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PRODUCT LIABILITY & SPORTS LAW

ALERT

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GINGKO, ROSES OR JUST FILLER? THE NEW YORK ATTORNEY GENERAL'S ATTACK ON SUPPLEMENTS

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We all know that a rose by any other name would smell as sweet. But what if the roses you give to your sweetheart are actually painted daisies or thorns without flowers? Or worse, if they do not contain flowers at all but instead are made from lychee berries that most certainly would not smell sweet?

The issue now facing four national retailers – and by association, the entire Dietary Supplement industry – is similar. The industry has always faced challenges, whether from bad press due to unsavory producers slipping methamphetamine derivatives into products or due to —or in response to pressure (legitimate and not) from —the FDA. Most of the time, the challenges create a better environment. In a historically self-regulated industry, a little pressure from the FDA, in concert with valid customer complaints, can foster an environment where the smartest companies can respond with better, safer products.

But sometimes the challenges come from an unanticipated source. Last week, New York Attorney General Eric Schneiderman lodged very serious allegations against four major retailers: GNC, Walgreens, Walmart, and Target. The AG alleges that the vast majority of certain of the retailers' store-brand dietary supplements contained zero of the ingredients presented on the label. The AG relied on a Clarkson University study that he commissioned.[1] The study concluded that four out of five of the hundreds of herbal supplements tested contained none of the herbs listed on the labels. The products included such popular supplements as Gingko Biloba, St. John's Wort, Ginseng, and Garlic. The study also concluded that, instead of the listed ingredients, the products contained various other inexpensive fillers like wheat, rice, beans or house plants. Given the results of the study, the AG issued Cease & Desist letters on February 2, 2015.[2] On February 11, the AG issued subpoenas (currently sealed) seeking certain records from the four retailers.

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1 N.Y. Att'y Gen., Press Release: A.G. Schneiderman Asks Major Retailers To Halt Sales Of Certain Herbal Supplements As DNA Tests Fail To Detect Plant Materials Listed On Majority Of Products Tested (February 3, 2015), http://www.ag.ny.gov/press-release/ag-schneiderman-asks-major-retailers-halt-sales-certain-herbal-supplements-dna-tests.

2 Letters from Martin J. Mack, Executive Deputy Attorney General, to Various Retailers (Feb. 2, 2015), https://s3.amazonaws.com/s3.documentcloud.org/documents/1532311/supplements.pdf.

This is a serious threat from an activist attorney general that may not be supported by acceptable science. It calls for two primary considerations. First, how accurate are the allegations? Second, how can a company address the attorney general's demands, especially in today's class action environment?

Addressing the Allegations

While CSI-style DNA testing sounds like a fool-proof method of catching the bad guy, the methods of this particular type of analysis have been called into question. The study relied on a form of DNA testing known as DNA barcode analysis. DNA barcodes consist of short genetic markers in an organism's DNA. By analyzing the barcodes, one can identify the specimen as belonging to a particular species. However, it has not been generally accepted as a means to identify a particular herb.

Research groups are critical of this type of testing in confirming or discrediting product content claims. The American Botanical Council stated that "DNA testing seldom is able to properly identify chemically complex herbal extracts, because often DNA often does not survive the extraction process."[3] Given that the products are often extracts, the DNA barcode may not be the best way to test them. There are other more reliable, conventional methods of testing products for purity (chemical, spectroscopic, or chromatographic tests) already in use by a number of third-party testers. US Pharmacopeia, for example, provides independent certification to supplement manufacturers who then place the USP mark on their label as a measure of quality.[4] The United Natural Products Alliance reported that in an effort to refute the AG's claims, it plans to conduct its own tests of the products in dispute, utilizing the more standard chemical tests; it will then make the (hopefully more favorable) results publicly available.[5]

The question of valid testing is not a new one from a general liability perspective. The issue routinely rears itself following an allegation related to a customer complaint, whether it be on a company's website, a product review, or in a court complaint, that a supplement caused heart palpitations, loss of hair or some other ailment. However the complaint is delivered to the company, the initial reaction internally or with counsel is to go into defensive mode. But as with any set of allegations, by taking a moment to breathe and assess the facts and ask reasonable questions the situation can change. Is there any history of the substance causing those side effects? If the customer relies on an expert's allegations, is that expert's testing on solid foundation? Does the company's or a third-party's tests verify the product was safe or what it purported to be? The four retailers targeted by the AG have all indicated, with various levels of conviction, that they have test data to show that what they put out for sale is what it purports to be. That leads to the second consideration: preparation for this type of an event.

Reaction Based on Preparation

An interesting way of looking at the issue is to review the Cease & Desist letters themselves.[6] A retailer or distributor of dietary supplements with a strong compliance program should have retained most of the records and test data (as most are required by the FDA). The AG called for:

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3 Mary Esch, Supplements Industry Derides NY Attorney General's DNA Tests, Associated Press, February 8, 2015, http://hosted.ap.org/dynamic/stories/u/us_herbal_supplements_investigation.

4 U.S. Pharmacopeia, USP Verified Dietary Supplements, http://www.usp.org/usp-verification-services/usp-verified-dietary-supplements.

5 See note 3.

6 See note 2.

1. The name of the manufacturer and the location of the production;
2. A listing of DNA or other testing for content and quality, and copies of the test results;
3. Licensing and production contracts with the manufacturer and/or distributor of the product;
4. Ingredients lists and measurements of the ingredients;
5. Standards or procedures followed to authenticate content per #4;
6. Bioterrorism Registration documentation for the manufacturer (a specific registration requirement from the FDA)[7];
7. Evidence that the manufacturer complied with current Good Manufacturing Practices (CGMP, another specific FDA provision)[8] for quality control; and
8. Any serious adverse event reports (defined events pursuant to FDA guidelines) related to the listed products.

A company should be prepared to present most of the items identified in 1-8 in response to routine FDA investigations, so in theory the demands are not out of the blue. When put in the context of rare serious allegations, such as those brought by the AG, they take on new meaning. As evidenced by the challenges to the energy drink industry in New York, as well as with supplements themselves, given that these four retailers have now pulled all the identified products off their shelves, the NY AG can wreak havoc on sales of given consumer products. The retailer or supplement manufacturer who has gone through every product development or transaction anticipating that it could be the one that undergoes an audit by the FDA is the best way to prepare for even a rare occurrence such as this.[9]

Another significant threat involved with the most recent subpoenas is the demand that the retailers provide evidence to back up the authenticity of the claims: for example, "supports healthy brain activity," "improve immune function," or "increases bone density." Under DSHEA (the 1994 federal law governing dietary supplements as distinct from pharmaceuticals)[10] dietary supplements can make general health claims. These are called "structure/function claims" because, as the above examples show, they are only general claims of support for structures and functions of body systems. They cannot, however, purport to prevent or treat disease. The AG appears to be attacking the retailers on the basis of claims that the FDA has not pursued.

Manufacturers must have competent and reliable scientific evidence of their claims, but they do not need to provide such support to the FDA prior to the sale of a product under current DSHEA guidelines. Now that the AG has issued a subpoena for that evidence, one can only hope that the retailers and their partner manufacturers have the appropriate records. The records will prove just as

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[7] See FDA, Guidance and Regulation: Registration of Food Facilities, available at: http://www.fda.gov/food/guidanceregulation/foodfacilityregistration/default.htm.

[8] See FDA, Guidance and Regulation: Current Good Manufacturing Practices (CGMPs), available at: http://www.fda.gov/food/guidanceregulation/cgmp/default.htm.

[9] This article does not comment on whether or not to aggressively fight the AG on his power to make these types of requests.

[10] Dietary Supplement Health and Education Act of 1994 (DSHEA), Pub. L. No. 103-417, 108 Stat. 4325 (codified as amended in scattered sections of 21 U.S.C. and 42 U.S.C.).

important with the class actions suits that have predictably been filed.[11]

There are two takeaways from this attack by the AG. First, there is the danger of unproven science being used to attack companies in stores and in the court of public opinion. If an allegation is repeated enough, it can become fact in the public eye. In the 24-hour news cycle, the issue could fade away just as quickly as it arises, but perhaps not, particularly when the AG follows up Cease & Desist letters with subpoenas and class action lawyers begin churning out cases. Companies should understand the relevant body of scientific work which can discredit or support the products they sell.

The second takeaway is to have the hard work of proving your case complete before it becomes an issue. Retailers and manufacturers already know the types of records that must be maintained, and the manufacturing practices they and their business partners must abide by. There will always be some bad actors in a self-regulated industry who will try and get by without doing everything they are required to or who persist on making claims without the proper foundation to the detriment of the segment as a whole. The important thing is to be sure your company has done all the right things before the FDA, an attorney general, or a plaintiff's counsel comes knocking. So have your testing records in order and don't forget to relax and stop to smell the roses.◆

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[11] See *Reyes v. General Nutrition Corp.*, No. 1:15-cv-20513 (S.D. Fla.) and *Mager v. GNC Holdings Inc. et al.*, No. 5:15-cv-00267 (N.D. Ohio).