1990-2015 25th CMG ANNIVERSARY
COLLINS, McDONALD & GANN, P.C.
ATTORNEYS AT LAW
Celebrating 25 Years of Protecting Your Rights

Health & Fitness Supplement News

Volume 11, Issue 2 — *A Journal for Industry from CMG* — Spring 2015

Is Your Ingredient Actually in the Bottle?

New York Attorney General and Class Action Lawyers Attack

By Robert Danko

In February, New York Attorney General Eric Schneiderman made headlines throughout New York – and nationwide – as he called for dietary supplements at four major retailers to be removed from store shelves. His claims and accusations against retailers Target, Walmart, Walgreens and GNC prompted the filing of class action lawsuits and incited a public frenzy about the safety of dietary supplements. The *New York Times* reported how the Attorney General's "tests" found his sample of store brand dietary supplements sold at these popular retail chains to contain "little more than cheap fillers like powdered rice, asparagus and houseplants, and in some cases substances that could be dangerous to those with allergies."

As all sensationalistic news reports typically do, the story of these allegedly "fraudulent and dangerous dietary supplements" spread like wildfire. Consumers once again were frightened and the supplement industry was put on the defensive. Just over a week after Schneiderman's office released its report of its test results and called for the retailers to pull the products from store shelves, the AG's office issued subpoenas to Target, Walmart, Walgreens and GNC "demanding that they provide evidence for a variety of health claims printed on the labels of the dietary supplements sold in their New York stores."

"with rare exception, DNA bar coding is not an appropriate technology for testing the identity of ingredients in extracts"

There are many problems with how this

most recent attack on the dietary supplement industry played out in New York. Leading regulatory agencies and top supplement industry professionals have noted that the supposed testing of these dietary supplements – using DNA bar coding – wasn't the right, or a valid, type of test for these products, most of which contained extracts (industry professionals have noted that "with rare exception, DNA bar coding is not an

(Continued on p.3)

The New Prohormone "Ban"

By Rick Collins

On December 18, 2014, President Obama signed the Designer Anabolic Steroid Control Act of 2014 – DASCA for short. Several years in the making, DASCA cracks down on the over-the-counter "prohormone" segment of the sports nutrition supplement market.

- **25 New "Anabolic Steroids."** DASCA lists 25 steroidal compounds as newly criminalized anabolic steroids. [Note that most if not all of these substances do not meet the criteria to be marketed and sold as dietary supplements and the FDA has had, and continues to have, the authority to bring cases for federal prosecution under the Food, Drug, and Cosmetic Act.] Like all the anabolic steroids that are already Schedule III drugs, these substances are now illegal not only to sell, but to possess.
- **Analogues of Listed Steroids Also Illegal.** DASCA criminalizes very close relatives of explicitly listed steroids. It says that "a drug or hormonal substance (other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone) that is not listed … and is derived from, or has a chemical structure substantially similar to, 1 or more [listed] anabolic steroids [is considered an anabolic steroid] if … [it] has been created or manufactured with the intent of [promoting muscle growth or having pharmacological effects like testosterone or] has been, or is intended to be, marketed or otherwise promoted [to suggest it will promote muscle growth or have pharmacological effects like testosterone]." In other words, derivatives and slight variations on compounds which are on the list can violate the law if they are made or if they are marketed, or intended to be marketed, to build muscle or have effects like testosterone.

(Continued on p.3)

ADVERSE EVENT REPORTS (AERS)

A consumer claims illness from your product. How do you handle it? What system do you have in place? We have teamed up with ***Supplement Safety Solutions*** *to establish SOP's and deal with adverse events. Call us!*

GMP COMPLIANCE: AVOIDING A SHUT-DOWN BY FDA

Timely Action Now Can Save Money, Your Reputation … and Your Company

By Alan Feldstein

FDA has announced it will implement more aggressive enforcement of Current Good Manufacturing Practices (GMPs), and the agency has already begun shutting down operations of dietary supplement companies that violate the regulations. **Robert Danko, Esq.**, Of Counsel to Collins, McDonald & Gann, is a California dietary supplement lawyer and GMP consultant with decades of experience in the supplement industry. Mr. Danko offered his thoughts on how to avoid the regulatory nightmares that can result from GMP failures.

Q: Are most companies prepared for FDA inspections?

A: No. Companies need accurate legal and regulatory advice on GMP compliance *before* FDA inspectors show up at the door. They don't know how to handle an inspection, don't know their rights and responsibilities under 21 CFR Part 111, and only seek legal advice when it's late in the game. Waiting until inspectors are in your facility can be very costly.

Q: What are some common violations uncovered in FDA inspections?

A: A wide variety of failures in Standard Operating Procedures (SOP's) regarding quality control can render a product "adulterated" and illegal to sell. Failure to conduct identity testing is a huge problem, and the number one violation cited in recent FDA Warning Letters. Other examples include failure to establish proper laboratory control processes, faulty batch records, and inadequate instrument calibration records. A company needs to be prepared and know what to do from the moment FDA shows up at the door until they leave.

Companies need accurate legal and regulatory advice on GMP compliance before FDA inspectors show up at the door.

Q: What's the biggest mistake that companies make after an inspection?

A: Some companies either fail to respond to the Form 483 (which is the notice of violations) or try to do it themselves. Often they submit information too late, supply inadequate supporting documentation, and fumble their corrective actions. These faulty responses often result in FDA issuing a public Warning Letter to the company, which is a matter of public record that can sully the firm's brand and reputation.

Q: What about brand owners who use contract manufacturers?

A: Even though you may have another company manufacturing (or blending, producing, or making) your product, you as the brand owner are still required to meet all the FDA regulatory requirements. You cannot assign this responsibility to a contract manufacturer. All brand owners must understand their regulatory obligations, or face the consequences when FDA comes calling.

Q: How can companies and their owners best protect themselves?

A: Get a GMP review and audit of your facility and put in place SOP's right now, before FDA inspectors show up. Make sure everyone is trained and knows what to do. Both FDA and FTC have become very active in scrutinizing dietary supplement materials, and FDA-OCI has even brought felony charges against company owners for making improper product claims. Good advice in advance can avoid a regulatory nightmare.

If you have questions on GMPs or on other regulatory matters, or if you would like to arrange a GMP review and audit with Robert Danko, call Collins, McDonald & Gann at 516-294-0300.

[Edited from an interview in the Winter 2015 Newsletter.]

CLAIMS SUBSTANTIATION POST-POM

By David Torreblanca

Do you now always need at least two randomized and well-controlled human clinical trials (RCTs) to substantiate your claims? We may have an answer from the U.S. Court of Appeals for the D.C. Circuit, which in January 2015 issued its highly anticipated opinion in POM Wonderful, LLC v. F.T.C.

First, the bad news, at least for POM: The D.C. Circuit Court largely upheld the Federal Trade Commission's January 2013 ruling, which found that POM violated the FTC Act and prohibited POM from making health-related claims without competent and reliable scientific evidence. The Court ruled that the Commission's finding that a number of POM ads contained misleading information in violation of the FTC Act was supported by "substantial evidence." The Court pointed to POM's cherry-picking of the science it used to support its claims, incorporating favorable studies into its advertising while failing to acknowledge studies that run directly counter to the advertised results. Similarly, the Court noted POM's failure to address the limitations of the studies it used to support its claims.

Now, the good news: While the Court's opinion mostly upheld the Commission's order, the Court overrode the Commission on one key point—the requirement that POM support disease claims with two RCTs. The Court ruled that FTC may require *one* RCT to support such claims, since it has a "substantial interest" in ensuring the truthfulness of advertising and it sufficiently demonstrated that requiring an RCT was "not more extensive than necessary to serve . . . the interest in preventing misleading commercial speech." However, the Commission failed to adequately "justify a categorical floor of two RCTs for any and all disease claims." The Court held that requiring two (costly) RCTs to substantiate a claim could keep marketers from adver-

(Continued on p.3)

For industry news and updates, visit our blog at www.supplementcounsel.com/blog

IS YOUR INGREDIENT ACTUALLY IN THE BOTTLE?

(Continued from p.1)

appropriate technology for testing the identity of ingredients in extracts"). In fact, although the FDA did not specifically question the New York investigation, the agency did say (as published in the February 9, 2015 issue of "*The Tan Sheet*") that "the FDA does not currently use DNA sequencing for dietary supplement ingredient verification, but is actively working toward developing validated methods for plant identification for use by both industry and the agency."

Regardless of the merits of the recent actions of the New York Attorney General, the supplement industry is positioned in the regulatory crosshairs like never before. The focus on identity testing, quality control, purity, and compliance with current Good Manufacturing Practices (GMP's) will continue to escalate. Industry should be prepared for more FDA inspections than ever before.

We can help. The time for GMP compliance is NOW. If your company or facility is not prepared for an inspection of your GMP's, you stand to risk your stock, your reputation and maybe even your company. To discuss the latest issues surrounding dietary supplements, GMP compliance, FDA inspections and other regulatory issues, call us at 516-294-0300.

THE NEW PROHORMONE "BAN"

(Continued from p.1)

- **Exemptions.** DASCA exempts a compound from being a drug or hormonal substance under the law if it is "an herb or other botanical" or "a concentrate, metabolite, or extract of, or a constituent isolated directly from, an herb or other botanical" AND if it is a dietary ingredient (under DSHEA) AND "is not anabolic or androgenic." DASCA places the burden of proof upon anyone seeking to claim an exemption.
- **Mislabeling Provision.** DASCA introduces a whole new theory by which to prosecute steroid cases by making it a crime to import, export, manufacture, distribute, dispense, sell, offer to sell, or possess with intent to manufacture or sell any anabolic steroid, or any product containing an anabolic steroid, unless it bears a label clearly identifying the anabolic steroid by accepted (IUPAC) nomenclature. This provision would apply to manufacturers who use deceptive or "creative" ingredient labeling to conceal that the product is an anabolic steroid.

It would also apply to distributors and retailers who know, intend, or have reasonable cause to believe that the product contains an anabolic steroid.

- **Shortcut to Adding New Compounds.** The Attorney General will be able to add new "designer" compounds to the list of anabolic steroids with greater ease and speed (with only 30 days' notice for temporary scheduling).
- **Increased Penalties.** Criminal penalties can be up to 10 years imprisonment and massive fines (up to $2.5 million on corporations). Civil penalties can be up to $500,000 per product violation for importers, exporters, manufacturers and distributors. Even retailers can be hit with a $25,000 penalty per product violation (each package size, form, or differently labeled item is a separate product).

Opinions about the law vary widely. Supplement industry trade associations applaud DASCA as a way to protect consumers. But some supplement consumers believe Congress should focus on more urgent matters and stay away from telling adult Americans what they can and can't do with their own bodies. Even some who feel prohormones shouldn't be on the market have grave concerns about creating a law that makes federal drug criminals out of fitness-minded consumers.

CLAIMS SUBSTANTIATION POST-POM

(Continued from p.2)

tising truthful information and reduce consumers' access to truthful information. However, the Court was careful to note that while FTC could not justify the two-RCT requirement in *this* case, it is not necessarily barred from imposing the requirement in other circumstances.

So how does the POM Wonderful decision affect the claims a supplement marketer may make about its products? First, after the decision, FTC may retreat from its blanket policy of requiring two RCTs for many health-related claims. Since one court found that the requirement does not meet constitutional muster, FTC may instead require just one RCT in future actions. Second, while all claims must be substantiated, the POM Wonderful decision suggests that supplement marketers may avoid a requirement to support such claims with even one RCT by providing an effective disclaimer or disclosure. The Court found that noting results are "preliminary" or "initial" may not be effective to negate a requirement for an RCT, but that more "substantive" disclaimers may serve that purpose. Finally, while not addressed in the POM Wonderful decision, supplement marketers must know that they cannot make "disease claims"—claims that their products diagnose, treat, prevent, or mitigate a disease. In fact, POM Wonderful received an FDA Warning Letter for many of the same claims at issue in the POM Wonderful case. The disease claims that it disputes with FTC make the products "unapproved new drugs," and illegal to market, from an FDA perspective.

That claims by a company as big as POM could run afoul of federal laws and regulations highlights the complexity of this legal area. Keeping claims in full compliance with the many laws governing them can be a difficult task. Even after the POM Wonderful decision, uncertainty in the realm of claims and substantiation will continue. Getting solid legal advice from lawyers specifically experienced in the complicated area of advertising and marketing law is essential. If you have any questions about whether your claims comply with FDA and FTC laws and regulations, call the dietary supplement lawyers at Collins, McDonald & Gann, P.C.

HOW CAN CMG HELP YOU?

In the ever-changing landscape of the dietary supplement and functional food industries, you need to stay ahead of the curve. But how do you navigate a maze of regulations ... and run your business at the same time?

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 range of companies from start-ups to established organizations. CMG offers in-depth experience and personalized attention you can trust to get you the answers you need ... when you need them in the most cost efficient manner. 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). CMG can help you stay ahead of the curve.

- Are all your product names and intellectual property protected?
- Have your product labels been reviewed by legal counsel?
- Do you have proper licensing and manufacturing agreements in place?
- Are you covered by adequate indemnification agreements?
- Are all your ingredients DSHEA-compliant?
- How can you bring a New Dietary Ingredient to market or obtain GRAS status?
- Do you have SOP's for recording and reporting Serious Adverse Events?
- How can you substantiate your claims to satisfy FDA, FTC, and other federal and state regulatory agencies?
- Do you have proper insurance coverage and SOP's for customer complaints?
- Have you received a Civil Investigative Demand from the FTC?
- Have you been served with a Class Action suit? How would you handle one?
- Could you survive a 483 inspection?
- Could you survive an investigation of your facility, products, labels or claims?
- Are you fully compliant with GMP's?

Selected Firm Profiles

Rick Collins, Esq., is based in New York and 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. He has defended dietary supplement and sports nutrition companies against claims of distribution of misbranded or adulterated products and against serious criminal investigations by FDA and DEA. He is admitted to practice in the courts of New York, Massachusetts, Pennsylvania, Texas and the District of Columbia, and in numerous federal courts.

Alan Feldstein, Esq., 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 and has extensive experience with contracts, copyright and trademark, 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.

Robert Danko, Esq., is based in Southern California and serves Of Counsel to CMG. He concentrates his practice in the area of GMP regulations and FDA compliance. With decades of experience representing food and beverage manufacturers, he provides important legal guidance to CMG clients, including responses to 483 notices and FDA Warning Letters. A graduate of Pepperdine University in Malibu, he received his law degree from Western State University College of Law and has been a member of the California State Bar Association since 1988.

David Torreblanca, Esq., joined CMG's dietary supplement practice group to serve the day-to-day legal needs of clients in the fields of sports nutrition, health, and dietary supplements. David earned a degree in psychology from Providence College, and he graduated *magna cum laude* from St. John's University School of Law. David has an in-depth understanding of FDA and FTC regulatory law and excels at label and claims reviews.

Michael Bassett, Jr., Esq., is an associate lawyer at CMG focusing primarily on dietary supplement matters. He is a graduate of the Touro College Jacob D. Fuchsberg Law Center, where he served as a prominent member of the Criminal Law Society. He has handled a plethora of court cases throughout Long Island, where he also serves as a volunteer hockey coach and instructor for the Long Island Gulls ice hockey team.

Ellie R. Sladic, Paralegal, provides support to the attorneys of CMG and works extensively with dietary supplement trademark matters. She is a Highest Distinction graduate from Suffolk County Community College's ABA-approved A.A.S. Paralegal Studies program, attending on a full academic scholarship. Ms. Sladic is a member of the National Association of Paralegal Assistants (NALA).

For industry news and updates, visit our blog at www.supplementcounsel.com/blog

ATTORNEY ADVERTISING

138 Mineola Blvd., Mineola, NY 11501 · Phone: 516-294-0300 · Fax: 516-294-0477 · www.supplementcounsel.com