UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

Undetermined quantities of all articles of finished and in-process foods, etc.

Defendants,

and

HI-TECH PHARMACEUTICALS, INC. and JARED WHEAT,

Claimants.

HI-TECH PHARMACEUTICALS, INC.,

Plaintiff,

v.
MARGARET A. HAMBURG, M.D., *et al*.

Defendants.

Civil Action No. 1:13-cv-3675

Hon. Willis B. Hunt, Jr.

CLAIMANTS HI-TECH PHARMACEUTICALS, INC., AND JARED WHEAT'S MOTION FOR RECONSIDERATION AND TO VACATE THE SUMMARY JUDGMENT ORDER AND JUDGMENT

I. INTRODUCTION

Claimants, Hi-Tech Pharmaceuticals, Inc. ("Hi-Tech") and Jared Wheat, respectfully file this motion for reconsideration to correct the legal and factual errors that underpin the Court's April 3, 2017 Order (the "April 3 Order"), Doc. No. 140, and to vacate the order which granted the Government's motion for summary judgment and denied Claimants' motion for summary judgment. Although the Court adopted Claimants' position that DMAA is present in geraniums, and rejected the Government's many weak arguments to the contrary, it surprisingly held that DMAA should not be considered a dietary ingredient under the Dietary Supplement Health and Education Act of 1994 ("DSHEA") because there was purportedly no evidence in the record that DMAA could be extracted from geraniums in "usable quantities." April 3 Order at 9. That holding is erroneous should be reconsidered and vacated for two reasons.

First, there is no requirement under DSHEA—in the statute, the legislative history, or the case law—that a substance only qualifies as dietary ingredient if it can be extracted in "usable quantities." In fact, DSHEA clearly states that the "constituents" of a botanical are considered a dietary ingredient and sets no quantitative threshold for what constitutes a constituent of a botanical. Importantly, the Government agreed with this interpretation of DSHEA. Simply

put, the Court's conclusion otherwise impermissibly interjected its policy opinions in place of statutory interpretation. The Court's conclusion is thus reversible legal error and must be reconsidered.

Second, the Court entered summary judgment resolving a factual issue—whether DMAA can be extracted from geraniums in "usable quantities"—based on an incomplete record. The case law is clear: *sua sponte* entry of summary judgment on a factual issue that was not fully developed, which no party advocated, and which the losing party neither had been properly noticed nor provided an opportunity to present evidence regarding, is inappropriate as well as reversible error. Moreover, this finding ignored certain evidence in the record, which Claimants are entitled to supplement, regarding the ability to extract DMAA from geraniums in "usable quantities." The Court committed an error by relying on this incomplete factual record to grant summary judgment. Reconsideration of the April 3 Order should be granted on this basis as well and the judgment and order should be vacated.

II. STATEMENT OF FACTS

Hi-Tech is a Georgia corporation with its principal place of business in Georgia. Hi-Tech is one of the largest manufacturers and distributors of dietary supplements, including weight loss products, in the United States. Hi-Tech sells its

products through more than 100,000 retail locations including, for example, GNC, CVS, Wal-Mart, K-Mart, Kroger, and convenience stores nationwide. Hi-Tech also sells directly to consumers, healthcare practitioners, and food and dietary supplement companies. Doc. No. 41-1, ¶ 5. *See also*, MSJ Wenik Decl.[1] (Doc. No. 108-3), Ex. 66, Claimants' Administrative Procedure Act ("APA") Complaint; Answer of United States, Doc. No. 52, ¶ 5.

As this Court has acknowledged, Hi-Tech incorporates DMAA into many of the dietary supplements it manufactures and sells including, for example, Black Widow, Lipodrene, Yellow Scorpion, Fastin XR, and Stimerex-ES. April 3 Order at 1. Since 2010, Hi-Tech has sold over 200 million doses of DMAA containing products with only a handful of adverse events of any sort. MSJ Wenik Decl. (Doc. No. 108-3), Ex. 2, Declaration of Michael Lumpkin, Ph.D., DABT ("Lumpkin Decl.") at ¶¶ 98-99.

A. The FDA's Campaign to Ban DMAA

As detailed in Claimants' summary judgment motion, Doc. No. 108, after Amy Eichner of the United States Anti-Doping Agency ("USADA") undertook a

[1] All citations to the MSJ Wenik Decl. refer to the declaration of Jack Wenik, Esq., submitted in support of Claimants' Motion for Summary Judgment, Doc. 108-3, and the exhibits thereto, Docs. 108-4 to 108-8.

campaign to ban DMAA, in April 2012, the U.S. Food and Drug Administration ("FDA") sent Warning Letters to several companies that marketed DMAA-containing products, advising them that DMAA was dangerous and not a dietary ingredient under DSHEA. MSJ Wenik Decl. (Doc. No. 108-3), Ex. 19, April 27, 2012 Press Release. Hi-Tech was not one of the companies to receive such a letter.

Subsequently, the FDA trumpeted its success by noting that all but one of the companies that had received a warning letter had removed DMAA from their products and the marketplace. MSJ Wenik Decl. (Doc. No. 108-3), Ex. 20, FDA Consumer Alert entitled "Stimulant Potentially Dangerous to Health, FDA Warns," which was Exhibit 28 to the Deposition of Daniel Fabricant, Ph.D. ("Dr. Fabricant"), at 2. The one holdout, USP Labs, LLC, ("USP Labs") ultimately caved to FDA pressure and removed DMAA from its products in April 2013. MSJ Wenik Decl. (Doc. No. 108-3), Ex. 21, (April 2013 email correspondence among Dr. Fabricant, Mahmoud ElSohly, Ph.D. ("Dr. ElSohly"), and Ikhlas A. Khan, Ph.D. ("Dr. Khan") containing the USP Labs press release). In July of 2013, under continuing FDA pressure, USP Labs "voluntarily" destroyed $8 million worth of DMAA containing products. Doc. No. 41-1, ¶ 21.

B. The FDA Turns Its Intimidation Campaign Against Hi-Tech

In early November 2013, the *Atlanta Journal Constitution* published a lengthy article that discussed Claimants' sale of products containing DMAA. Wenik Decl. (Doc. No. 108-3), Ex. 28, November 2, 2013 *Atlanta Journal Constitution* article. In the article, reporter Danny Robbins related comments by the FDA's Dr. Fabricant that the FDA was not aware that Claimants were marketing DMAA-containing products until being informed about this by the *Atlanta Journal Constitution*. *Id.*

Following an inspection of Hi-Tech's facilities in Norcross, Georgia, in November, 2013, the FDA issued an Administrative Detention Order against inventories of dietary supplement products containing DMAA, with an approximate value of $2.2 million. Doc. No. 41-1, ¶ 22; Doc. No. 41-7 (Ex. 1). Hi-Tech filed a Notice of Intent to request a hearing and to appeal and timely filed an administrative appeal from the FDA's Detention Order. Doc. No. 41-8 (FDA Br., Ex. 2); Doc. Nos. 41-9, 41-10 (FDA Br. Ex. 6). Before it filed its administrative appeal, Hi-Tech also filed its Administrative Procedure Act ("APA") action in the District of Columbia District Court seeking declaratory and injunctive relief to require the FDA to comply with its legal obligations under DSHEA and to refrain

from taking arbitrary and capricious actions against Hi-Tech and its DMAA-containing products.

C. The FDA Responds to Hi-Tech by Terminating Its Detention Order and Filing Its *In Rem* Seizure Complaint

After Hi-Tech filed its APA claims, and after Hi-Tech gave notice of its intent to appeal the FDA's Detention Order, the FDA filed its *in rem* seizure complaint in the Northern District of Georgia and issued a warrant of arrest for the products covered by its Detention Order. Doc. No. 1. Additionally, after the FDA received Hi-Tech's administrative appeal, it terminated the Detention Order. Doc. Nos. 41-8, 41-9, 41-10. Thereafter, Hi-Tech and its owner, Jared Wheat, filed a Claim of Interest and an Answer in response to the seizure complaint. Doc. Nos. 11, 14. An Amended Complaint and an Amended Answer were subsequently filed. Doc. Nos. 25, 26.

In July 2014, the District of Columbia District Court transferred the APA claims to this Court. On August 1, 2014, the Court merged Hi-Tech's APA action with the FDA's seizure action and dismissed the separately docketed case created by the transfer of the APA action. Doc. No. 29. On August 28, 2014, this Court clarified that its August 1, 2014 Order was procedural only; Hi-Tech's claims against the FDA were not affected by the administrative dismissal of the other case. Doc. No. 33.

D. The Government's Experts Engage in Unethical Manipulation and Concealment of Test Results Detecting DMAA in Geraniums and Violate Claimants' Due Process Rights

During the course of this litigation, the Government put forth the expert reports and declarations of Dr. Khan in support of its now-defunct theory that geraniums cannot produce DMAA. At this juncture, it is clear that Dr. Khan's findings are tainted by the fact that he and his co-researchers intentionally suppressed positive findings of DMAA in geraniums to further the FDA's attempts to wrongfully ban DMAA and because of their personal biases against DMAA's use in dietary supplements. Claimants' MSJ Br. (Doc. No. 108-1), at 4-12; 32-35; 43-48. Indeed, there is strong evidence, as set forth at length in Claimants' prior submissions and as set forth below, that Dr. Khan manipulated the findings in his academic research to cover-up the detection of DMAA in geranium plant samples because his "bosses" at the FDA wanted to ban DMAA.

Dr. Khan is a co-author, along with Dr. ElSohly and others, of a study titled *Pelargonium Oil and Methyl Hexaneamine (MHA): Analytical Approaches Supporting the Absence of MHA in Authenticated Pelargonium graveolens Plant Material and Oil*, Journal of Analytical Toxicology (2012).[2] *See* MSJ Wenik Decl.

[2] This study was funded by the USADA. Beginning in December 2010, Eichner negotiated with Drs. Khan and ElSohly for them to conduct a study of DMAA and

(Doc. No. 108-3), Ex. 15, GOV-027840-GOV-027854. Although Dr. Khan and Dr. ElSohly developed a very sensitive method for detecting DMAA for purposes of this study and did detect levels of DMAA in geraniums samples, they conspired with the USADA to simply change the reporting detection limit in the published article so as to show no DMAA detected. *See* MSJ Wenik Decl. (Doc. No. 108-3), Ex. 14, June 2011 email correspondence among Amy Eichner, Dr. ElSohly, Dr. Khan, and Larry Bowers of the USADA regarding Dr. ElSohly's detection of DMAA in geranium, stamped ElSohly 4330-4335.

Similar unethical behavior occurred regarding another DMAA study that Drs. Khan and ElSohly conducted titled: *Methylhexanamine is not detectable in Pelargonium or geranium species and their essential oils: A multi-center investigation*, Drug Testing and Analysis (2014), 7(7), 645-54 (the "Multi-Center Study"). This study was intended to be the definitive word on whether or not DMAA could be detected in geraniums. However, the Multi-Center Study intentionally omitted data from one of its four laboratories that detected DMAA in

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geraniums. MSJ Wenik Decl. (Doc. No. 108-3), Ex. 4, Eichner Dep. at 85:11-86:1. In April of 2011, Eichner arranged for a consulting agreement to be executed between the USADA and Dr. ElSohly's company wherein his company would test geranium samples for the presence of DMAA. *See* MSJ Wenik Decl. (Doc. No. 108-3), Ex. 12, April 2011 email correspondence between Amy Eichner and Dr. ElSohly, stamped ElSohly 3480-3489.

multiple geranium samples. *See* MSJ Wenik Decl. (Doc. No. 108-3), Ex. 26, correspondence from Min Yang of the Shanghai Institute of Materia Medica notifying Dr. Khan of the detection of DMAA in geranium in the Multi-Center Study, stamped ElSohly 2267-2272; Ex. 11, Khan Dep. at 135:3-151:20. As with their 2012 study, Dr. Khan and Dr. ElSohly achieved this illusion by simply adjusting the detection limits in the published article to suppress positive findings of DMAA in geraniums. *Id*. Of course, like the prior DMAA positive test results, the positive DMAA test results from the Multi-Center Study did not make their way into the article published by Drs. Khan and ElSohly. *See* MSJ Wenik Decl. (Doc. No. 108-3), Ex. 25, Multi-Center Study. Despite the fact that the FDA funded and directed research that confirmed that DMAA was found in geraniums, at no time did the FDA revise its website or Q&As regarding DMAA to advise the public of these findings. *See* DMAA in Dietary Supplements – Questions & Answers, available at http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm346576.htm.

Dr. Khan was provided both substantial amounts of funding[3] and his marching orders by the FDA, regardless of the ethical implications of doing so.

[3] According to his CV, from 2005 through the summer of 2016, Dr. Khan received over $22.6 million from the FDA to research dietary supplements. Wenik Decl.

The Government's conduct in funneling millions of dollars to researchers that committed scientific fraud renders it liable to the Claimants under the APA as well as the Due Process Clause.

E. Motions for Summary Judgment

On December 30, 2016, both Claimants and the Government moved for summary judgment. Doc. Nos. 107, 108. After spending millions in taxpayer funds on Dr. Khan's fraudulent DMAA research and expert declarations/reports, the Government did not rely on either his research or his opinions in support of its motion for summary judgment. *See* Doc. 107.

On April 3, 2017, the Court granted the Government's Motion for Summary Judgment and denied Claimants' Motion for Summary Judgment. April 3 Order; Doc. No. 141 (the "April 3 Judgment"). The Court held that "judgment is entered as to all claims in favor of the Government and against the Defendants unde[te]rmined quantities of all articles of finished and in-process foods, raw ingredients (bulk powders, bulk capsules) containing DMAA with any lot number, size, or type container, whether labeled or unlabeled and also against Claimants . . . as to the forfeiture action, and to all claims in the suit originally filed in the District

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(Doc. No. 108-3), Ex. 10, Khan CV at 118-125. His expert fees in this matter were additional compensation.

Court for the District of Columbia as 1:13-CV-1747, later transferred to this Court as 1:14-CV-2479 and later merged into this action." April 3 Judgment.

III. ARGUMENT

A. Legal Standard for Motion for Reconsideration

Claimants are keenly aware that motions for reconsideration should "not be filed as a matter of routine practice." LR 7.2(E). Such a motion is appropriate, however, in instances of: "(1) newly discovered evidence; (2) an intervening development or change in controlling law; or (3) a need to correct a clear error of law or fact." *Bryan v. Murphy*, 246 F. Supp. 2d 1256, 1258-59 (N.D. Ga. 2003). As detailed below, because the Court's interpretation of DSHEA in its April 3 Order was, respectfully, clearly erroneous from both a legal and factual perspective, reconsideration is required. *See Richards v. City of Atlanta*, No. 1:10-CV-3928-CC, 2014 U.S. Dist. LEXIS 187824, at *7 (N.D. Ga. Mar. 31, 2014) (granting motion for reconsideration, and vacating summary judgment, where court committed legal error by failing to view "the evidence in the light most favorable" to the non-moving party, as required by Rule 56).

B. Claimants Respectfully Request that the Court Reconsider the April 3 Order as It Is Based on a Clearly Erroneous Interpretation of DSHEA

i. The April 3 Order and the Government's Failure to Meet Its Burden

In the April 3 Order, the Court correctly acknowledged that "the Government ha[d] failed to meet its burden of establishing that DMAA ha[d] not been found in geraniums." April 3 Order at 7. That holding was based on the fact that DMAA has "been found in a species of a geranium plant," as proven by "three published papers that provided the details of tests detecting DMAA." *Id*. at 5. The Court took judicial notice of a paper surveying DMAA studies, Thomas D. Gauthier, *Evidence for the Presence of 1,3-Dimethylamylamine (1,3-DMAA) in Geranium Plant Materials*, Analytical Chemical Insights, 8: 29-40 (2013), and noted that the author concluded: (1) "[o]verall, these studies show that 1,3-DMAA is found naturally in some, but not all, geranium plants and extracted geranium oils;" and (2) "the studies that failed to find DMAA used extraction techniques that may not have been suitable for retention of DMAA due to its volatility." *Id*.

Furthermore, the Court rejected the Government's three main critiques of scientific papers failing to detect DMAA, explaining: (1) the papers cited by the Government that did not detect DMAA "may not have been suitable for [detection] of DMAA due to its volatility;" (2) Dr. Paula Brown's testimony regarding the

ability of geraniums to produce DMAA was not "unequivocal" and did not provide anything "close to uncontroverted evidence that geraniums cannot make DMAA;" and (3) the Government's claims that DMAA detected in geraniums was the result of contamination "fail[ed] to address the fact that other studies did find DMAA." *Id*. at 5-6. As such, the Court was "unswayed by the Government's argument that it is impossible for the geranium in question to synthesize DMAA," and concluded that "the question as presented by the parties is whether DMAA has been detected in geraniums, not how the geraniums happened to put the chemical there. . . this Court would be inclined to find that the Government has failed to meet its burden of establishing that DMAA has been found in geraniums." *Id*. at 6-7.

With due respect to the Court, because this was the dispositive issue in this case, that should have been the end of the Court's analysis and summary judgment should have been entered in favor of Claimants.

ii. The Court's *Sua Sponte*, Novel Interpretation of DSHEA Is Clearly Erroneous and Ignores Critical Language in 21 U.S.C. § 321(ff)(1)(F)

The Court's ensuing analysis, however, suffers from a key legal error. Absent any briefing on the point from either Claimants or the Government, the Court concluded that "in using the term botanical, Congress intended that there must be at least some history of the substance in question having been extracted in

usable quantities from a plant or a plant-like organism . . . .” *Id.* at 9 (emphasis added). The Court cited no reference within DSHEA, its legislative history, or the case law to support this novel position. Moreover, this interpretation ignores the fact that Congress clearly could have, but did not, include a requirement that a substance qualifies as “a concentrate, metabolite, constituent, extract, or combination” of a dietary ingredient only if it can be extracted in “usable quantities.” By engrafting this novel “usable quantity” requirement onto 21 U.S.C. § 321(ff)(1), the Court has impermissibly encroached on the policy making prerogative of Congress. Simply put, there is no requirement that any such extract or constituent be present in anything above “trace” quantities.

Notably, the Government in its briefing did not even advocate the position reached by the Court. *See* Gov’t Motion for Summary Judgment, Doc. No. 107-1, at 1 (“The issue in this case is whether [DMAA] is a ‘dietary ingredient’ . . . . To decide this issue, this Court needs to resolve [whether] DMAA is naturally produced by geranium plants[.]”). The Government—similar to Claimants—took the position that the presence of DMAA in geraniums, even in trace amounts, would render it a dietary ingredient under DSHEA. In fact, the Government’s Answer acknowledged that the mere fact that the DMAA used in Claimants’ products is synthetic has no bearing on whether DMAA qualifies as a dietary

ingredient so long as it is a constituent of the geranium plant. Answer of United States, Doc. No. 52, ¶ 14; *see also* MSJ Wenik Decl. (Doc. No. 108-3), Ex. 35, Welch Dep. at 27:7-27:23 (the Government's regulatory expert, Dr. Cara Welch, testified that synthetic ingredients can be dietary ingredients under DSHEA). Moreover, the Court accepted the parties' position that synthetically produced DMAA could qualify as a botanical under DSHEA. *See* April 3 Order at 8.

"Any exercise of statutory interpretation begins first with the language of the act" and "[t]erms that are not defined in [a] statute . . . are given their ordinary or natural meaning." *Nat'l Coal Ass'n v. Chater*, 81 F.3d 1077, 1081 (11th Cir. 1996). DSHEA defines the following substances as a dietary ingredient:

> (A) a vitamin;
>
> (B) a mineral;
>
> (C) an herb or other botanical;
>
> (D) an amino acid;
>
> (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
>
> (F) a concentrate, metabolite, **constituent**, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E);

21 U.S.C. § 321(ff)(1) (emphasis added).

The April 3 Order simply ignores the import of the final subsection of this key part of DSHEA. Rather than focus on the definition of **"constituent**," which is the relevant definition, the Court instead focused on the definition of "**botanical,**" concluding that "[i]n normal usage, a botanical is a plant, a part of a plant, or a substance that is derived from a plant for a medicinal, cosmetic, or other purpose." April 3 Order at 8. Claimants take no umbrage with the Court's definition of botanical. What is missing, however, is an analysis of what a **constituent** of a botanical is under DSHEA.

A "constituent" is defined by the Oxford Dictionary as a: "component part of something" or "[b]eing a part of a whole," available at https://en.oxforddictionaries.com/definition/constituent. Critically absent from this definition is a requirement that something only qualifies as a "constituent" if it reaches a certain threshold or is present at more than trace levels. There is surely no requirement that a substance be present in "usable quantities," be present "in the marketplace as a result" of direct "extract[ion] from geraniums or any other plant," or "extracted from a plant or plant-like organism and used, for example, in or as a medicine." April 3 Order at 8-9.

As noted above, Congress explicitly included "constituents" of botanicals as dietary ingredients under DSHEA and **did not** set any quantitative limit as to what

qualifies as such. *See* 21 U.S.C. § 321(ff)(1)(F). Based on this irrefutable definition of "constituent," DMAA qualifies as a dietary ingredient, even if it is only present at "trace" levels in geraniums. The Court's reading of DSHEA simply reads the word constituent out of the statute in order to further the Court's opinion about what it thinks Congress conceivably or "inconceivabl[y]" meant when it drafted DSHEA. April 3 Order at 8. The Court may consider its interpretation the wiser one from a policy perspective[4]—but that is not its role here. *See Badaracco v.*

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[4] The Court, respectfully, is also wrong as to policy. Geraniums are not an "obscure plant" similar to the example that the Court provided regarding a "fungus found in a remote Tibetan river valley" that might contain a chemical that a dietary supplement company would like to exploit after its discovery. April 3 Order at 9. Rather, geraniums have been part of the food supply for centuries. MSJ Wenik Decl., (Doc. No. 108-3), Ex. 38, Declaration of Marvin Heuer ("Heuer Decl.") at ¶¶ 51-53; 90-93. As the legislative history of DSHEA makes clear, the point of the statute was to amend the Food, Drug and Cosmetic Act ("FDCA") to allow consumers greater access to dietary supplements in order to promote increased wellness, including increased access to safe dietary supplement ingredients (such as geranium), which were sold to consumers prior to the statute's effective date of passage. DSHEA, Pub. L. No. 103-417, § 2 (1994). The drafters of DSHEA noted that the FDA had "pursued a heavy-handed enforcement agenda against dietary supplements for over 30 years," resulting in attempts by Congress to reign in the FDA's approach. S. Comm. on Labor and Human Res., Dietary Supplement Health and Education Act of 1994, S. Rep. 103-410, at 14-15 (1994). Furthermore, the drafters noted that historically, the "FDA tried to 'protect' the public against 'unsafe' products for which there is no evidence that the product is unsafe." *Id*. at 16. Once such common tactic was for the FDA to label ingredients as "food additives." As such, DSHEA was enacted "to clarify that dietary supplements are not drugs or food additives, that dietary supplements should not be regulated as drugs, and that the burden of proof is on the Food and Drug Administration

Commissioner, 464 U.S. 386, 398 (1984) ("Courts are not authorized to rewrite a statute because they might deem its effects susceptible of improvements."); *Blount v. Rizzi*, 400 U.S. 410, 419 (1971) ("It is for Congress, not this Court, to rewrite the statute."); *Korman v. HBC Florida, Inc.*, 182 F.3d 1291, 1296 (11th Cir.1999) ("It is not the business of courts to rewrite statutes.").

As the Court is well aware, "[w]here the intent of Congress is expressed in the text of a statute in reasonably plain terms, [it] must give effect to that intent." *Chater*, 81 F.3d at 1081 (citing *Griffin v. Oceanic Contractors, Inc.*, 458 U.S. 564, 570 (1982)). Here, the intent of Congress is clear: even mere constituents of a botanical can qualify as a dietary ingredient under DSHEA.[5] To this point, even the

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("FDA") to prove that a product is unsafe before it can be removed from the marketplace." *Id*. at 2.

[5] The legislative history surrounding DSHEA also does not support the Court's "usable quantities" requirement. The Senate Committee on Labor and Human Resources' report, issued shortly before DSHEA's passage, in large part mirrors the final language of the statute and reflects Congress's concern that there needed to be increased access by consumers to a variety of different kinds of organic substances. As such, the Senate Report states that a "dietary supplement must bear or contain one or more of a vitamin, a mineral, an herb or other botanical . . . . In addition, concentrates, metabolite, **constituents**, extracts, or a combination of the items previously described may be included in a dietary supplement." S. Comm. on Labor and Human Res., Dietary Supplement Health and Education Act of 1994, S. Rep. 103-410, at 34 (1994) (emphasis added). As such, the concept that a constituent of a botanical qualifies as a dietary supplement is clear from the statute itself—which should alone end any analysis—as well as the legislative history.

Government agrees. *See* Gov't Motion for Summary Judgment, Doc. No. 107-1, at 1 (explaining that the key legal and factual issue in this case revolved around whether DMAA is present in geraniums). The Court's interpretation of DSHEA otherwise constitutes clear error that requires reconsideration.

Lastly, aside from DMAA, there are numerous other constituents of organic substances that naturally occur in minute quantities which are made synthetically for dietary supplements. For example, both Resveratrol, an ingredient in grapes (and in wine) and CoQ10, which is an antioxidant that is synthesized in the body and is found in foods such as beef, chicken, fish, peanuts, and strawberries, can be commercially synthesized and are routinely included in dietary supplements. Both of these substances have long been recognized as dietary ingredients under DSHEA. Yet, Resveratrol is found only in very small amounts in red wines, which have a Resveratrol content (per 5-oz glass) of 0.03-1.07 mg. *See* Oregon State University, Linus Pauling Institute Micronutrient Information Center – Resveratrol Entry, available at http://lpi.oregonstate.edu/mic/dietary-factors/phytochemicals/resveratrol. Indeed, the levels of Resveratrol found in food varies considerably,

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Any other interpretation would mean that the FDA could define almost anything as a "food additive," as opposed to a dietary ingredient as set forth in 21 U.S.C. § 321(ff)(1), which was the very problem that Congress intended to fix by enacting DSHEA.

even in the same food from season to season and batch to batch.[6] As the Court explained, DMAA has been found as high as 13 parts per million (ppm), which is approximately the same as the highest amount of Resveratrol found in red wine at 14.3 ppm or mg/L. *See* April 3 Order at 7. So long as DMAA is found in a botanical, as a constituent of geraniums, its synthetic sourcing for Hi-Tech's dietary supplements has no bearing on whether or not it is a dietary ingredient under DSHEA.

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[6] The following table sets out the average *trans*-Resveratrol content of red wines:

Variety	**Lowest (mg/L)**	**Highest (mg/L)**	**Mean (mg/L)**	**5-oz Glass (mg)**
Pinot Noir	0.2	11.9	3.6 ± 2.9	0.5
Merlot	0.3	14.3	2.8 ± 2.6	0.4
Zweigelt	0.6	4.7	1.9 ± 1.2	0.3
Shiraz	0.2	3.2	1.8 ± 0.9	0.3
Cabernet Sauvignon	-	9.3	1.7 ± 1.7	0.2
Red wines (global)	-	14.3	1.9 ± 1.7	0.3

See id. (noting that Resveratrol is produced in certain plants in response to stress, injury, fungal infection, or ultraviolet radiation).

C. The Court Incorrectly Concluded that Claimants Lack Evidence that DMAA Cannot Be Extracted from Geraniums in a Commercially Usable Quantity

Reconsideration is appropriate for another reason. The Court found that "while studies might have found the presence of DMAA in geraniums, no one has ever extracted DMAA for any commercial, medicinal or other purpose. It merely has been detected." April 3 Order at 7.

Assuming, *arguendo*, that the Court is correct that, in order to qualify as a dietary ingredient under DSHEA, a constituent of a botanical must be extractable in a "usable quantity," there is no evidence in the record that DMAA cannot be extracted from geraniums in a usable amount. Rather, one of Claimants' experts, Dr. Marvin Heuer, whose declaration was submitted in support of Claimants' Motion for Summary Judgment and whose deposition transcript is also part of the record, Doc. No. 130, noted that patent applications were filed to commercially extract DMAA from geraniums. MSJ Wenik Decl. (Doc. No. 108-3), Ex. 38, Heuer Decl., ¶ 58. Dr. Heuer was questioned about these specific patent applications at his deposition by the Government. Heuer Dep. Tr. (Doc. No. 130), at 225:21-232:12 and exhibits 7 and 8 thereto (U.S. Patent Applications 2012/0225144 and 2012/0225142). These patent applications describe an extraction method that optimizes the DMAA content of the oil by extracting the oil

with an alcohol/water mixture, separating geranium oil and water phases, concentrating and drying the aqueous phase to a powder, and then, after purifying the oil, combining the powder with the purified oil, achieving a 1% to 3% DMAA concentration. *See id*. (Heuer Dep. Exs. 7 and 8). These patent applications, and Dr. Heuer's testimony regarding them, surely create a disputed issue of fact regarding the ability to extract DMAA from geraniums in "usable quantities."

D. The Court Erred by Refusing to Allow Claimants to Present Additional Evidence on this Issue

Finally, entry of summary judgment against Claimants on the basis that DMAA cannot be extracted in "usable quantities" was inappropriate because Claimants were never put on notice that such evidence would be dispositive. Until the Court issued its April 3 Order, the ability to extract DMAA from geraniums in a "usable quantity" was not in dispute amongst the Parties, and Claimants were unaware that the Court would consider this issue dispositive in its analysis. *See Artistic Entm't, Inc. v. City of Warner Robins*, 331 F.3d 1196, 1201 (11th Cir. 2003) (*sua sponte* summary judgment decision appropriate only where "(1) purely legal issues are involved or (2) the evidentiary record is complete and the parties have been given the opportunity to respond."); *Montgomery v. City of Ames*, 749 F.3d 689, 697 (8th Cir. 2014) ("A district court commits reversible error by granting summary judgment on an issue not raised or discussed by the parties if the

losing party did not have notice and an opportunity to respond."); *Acumed LLC v. Advanced Surgical Servs.*, 561 F.3d 199, 223–24 (3d Cir. 2009) (A court "must provide the parties with notice of its intention to consider granting summary judgment so that they have an opportunity to marshal evidence on the motion for submission to the court."); *Simpson v. Merchants. Recovery Bureau, Inc.*, 171 F.3d 546, 549 (7th Cir. 1999) ("While not encouraged, a district court can enter summary judgment *sua sponte*, or on its own motion, under certain limited circumstances … [However,] granting summary judgment *sua sponte* warrants special caution" and generally requires that the party against whom summary judgment is entered have notice and an opportunity to present its evidence.); 11-56 Moore's Federal Practice - Civil § 56.71 ("A court may not grant summary judgment for a nonmovant, grant summary judgment on a ground not specified in a motion, or grant summary judgment *sua sponte* until the court provides the parties "notice" of its intention to do so and grants the parties "a reasonable time" to respond to the proposed summary judgment before acting.").

As such, and at a minimum, the Court should vacate the April 3 Order and Judgment to permit Claimants to present additional evidence that DMAA can be extracted from geraniums in "usable quantities."

IV. CONCLUSION

For the foregoing reasons, Claimants respectfully request that the Court enter an order granting Claimants' Motion for Reconsideration, vacating the April 3 Order and granting Claimants' Motion for Summary Judgment and dismissing the United States' seizure action, lifting the Government's detention of Claimants' goods, and granting summary judgment on the claims articulated in Claimants' Administrative Procedure Act Complaint.

Respectfully submitted,

/s/ Jack Wenik
Jack Wenik, Esq.
Epstein Becker & Green, P.C.
One Gateway Center, 13th Floor
Newark, New Jersey 07102
(973) 639-5221
jwenik@ebglaw.com
Admitted Pro Hac Vice

/s/ E. Vaughn Dunnigan
E. Vaughn Dunnigan, Esq.
E. Vaughn Dunnigan, P.C.
2897 N. Druid Hills Rd., Suite 142
Atlanta, Georgia 30329
(404) 663-4291
evdunnigan@hotmail.com
Georgia Bar No. 234350

/s/ Arthur Leach
Arthur Leach, Esq.
Law Offices of Arthur Leach
5780 Windward Parkway, Suite 225
Alpharetta, Georgia 30005
(404) 786-6443
art@arthurleach.com
Georgia Bar No. 442025

/s/ Bruce S. Harvey
Bruce S. Harvey
Law Office of Bruce Harvey
146 Nassau Street, NW
Atlanta, GA 30303
404-659-4628
Email: bruce@bharveylawfirm.com
Georgia Bar No. 335175

Attorneys for Hi-Tech Pharmaceuticals, Inc. and Jared Wheat

CERTIFICATION PURSUANT TO LOCAL RULE 7.1(D)

Pursuant to Local Rules 5.1(C) and 7.1(D), I hereby certify that the above document was prepared in Microsoft Word using 14-point Times New Roman font.

CERTIFICATE OF SERVICE

I hereby certify that the above document was electronically filed using the CM/ECF system and was served upon counsel of record via electronic mail on this 17th day of April, 2017.

/s/ Jack Wenik

Jack Wenik, Esq.
Epstein Becker & Green, P.C.
One Gateway Center, 13th Floor
Newark, New Jersey 07102
(973) 639-5221
jwenik@ebglaw.com
Admitted Pro Hac Vice

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

Undetermined quantities of all articles of finished and in-process foods, etc.

Defendants,

and

HI-TECH PHARMACEUTICALS, INC. and JARED WHEAT,

Claimants.

HI-TECH PHARMACEUTICALS, INC.,

Plaintiff,

v.
MARGARET A. HAMBURG, M.D., et al.

Defendants.

Civil Action No. 1:13-cv-3675

Hon. Willis B. Hunt, Jr.

[PROPOSED]

ORDER GRANTING HI-TECH PHARMACEUTICALS, INC., AND JARED WHEAT'S MOTION FOR RECONSIDERATION AND TO VACATE THE SUMMARY JUDGMENT ORDER AND JUDGMENT

Having read and considered Hi-Tech Pharmaceuticals, Inc. and Jared Wheat's (collectively "Claimants") Motion for Reconsideration and to Vacate the Summary Judgment Order and Judgment, and the Court having reviewed the submissions and arguments of the parties, and for other good cause shown:

IT IS, on this _____ day of _____, 2017, **ORDERED** that:

1) Claimants' Motion for Reconsideration is **GRANTED**;
2) The Court's April 3, 2017 Order and Judgment (Docs. 140, 141) are hereby **VACATED**; and
3) Claimants' Motion for Summary Judgment, Doc. 108, which sought the dismissal of the United States' seizure action, the lifting of the Government's detention of Claimants' goods, and the grant of summary judgment on the claims articulated in Claimants' Administrative Procedure Act Complaint, is **GRANTED**.

_____
WILLIS B. HUNT, JR.
United States District Judge

Submitted by:
Jack Wenik