

CRN: STANDING UP FOR THE INDUSTRY



The New York Times

New York Attorney General Targets Supplements at Major Retailers

By ANAHAD O'CONNOR
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The New York State attorney general's office accused four major retailers on Monday of selling fraudulent and potentially dangerous herbal supplements and demanded that they remove the products from their shelves.



In February, the New York State attorney general's (AG) office launched an attack on the dietary supplement industry, releasing results of DNA barcode tests alleging that herbal supplements sold by four major retailers were misbranded, and demanding the retailers remove the products from the shelves. The Council for Responsible Nutrition (CRN) was the first industry voice to question the AG's specious assertions and continues to push back against this stunt, calling on the AG to demonstrate the same transparency it has demanded of retailers.

Note: We are providing this information under embargo.
No dissemination should be made until the embargo is lifted today, Feb 3, 2015 at 8 AM Eastern

Press Release

www.crnusa.org



Council for Responsible Nutrition

The Science Behind the Supplements

EMBARGOED UNTIL 8 AM EASTERN, FEB 3, 2015 Contact: Nancy Stewart, 202-204-7684

CRN Criticizes New York State Attorney General 'Sting' on Herbal Dietary Supplements As Uninformed, Reckless and Inexcusable
—Non-Validated DNA Barcode Testing on Finished Products Ignores Well-Established Quality Control Procedures for Herbal Products—



Council for Responsible Nutrition

The Science Behind the Supplements

STANDING UP FOR THE TRUTH

Keeping CRN Members Informed

CRN learned of the impending announcement of the AG's actions the evening before it was to be released by The New York Times at midnight and immediately alerted members pre-embargo about the upcoming announcement. CRN members have subsequently received pre-release versions of our numerous press statements to help them form their own media messages and responses to customer inquiries. Throughout the ordeal, CRN has sent weekly updates to members through memos, special alerts and through the CRN newsletter to keep them fully apprised of developments and CRN's activities to combat the damage. CRN held two "All CRN Member" conference calls with additional updates on matters too sensitive to send via email.

CRN's Immediate Response

Even before the AG's announcement went public, CRN issued a pre-embargo press statement calling the AG's actions "uninformed, reckless and inexcusable." CRN's [pre-embargo press statement](#) criticizing the AG's actions was followed by relentless outreach that night and the following day to as many media outlets as we could reach with our side of the story. These efforts resulted in numerous stories that included CRN's perspective with quotes challenging the accuracy of the tests and reiterating that dietary supplements are thoroughly regulated by FDA under the Good Manufacturing Practices (GMPs) regulations.

Relentless Media Outreach

CRN's communications staff has conducted extensive outreach and "pitches" to media to disseminate the industry's defense. As a result, CRN and its views have been quoted in major outlets such as AP, NBC Nightly News, The Atlantic, The New York Times, NPR, the New York Daily News, the Albany Times Union and more. Other stories, including those in The New Yorker and Prevention magazine, have reflected CRN's perspective on the issue.



CRN President & CEO Steve Mister appears on NBC Nightly News.

A screenshot of a microsite with a blue and white color scheme. The title at the top is "CRN RESPONDS TO NY ATTORNEY GENERAL ACTIONS AGAINST HERBAL SUPPLEMENTS" with a "CRN HOME" link. The content is organized into a grid of four main sections: 1. Top-left: A green leaf with the word "DNA" written vertically on its stem. 2. Top-right: "CONSUMER Q&A: Herbal Dietary Supplements and Recent Actions by the New York Attorney General" with a DNA double helix and question marks. 3. Bottom-left: "New White Paper on DNA Barcode Testing". 4. Bottom-right: "Additional Resources & Materials" with bullet points: "• CRN Responds" and "• What Others Are Saying". In the center of the grid is an image of a white pill bottle labeled "HERBAL SUPPLEMENT" with two green pills below it. At the bottom of the microsite is the URL "www.crnusa.org/NYAG".

CRN's microsite provides the science-based side of the story.

Reassuring Consumers & Retailers

CRN created a microsite specifically on the AG issue to provide the public with accurate and balanced information on the investigation and share resources including a white paper, FDA's response to Congress, and our press statements. CRN also developed an infographic for use with consumers and media that explains the extraction process and why fully intact DNA is unlikely to survive the process. In addition, CRN provided updates to the retailer community via The Short Report, CRN's online newsletter for retailers, and was available to retailers to answer questions about industry regulation and errors in the AG's report.

Bylines, Op-Eds & Letters to the Editor

CRN published numerous bylines and letters to the editor including one in the Washington Post—"Supplements are Safe"—and a letter in The New York Times defending the ability of industry to serve at FDA. Bylines on various aspects of the AG's investigation have appeared in [Natural Products INSIDER](#), [Nutralngredients](#) and more.

STANDING UP FOR TRANSPARENCY

Release the Report

When the AG refused to disclose the full report from its investigation, CRN began a campaign to pressure the AG's office to release its full DNA test methodology and results, including the lab report and protocols in place to prevent cross-contamination. CRN used #ReleaseTheReport on social media and mirrored that phrase in press interviews and public materials. CRN repeated its call for transparency throughout and filed a formal Freedom of Information Law ("FOIL") request and appeal to obtain the tests.

Other State AGs: A Strategy of Isolation & Containment

Early in the investigation the New York AG began to seek support from other state AGs, calling on other states to join in his investigation and to co-sign a letter to Congress. CRN launched a strategy and devised a program to educate state AGs on the New York AG's flawed tests and the extent of federal regulation of supplements. Intent on isolating and limiting the New York AG's impact, CRN retained a national law firm specializing in state AG actions to assist with this outreach. As part of this effort, CRN has attended gatherings of state AGs and met individually with more than 20 AG offices by May, significantly reducing their interest in a multi-state investigation.



Darryl Sullivan of CRN member company Covance talks to congressional staff on Capitol Hill during the DSC lunch briefing.

Inoculating Congress, FDA and FTC

CRN's lobbyists proactively dispatched to Capitol Hill to brief both our allies and our detractors on the situation, aware that the actions in New York could affect policy making in Washington. When a multi-state letter arrived in Congress from 14 AGs asking them to launch an inquiry into herbal supplements, those Members had already been educated on the investigation and the wealth of federal regulation of dietary supplements. Calling for more enforcement of the federal requirements, CRN urged Congress to provide more resources to FDA, but to leave the current legal requirements alone. The congressional Dietary Supplement Caucus (DSC) conducted a lunch briefing in May on the issue, with CRN as one of the hosts.

On the AG's Doorstep— the Campaign in Albany

CRN took our defense of the industry to Albany to communicate directly with lawmakers in New York who might support state legislation as a result of the AG's investigation. We retained local lobbyists in Albany, along with a local PR agency, to assist in meetings with legislators and the Governor's staff. We targeted the media most utilized by Albany decision makers. Bills in Albany calling for tighter state regulation have been introduced, but failed to attract much support.

STANDING UP FOR GOOD SCIENCE

The White Paper: Addressing DNA Testing Head On

Working with other industry trade associations, CRN spearheaded the development of an [authoritative white paper](#) that examined the applicability—and limitations—of DNA barcode testing to finished herbal extract products. Prepared by experts in DNA testing, the document raised substantial concerns about the validity of the AG's tests.

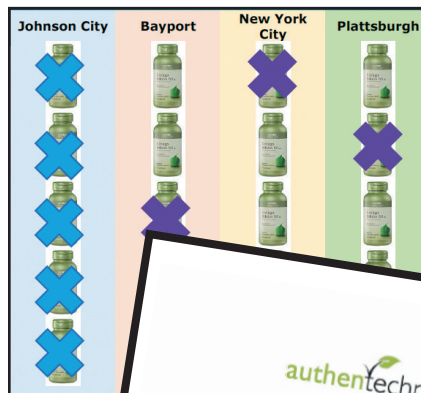
Doing the Math—Why the AG's Tests Don't Add Up

CRN prepared a comprehensive analysis of the AG's description of its test results in the cease-and-desist letters to industry. The analysis illustrates that test results were internally inconsistent, unreliable and not reproducible, calling into question even the findings of alleged contamination. Early results of the analysis were presented at Ingredient Marketplace in April, and a bylined article followed.

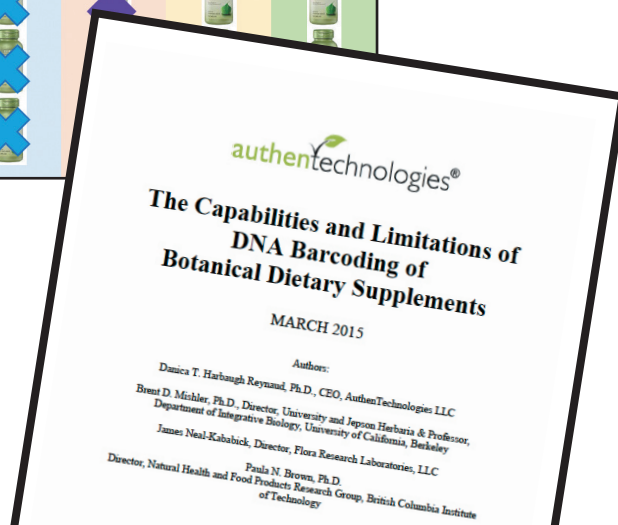
Congress Gets FDA to Respond

Knowing that many would look to FDA to react to the AG's allegations, CRN conducted a meeting with senior FDA staff the week following the announcement. Then CRN worked closely with Senators Orrin Hatch (R-UT) and Martin Heinrich (D-NM) on a letter they sent to FDA asking about the agency's views on DNA testing. [FDA's response](#) acknowledged publicly that FDA does not use DNA barcode testing for herbal supplements, it does not require DNA testing for identity verification, and would not permit DNA barcoding as the sole form of testing on either raw materials or finished products.

For more information on CRN, contact Carl Hyland, Director of Membership chyland@crnusa.org / 202-204-7674.



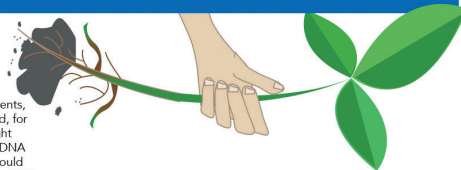
CRN's Steve Mister presented the flawed data and limitations of DNA barcode testing at Ingredient Marketplace.



Why DNA Barcode Testing is Not Appropriate for Use on Herbal Extracts

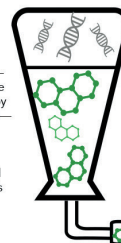
1 IT STARTS WITH THE PLANT

Herbal supplements, also known as botanical supplements, start with plants. If you tested, for example, a ginseng plant right out of the ground using the DNA barcode test method, you would rightly expect to find ginseng DNA.



2 THEN COMES THE EXTRACTION

But many herbal supplements—including those that "failed" the DNA barcode test conducted by the New York Attorney General—go through a manufacturing extraction process where the active ingredients—known as phytochemicals—are separated from the plant cells. The DNA is found in the plant cells.



3 WHERE'S THE DNA?

During this extraction process, DNA can be damaged or left behind. What goes into the finished herbal supplements are the extracts containing the phytochemicals.



4 IT'S THE WRONG TEST

DNA barcode tests are not appropriate tests for finished products made from herbal extractions. In general, DNA barcode tests can identify plant material from unprocessed and properly handled samples from whole plants. Even in whole plant samples, DNA tests are not particularly helpful to determine how much plant material is there, only that it is present.



5 THE RIGHT TESTS

FDA requires that dietary supplement manufacturers adhere to good manufacturing practices—which include meeting product specifications for identity, purity, strength and composition. Manufacturers use appropriate and valid test methods to ensure that the right phytochemicals exist in the final product.

