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DNA Barcoding: What Is It And What Does It Mean For Your Nutraceutical Business?

In February 2015, New York Attorney General ("NYAG") Eric Schneiderman issued a cease and desist order to four major retailers, ordering them to stop selling store brand herbal supplements. Using DNA barcode technology to test popular herbal supplements (echinacea, ginseng, St. John's wort, ginko biloba, garlic, valerian, and saw palmetto) from Target, Walmart, Walgreens, and GNC, the NYAG found that some did not contain the plant products they claimed to contain, while many contained other undisclosed ingredients. According to one report, only 21% of the tested supplements contained the plants listed on the products' labels. Since the FDA does not regulate herbal supplements as drugs, consumers depend on manufacturers and retailers to ensure that these products are accurate, safe, and effective. The NYAG's investigation determined that manufacturers were deceiving the public and selling products that were at best ineffective and at worst hazardous.

The AG's office soon came to an agreement with GNC to implement new quality control measures that would use DNA barcoding as an additional method to ensure the purity and authenticity of the herbal supplements. New labels would identify active ingredients as well as alert consumers to the presence of five potential allergens (peanuts, milk, soy, eggs, and wheat). By September 2016, Nature's Way and NBTY, the manufacturer and supplier of herbal supplements to Walmart and Walgreens, also agreed to phase in DNA barcoding.

In the meantime, however, the NYAG's initial order prompted numerous individuals across the country to file lawsuits against the four retailers, alleging violations of state consumer protection and warranty laws. By early 2016, these individual lawsuits had been consolidated into a class action in Illinois Federal Court.

A major point of contention in the class action revolves around the plaintiffs' reliance on the NYAG's DNA barcoding to support their claims. The retailers argue that DNA in supplement products can be destroyed or degraded by solvents and heat used in the extraction process, and that, as a result, the DNA barcoding method that prompted the cease and desist order is an unreliable method of testing herbal supplements that is not widely used in the scientific community. The court appointed independent expert appears to have agreed with the retailer defendants, concluding that DNA barcoding analysis is not reliable, though the report has not been made publicly available.

Since September 2016, the retailers have submitted motions to dismiss the class action arguing that (1) the results of the NYAG's investigation, without more, are not "first-hand" facts that may serve as the basis for the plaintiffs' fraud claims, and, (2) even assuming the NYAG investigation could satisfy the "first-hand" rule, the DNA barcoding employed by the NYAG is scientifically untrustworthy. The Court's ruling on the motions is expected any day.

Thus, the ultimate decision could very well hinge on the question of whether DNA barcoding is an accurate test for determining the ingredients in herbal supplements. The defendants' challenge to DNA barcoding has been publicly supported by numerous scientific organizations. For example, at the 16th Annual Oxford International Conference on the Science of Botanicals, Mark Blumenthal, founder and Executive Director of American Botanical Council declared that DNA bar coding alone is "inadequate and inappropriate criteria for accurately and definitively determining the true identify of botanical dietary ingredients."

Regardless of the outcome of this case, the NYAG's success in convincing three major supplement producers to implement DNA barcoding technology has significant implications for the industry, even while many remain skeptical about its efficacy. However, it remains to be seen to what extent DNA barcoding will prevail as the sole method by which supplements are tested. By and large, the supplement industry (if not those such as the NYAG who regulate the industry) appear increasingly convinced that DNA barcoding alone is simply insufficient.

The question for manufacturers and retailers, then, is whether there is value in DNA barcode testing beyond traditional chemical testing. While the jury may still be out on whether DNA barcoding alone will ever suffice, there is little doubt that it can serve as another "tool in the toolbox," for several reasons: (1) to appease pro-DNA barcoding regulators, (2) to provide assurance as to the purity of the product, and (3) to improve public perception and consumer confidence.

DNA barcoding, and the broader impact of the NYAG's investigation and the ensuing litigation, have heightened the industry's focus on quality control and the accuracy of product labeling. That several industry heavyweights have already committed to phasing-in DNA barcoding is clear evidence of which way the wind is blowing. Those who do not follow along may risk being left behind.