is another delivery method that is commonly used for prescription medications such as cardiovascular drugs and barbiturates.

> "[a dietary supplement] is intended for ingestion in pill, capsule, tablet, or liquid form."

So where can we find the law that identifies acceptable delivery methods for sports nutrition products? The answer is found in DSHEA. As is the case with many aspects of the law which govern the dietary supplement industry, DSHEA provides for how a dietary supplement may be administered, as opposed to providing a laundry list of methods that are prohibited. Within the formal definition of a dietary supplement, DSHEA states that a dietary supplement "is intended for ingestion in pill, capsule, tablet, or liquid form." The key word in this definition is ingestion, which means to "take in for or as if for digestion." Digestion, by definition, cannot include transdermal, topical or sublingual delivery. This forms the basis for FDA's position on these kinds of products, which has been, is, and likely will continue to be that they are not dietary supplements and that they therefore violate the FD&CA.

What are the potential consequences of marketing these products? In some instances FDA may send a Warning Letter to a company found to be marketing a product in violation of the FD&CA, identifying the violation and indicating a time frame for corrective action to be taken. An example of the kind of language included in a letter of this kind is, "*only products that are intended for ingestion may be lawfully marketed as dietary supplements. Topical products and products intended to enter the body directly through the skin or mucosal tissues, such as transdermal or sublingual products, are not dietary supplements*." Companies that receive a Warning Letter are fortunate that FDA chose to invoke its regulatory discretion by notifying the company of the violation and providing an opportunity for the company to address the problem. Violation of Federal regulations can result in civil and criminal penalties for the company and even the individuals responsible for the violation. Companies seeking to market sports nutrition products should consult with experienced legal counsel *before* they introduce a product to market in order to ensure that the product is compliant with Federal laws and regulations. ■

Rick Collins, Esq.

Rick Collins provides advice to some of the top names in the sports nutrition industry, and is the legal advisor to the International Society of Sports Nutrition and the International Federation of BodyBuilders. Rick spearheaded a national coalition to protect adult consumer access to dietary supplements, working with two Washington political advocacy firms and a panel of scientific experts. He has defended dietary supplement companies against claims of distribution of misbranded or adulterated products and "unapproved new drugs," and against serious criminal investigations by the FDA and DEA. He is admitted to practice in the courts of New York, Massachusetts, Pennsylvania, Texas and the District of Columbia, and in various federal courts.

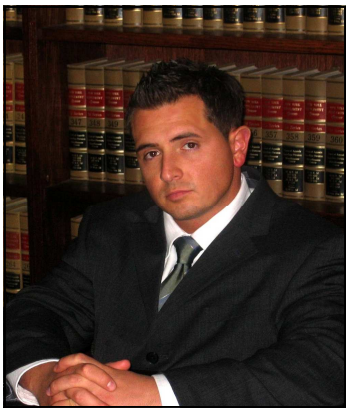
Marc Gann, Esq.

Marc Gann represents numerous companies and individuals in the dietary supplement industry. He has handled contractual disputes, trademark issues, and other civil matters, as well as regulatory investigations. He has provided advice on regulatory compliance issues and the status of supplement ingredients including New Dietary Ingredients under the Dietary Supplement Health and Education Act. He has defended supplement marketers against criminal prosecutions, including the defense of an individual charged with the sale of a misbranded and "unapproved new drug" that was implicated in a fatality. He is admitted to practice in both New York and Maryland.

Alan Feldstein, Esq.

Alan Feldstein, an attorney based in Los Angeles and admitted to practice in California, serves Of Counsel to CMG. He is responsible for advising some of the firm's biggest clients in the sports nutrition industry, having served as general counsel for a dietary supplement company that took the company to over 150 million dollars in annual sales. He has extensive experience with contracts, copyright and trademark, litigation supervision, label and advertising review, supplement fact panel review, claims substantiation and assorted regulatory issues. He brings with him more than a dozen years of advertising and marketing law experience and continues to serve on the adjunct faculty of Southwestern University School of Law.

Mike DiMaggio, Esq.



Mike DiMaggio puts his comprehensive knowledge of the sports nutrition industry to work advising CMG's clients in the area of dietary supplement law, including FDA and FTC regulatory compliance and general business matters. He has served as the Executive Director of a supplement freedom trade group, directly interfacing with industry, other dietary supplement trade associations, Capitol Hill lobbyists, and members of Congress. He received his J.D. from St. John's University School of Law and is admitted to the New York State Bar and the United States District Court for the Southern and Eastern Districts of New York.

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WHAT SERVICES DOES CMG OFFER?

In the ever-changing landscape of the health, fitness and nutrition industries, you need to stay ahead of the curve. Could you survive an investigation of your products, your labels, or your advertising copy? How do you navigate the maze of new regulations … and run your business at the same time? With FDA policies actively evolving, how can you bring a New Dietary Ingredient to market in compliance with DSHEA? How can you ensure your advertising complies with FTC regulations? What must you do in order to comply with the dietary supplement GMP's? When must you comply?

Collins, McDonald, & Gann, P.C. (CMG), is a law firm dedicated to helping clients in the health, fitness and nutrition communities. With recognized experts in sports performance supplements and regulatory, advertising and marketing law, CMG offers a powerful bi-coastal team providing a variety of legal services to a whole range of companies from start-ups to long-established ones. CMG offers in-depth experience and personalized attention you can trust to get you the answers you need ... when you need them. The partners of CMG have been formally rated by the professional legal community as practicing at the highest levels of skill and ethical integrity (AV-rated in Martindale-Hubbell). Los Angeles lawyer Alan Feldstein, Of Counsel to the firm, brings with him years of experience serving the dietary supplement industry. CMG can help you stay ahead of the curve by providing the following services:

- Review labels and advertising from an FDC and FTC standpoint (FDA laws deal with the safe and legal marketing of food and dietary supplement products; FTC regulations deal with truthful advertising that is not misleading);
- Review, negotiate and draft licensing agreements;
- Provide consultation on quality control and good manufacturing practices (GMP's);
- Review and advise clients regarding their Adverse Event Reporting System and their FDA Inspection Protocol;
- Provide general business advice;
- Advise and consult on various intellectual property issues including assisting clients in trademark and copyright registrations;
- Advise clients on DSHEA compliance of New Dietary Ingredients (NDI's);
- Provide consultation on drafting accurate and proper supplement fact panels;
- Assist in locating and coordinating review of products with toxicologists, research scientists and other outside experts regarding different aspects of manufacturing, labeling and marketing of products including appropriate contraindications;
- Coordinate and manage outside defense counsel and provide strategy on civil litigation including product liability claims and class action lawsuits;
- Manage and counsel on defense against State or Federal regulatory actions;
- Coordinate the defense against criminal investigations or FDA, DEA or other enforcement actions;
- Provide a "legal health checkup" of company's advertising, labels and other marketing materials to help avoid running afoul of FTC, FDA or State regulatory laws. The best time to ensure compliance with the law is up-front, before there's a problem.