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

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| UNITED STATES OF AMERICA,<br>Plaintiff, | : | |
| v. | : | CIVIL ACTION NO.<br>1:13-CV-3675-WBH |
| QUANTITIES OF FINISHED AND IN-PROCESS FOODS, et al.,<br>Defendants. | : | |

**ORDER**

Hi-Tech Pharmaceuticals, Inc., sells dietary supplements, including weight loss products containing 1, 3 Dimethylamylamine, commonly known as DMAA. The Federal Food and Drug Administration, contending that DMAA is a food additive that is not generally recognized as safe and that products containing DMAA are subject to seizure under federal law, seized a great deal of Hi-Tech's product and initiated this in rem forfeiture action. In response, Hi-Tech and its CEO entered the forfeiture action as claimants, contending that its DMAA products were not subject to seizure under the law and demanded that the Government[1] return Hi-Tech's products. Hi-Tech also filed suit against the Government, which action was merged into this forfeiture action.

[1] Hereinafter, "Hi-Tech" refers to both Hi-Tech and Jared Wheat. "The Government" refers to the FDA, the Commissioner of the FDA, and any other federal entities or individuals involved in this case.

Both sides have now filed motions for summary judgment, and this Court now considers those motions.

## Discussion

Summary judgment is appropriate where "'there is no genuine issue as to any material fact and the moving party is entitled to a judgment as a matter of law.'" Wooden v. Bd. of Regents of the Univ. Sys. of Ga., 247 F.3d 1262, 1271 (11th Cir. 2001) (quoting Fed. R. Civ. P. 56(c)).

### The Federal Food, Drug, and Cosmetic Act and the Dietary Supplement Health and Education Act

The Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 et seq., is a set of laws dating to 1938 that give authority to the FDA to oversee and regulate the safety of food, drugs, and cosmetics. The Dietary Supplement Health and Education Act of 1994 (DSHEA) amended the FDCA to require the FDA to characterize dietary supplements as food rather than drugs. Further, while the FDA may still establish standards for dietary supplements, the DSHEA shifted the burden of proof to the Government to have a dietary supplement declared unsafe and removed from commerce.

Under the DSHEA, this Court must first determine whether DMAA is a "dietary ingredient" or a "food additive." 21 U.S.C. § 321(s), (ff). If DMAA is determined to be a dietary ingredient, the seized Hi-Tech products qualify as dietary supplements which cannot be removed from commerce by the Government unless the FDA establishes that it "presents a significant or unreasonable risk of illness or injury under . . . conditions of use recommended or suggested in labeling," and this Court so finds "on a *de novo* basis." 21 U.S.C. § 342(f).

If the substance is determined not to be a dietary ingredient, then this Court must determine whether that substance is "generally recognized as safe." Id. § 321(s). If the substance is not generally recognized as safe, it is a food additive and presumed to be unsafe so that any supplements containing that substance are adulterated under the statute.

Whether DMAA is a Dietary Ingredient

Relevant to this case, dietary ingredients include "an herb or other botanical . . . or a concentrate, metabolite, constituent, extract, or combination of" an herb or other botanical. 21 U.S.C. § 321(ff). Accordingly, the first issue that must be determined under the statutory scheme is whether DMAA is a "botanical" as that word is used in

the statute. The Government stipulates that it bears the burden of proving that DMAA is not a botanical.

Nothing in the legislative history of the DSHEA or in the case law gives any guidance regarding what Congress meant by "botanical" in § 321(ff). Hi-Tech does not provide a definition of a botanical under the statute in its summary judgment motion. The Government asserts that a botanical is "a plant, alga, or fungus, or a physical part or secretion of a plant, alga, or fungus, such as bark, leaves or fruits." In support of this assertion, the Government cites to the affidavit of its expert, Cara Welch. In her affidavit, Dr. Welch gives generally the same definition of a botanical and cites to her report. Dr. Welch's report gives that same definition for botanical and cites to an online FDA publication[2] that gives the same definition in its glossary without citation to anything. The FDA publication merely purports to provide guidance to industry regarding the requirements of providing notice to the FDA relating to new dietary ingredients. The publication does not appear to be a scientific paper and there is no indication of who wrote it. In short, the Government has failed to provide an adequate basis for its interpretation of Congressional intent in using the term "botanical" in § 321(ff). This Court thus finds that the Government's definition

[2] *Dietary Supplements: New Dietary Ingredient Notifications and Related Issues: Guidance for Industry*, available at https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM515733.pdf

is arbitrary and not entitled to deference under Chevron, U.S.A., Inc. v. Nat. Resources Def. Council, Inc., 467 U.S. 837 (1984).

Hi-Tech has presented fairly substantial evidence that trace amounts of DMAA have been found in a species of a geranium plant in the form of three published papers that provided the details of tests detecting DMAA. The Government has asserted three arguments to dispute the presence of DMAA in geraniums, but this Court finds that those arguments are not sufficient to meet the Government's burden of establishing that DMAA is not in geraniums. This Court is first unimpressed by the Government's arguments regarding the fact that other studies have failed to find the presence of DMAA in geraniums. In particular, this Court takes judicial notice of a paper, 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) available at https://www.ncbi.nlm.nih.gov/ pmc/articles/PMC3682735/, in which the author surveyed the various studies that either found or did not find DMAA in geranium plants. He concluded that, "[o]verall, these studies show that 1,3-DMAA is found naturally in some, but not all, geranium plants and extracted geranium oils." The author further opined that the studies that failed to find DMAA used extraction techniques that may not have been suitable for retention of DMAA due to its volatility. It is undisputed that at least three different studies found DMAA in geraniums, and the

fact that other studies, which may well have used different methodologies, did not detect DMAA is not determinative.

This Court is likewise unswayed by the Government's argument that it is impossible for the geranium in question to synthesize DMAA. In its motion for summary judgment, the Government asserts that: "The uncontroverted evidence is clear: Geraniums cannot make DMAA. There is no biological process or biosynthetic pathway by which a geranium plant could do so." However, the expert that the Government cites for this statement is nowhere near as unequivocal. Rather, she states that it is "metabolically improbable" that DMAA naturally occurs in geranium plants, and points out that "[t]hose suggesting [DMAA] is naturally occurring in [geraniums] have not proposed a biosynthetic pathway by which the compound could be produced nor provided any evidence that such a pathway exists," [Doc. 113-1 at 29, 27], which is nothing close to uncontroverted evidence that geraniums cannot make DMAA. Further, 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.

Finally, in response to the Government's argument that the geraniums from one of the studies may have been contaminated by fertilizer that contained DMAA, the argument fails to address the fact that other studies did find DMAA.

Admittedly, there are reasons to doubt the veracity of the studies that detected DMAA in geraniums given the questions raised by the Government and the fact that the amounts found were so small. In addition, at least some of the studies upon which Hi-Tech relies were sponsored by companies in the supplement industry, and while this Court has no basis upon which to question the earnestness of the authors of those studies, it is no secret that scientific studies performed on behalf of industry tend to produce the results that industry wants to see. Nonetheless, this Court would be inclined to find that the Government has failed to meet its burden of establishing that DMAA has not been found in geraniums. That, however, does not end the inquiry in this Court's opinion. As mentioned, if DMAA is in geraniums, it exists there in only trace amounts. The Gauthier article cited above indicated that the studies that detected DMAA generally found concentrations of less than 500 parts per billion, and while one sample was as high as 13 parts per million, that is still a minuscule amount. It is significant to this Court that, while studies might have found the presence of DMAA in geraniums, no one has ever extracted DMAA from geraniums for any commercial, medicinal or other purpose. It has merely been detected.

This Court returns to the topic of Congress' intent in using the word botanical in 21 U.S.C. § 321(ff), having determined that the Government's definition is not entitled to Chevron deference. In 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. Oxford Dictionary defines botanical as "[a] substance obtained from a plant and used as an additive, especially in gin or cosmetics," available at https://en.oxford dictionaries.com/definition/us/botanical, while the web sight Dictionary.com defines it as "a drug made from part of a plant, as from roots, leaves, bark, or berries," available at http://www.dictionary.com/ browse/botanical. The clear implication is that to be a botanical, the substance must have been extracted from a plant or plant-like organism and used, for example, in or as a medicine. While very small amounts of DMAA might be present in geraniums, the DMAA in the marketplace has *never* been extracted from geraniums or any other plant.

This Court credits Hi-Tech's argument that a botanical can be synthesized in a laboratory without losing its status as a botanical under § 321(ff). Indeed, growing popularity of a substance in a certain plant might endanger that plant's existence if manufacturers were not permitted to synthesize the substance without running afoul of the requirements in the DSHEA, and chemical synthesis is often more economically efficient than extracting a particular compound from a plant. Nonetheless, it is inconceivable that in passing the DSHEA Congress intended for supplement manufacturers to take a chemical that heretofore had only been manufactured in a laboratory and to scour the globe in search of minuscule amounts of that chemical in

obscure plants so that they could declare the substance a dietary ingredient under the statute. To hold otherwise would be to open the door to bogus claims that, for example, a given chemical had been detected in a fungus found only in a remote Tibetan river valley, and the FDA would be left to refute that claim – to prove a negative – which the instant case demonstrates is not easily done.

This Court thus concludes 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, leading this Court to find that DMAA is not a botanical and thus not a dietary ingredient.

Accordingly, with one possible exception discussed below, DMAA is a "food additive." Relevant to this case, a food additive is presumed unsafe unless "there is in effect, and it and its use or intended use are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used." 21 U.S.C. § 348(a)(2). There is no such regulation.

The one possible exception is under 21 U.S.C. § 321(s), pursuant to which the FDCA exempts from the definition of "food additive" foods that are "generally recognized . . . as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe." This status is

referred to as "Generally Recognized as Safe" or "GRAS." Substances that are GRAS may be used in food without FDA approval or review. 21 U.S.C. §§ 321(s), 348(b). The burden of establishing that DMAA is GRAS rests with Hi-Tech.

As DMAA was not used in food prior to 1958, for it to be GRAS, Hi-Tech must demonstrate "both technical evidence of safety and a basis to conclude that this technical evidence of safety is generally known and accepted" among the scientific community. 62 Fed.Reg. 18940 (explaining the requirements of 21 C.F.R. § 170.30(a–b)); see United States v. Western Serum Co., Inc., 666 F.2d 335, 338 (9th Cir. 1982); United States v. Articles of . . . Promise Toothpaste, 624 F. Supp. 776, 778 (N.D. Ill. 1985), *aff'd* 826 F.2d 564 (7th Cir. 1987); United States v. Articles of Drug . . . Hormonin, 498 F. Supp. 424, 435 (D.N.J. 1980). Although unanimity among scientists is not required, there must be a general consensus regarding the safety of the substance in question for it to be considered GRAS. U.S. v. BioAnue Laboratories, Inc., 2014 WL 3696662 at *7 (M.D. Ga. July 23, 2014); see United States v. An Article of Food, 752 F.2d 11, 15 n.6 (1st Cir. 1985) (noting that evidence of a "genuine dispute among qualified experts" is "sufficient to preclude a finding of 'general recognition' of safe use").

Both sides of this dispute have presented extensive documentation regarding DMAA and the studies that have been performed on the effects of DMAA on humans

and animals. This Court's conclusion after reading the various expert reports and other documents is that there is no consensus regarding the question of whether the consumption of DMAA is safe.

This Court will avoid engaging in a detailed review of the numerous studies identified and discussed by the parties' experts. However, United States Magistrate Judge Anne T. Berton, in ruling on a Daubert motion in a DMAA products liability case in Texas, provided an exhaustive discussion of the various available studies of the effects of DMAA and noted that "[i]t is clear . . . that the scientific literature on DMAA presents insufficient data to conclude that DMAA is safe or that DMAA causes harm because the sample sizes are too small." Sparling v. Doyle, 2015 WL 4528759 at *35 (W.D. Tex. July 27, 2015).

This Court further notes that scientists have raised legitimate concerns regarding the safety of DMAA. DMAA is chemically similar to amphetamine, and some scientists have concerns that DMAA may have some of that drug's negative effects. The Government's expert, Dr. Dennis M. Keefe identified "[e]leven articles [that] described case reports or clinical studies involving adverse outcomes that occurred after the consumption of DMAA-containing products." [Doc. 107-8 at 33]. Five reports associated recreational DMAA consumption with substance abuse, [id.], three

studies identified liver toxicity, [id.], and several studies showed elevated blood pressure, [id. at 34].

To be sure, Hi-Tech has presented the results of studies that show no adverse (or no significant adverse) effect from DMAA. However, as the Government's expert points out, and as echoed by Magistrate Judge Berton, the sample sizes of those studies is simply too small to provide any convincing evidence regarding the safety of DMAA. Moreover, the safety of DMAA is not really the issue, and it does not matter that concerns about DMAA may be unfounded. The question is whether there is a consensus among experts regarding DMAA's safety, and this Court concludes that Hi-Tech has failed to present sufficient evidence to demonstrate that consensus, leading to the further conclusion that DMAA is not generally recognized as safe under the FDCA. Accordingly, products for human consumption containing DMAA are adulterated foods under the FDCA and subject to seizure pursuant to 21 U.S.C. § 334.

This Court's determination that Hi-Tech's products containing DMAA are subject to seizure and forfeiture necessarily requires this Court to further conclude that the officials involved in the seizure and sued by Hi-Tech did not violate the FDCA, the DSHEA, the Administrative Procedures Act (5 U.S.C. § 702), or the Due Process Clause of the Fifth Amendment to the United States Constitution as claimed by Hi-

Tech in the suit originally filed in Washington, D.C., and ultimately merged into this action.

## Conclusion

For the reasons discussed, the Government's motion for summary judgment, [Doc. 107], is **GRANTED** and Hi-Tech's motion for summary judgment, [Doc. 108], is **DENIED**. The Clerk is **DIRECTED** to enter judgment as to all claims in favor of the Government and against the Defendants undetermined 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 as listed in the amended complaint, [Doc. 25 as further amended by Doc. 138], and also against Claimants Hi-Tech Pharmaceuticals, Inc., and Jared Wheat in the forfeiture action. The Clerk is further **DIRECTED** to enter judgment as to all claims in favor of Defendants and against Plaintiffs in the suit originally filed in the District Court for the District of Columbia, Hi-Tech Pharmaceuticals, Inc. v. FDA, et al., No. 1:13-CV-1747 (D.D.C.), later transferred to this Court as Hi-Tech Pharmaceuticals, Inc. v. FDA, et al., 1:14-CV-2479 (N.D. Ga.), and even later merged into this action.

The Defendants in the forfeiture action, undetermined 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 listed in the amended complaint, [Doc. 25 as further amended by Doc. 138], are hereby **CONDEMNED**, and **FORFEITED** to the United States for destruction.

As this Court did not rely on the testimony of Iklas A. Khan, James P. Kababick, Rick Flurer, or Paula N. Brown, Hi-Tech's motions to strike their testimony, [Docs. 91, 100, 101, 102, 103, 122], are **DENIED** as moot.

The parties' various motions to seal documents, [Docs. 99, 105, 111, 112, 114], and to file excess pages, [Docs. 106, 110, 118], are **GRANTED** nunc pro tunc.

**IT IS SO ORDERED,** this 3rd day of April, 2017.

WILLIS B. HUNT, JR.
Judge, U. S. District Court