No. _____

In the Supreme Court of the United States

HI-TECH PHARMACEUTICALS, INC. AND JARED WHEAT,
Petitioners,
v.
FOOD & DRUG ADMINISTRATION, ET AL.,
Respondent.

On Petition for a Writ of Certiorari to the
United States Court of Appeals for the Eleventh Circuit

PETITION FOR A WRIT OF CERTIORARI

John C. Neiman, Jr.
Counsel of Record
Thomas W.H. Buck, Jr.
Brandt P. Hill
MAYNARD COOPER & GALE, P.C.
1901 Sixth Avenue North
2400 Regions/Harbert Plaza
Birmingham, AL 35203
(205) 254-1228
jneiman@maynardcooper.com

Counsel for Petitioners

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QUESTION PRESENTED

To increase the dietary supplements available to the public, the Dietary Supplement Health and Education Act of 1994 ("DSHEA"), 21 U.S.C. §321(ff), amended the Federal Food, Drug, and Cosmetic Act. DSHEA's amendments allow manufacturers to sell supplements, without first obtaining FDA approval, if their ingredients are, among other things, "constituent[s]" of "herb[s] or other botanical[s]." 21 U.S.C. §321(ff)(1)(C) & (F). The dietary supplements at issue in this case contain an ingredient known as DMAA, which studies have shown occurs in geranium plants. The courts below held that, even if these studies are accurate, DMAA is not, as a matter of law, a "constituent" of a "botanical"—and thus is not presumptively marketable as an ingredient in dietary supplements under DSHEA—because these studies show that DMAA appears in geraniums only in trace quantities, and DMAA has no prior history of being directly extracted from the plant for medicinal, cosmetic, or dietary use. The question presented is as follows:

> Did the Eleventh Circuit err in holding that a substance that naturally occurs in a plant is not a "constituent" of an "herb or other botanical"—and therefore cannot be included in presumptively marketable dietary supplements under the Dietary Supplement Health and Education Act—if the substance naturally occurs in the plant only in trace quantities and has no prior history of being extracted from the plant for medicinal, cosmetic, or dietary use?

PARTIES TO THE PROCEEDINGS

Petitioners Hi-Tech Pharmaceuticals, Inc. and Jared Wheat were appellants below. Respondents United States Food and Drug Administration, United States Department of Health and Human Services, and United States of America were appellees below. Respondent Alex Azar, in his official capacity as Secretary of the Department of Health and Human Services, succeeded to that office on January 29, 2018, at which time Secretary Azar was automatically substituted as a party under Federal Rule of Appellate Procedure 43(c)(2). Upon assuming office, Secretary Azar was an appellee below. Respondent Stephen M. Hahn, in his official capacity as Commissioner of the United States Food and Drug Administration, succeeded to that office on December 17, 2019, after the entry of judgment below, at which time Commissioner Hahn was automatically substituted as a party under Federal Rule of Appellate Procedure 43(c)(2).

CORPORATE DISCLOSURE STATEMENT

Hi-Tech Pharmaceuticals, Inc. is not a publicly traded company. It has no parent company, and no company owns 10% or more of its stock.

RELATED PROCEEDINGS

This case arises from the following proceedings in the United States District Court for the District of Columbia, the United States District Court for the Northern District of Georgia, and the United States Court of Appeals for the Eleventh Circuit, listed here in chronological order:

Hi-Tech Pharmaceuticals, Inc. v. Hamburg, No. 1:13-CV-01747 (D.D.C.) (transferred to N.D. Ga. Aug. 1, 2014).

Hi-Tech Pharmaceuticals, Inc. v. Hamburg, No. 1:14-CV-24790-WBH (N.D. Ga.) (merged into No. 1:13-CV-0675-WBH Aug. 1, 2014).

United States of America v. Undetermined Quantities of All Articles of Finished and In-Process Foods, No. 1:13-CV-03675-WBH (N.D. Ga. Apr. 3, 2017), *available at* 2017 WL 4456903.

United States of America v. Undetermined Quantities of All Articles of Finished and In-Process Foods, No. 17-13376 (11th Cir. Aug. 20, 2019), *reported at* 936 F.3d 1341.

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Just this past Term in *Bostock v. Clayton County, Georgia*, 140 S. Ct. 1731 (2020), this Court emphasized that a statute's unambiguous text governs even when it yields a result, as applied to a particular factual setting, that a court suspects Congress might not have anticipated. In this case—decided before *Bostock*—the Eleventh Circuit did what *Bostock* said courts must not do. The Eleventh Circuit placed artificial restraints on plain text found in the Dietary Supplement Health and Education Act and adopted, in the place of the most straightforward reading of the statute's language, what the court deemed to be the "safest conclusion" about what Congress would have wanted if it had been confronted with the specific facts of the case. App. A at 11a. The Eleventh Circuit's decision is at odds with DSHEA and the overarching principles that govern statutory interpretation, and the issue presented is of great import to the dietary-supplement industry. This case thus would be worthy of review even if this Court had not decided *Bostock* in the meantime. But *Bostock* at least makes it appropriate to grant certiorari, to vacate the Eleventh Circuit's judgment, and to remand for that court to reconsider its reading of DSHEA.

The statutory-interpretation question in this case is whether a chemical compound Petitioners synthetically produce for inclusion in dietary supplements—1,3-dimethylamylamine, known as DMAA—is a "constituent" of an "herb or other botanical" under §321(ff)(1)(F) of DSHEA. If so, then DSHEA makes it

a "dietary ingredient," which manufacturers may incorporate into dietary supplements without first seeking and obtaining the FDA's approval. The District Court and a divided Eleventh Circuit both held, on the Government's motion for summary judgment, that DMAA is not a "constituent" of an "herb or other botanical" as a matter of law. But under any reasonable interpretation of DSHEA's language, Petitioners are entitled to a trial. The Eleventh Circuit recognized that this record reveals "a genuine factual dispute over whether trace amounts of DMAA are naturally contained in geranium[]" plants. App. A at 7a. Everyone agrees that the geraniums in which DMAA has been found are "herb[s] or other botanical[s]." 21 U.S.C. §321(ff)(1)(C). Yet the Eleventh Circuit majority concluded that, even if DMAA naturally occurs in geraniums, it is not a "constituent" of an "herb or other botanical."

As Judge Jordan noted in his dissent, that result was driven not by DSHEA's plain text and the ordinary understanding of the terms "constituent," "herb," and "botanical," but instead by the majority's "policy" concerns. App. A at 25a. The majority theorized that DSHEA makes constituents of herbs or other botanicals marketable because "consuming them is ordinarily safe" and posited that "[t]he fact that DMAA can be found in trace amounts in geraniums, if true, says absolutely nothing about whether consuming the substance is safe." App. A at 11a, 12a. On that basis the majority read words into DSHEA, requiring not only that the compound be a "constituent" of an "herb or other botanical," but also that it be present in more

than "trace amounts," and that it have a prior history of being "derived" from the plant for "medicinal, cosmetic, or dietary" products. App. A at 12a. It was of no consequence to the majority that the phrases "trace amounts," "derived," and "medicinal, cosmetic, or dietary" appear nowhere in the statutory text.

Bostock makes clear that the Eleventh Circuit's reasoning cannot stand. Judge Jordan's dissent invoked almost precisely the same language this Court would use 10 months later in *Bostock*: "[T]he fact that a statute can be applied in situations not expressly anticipated by Congress does not demonstrate ambiguity. It demonstrates breadth." App. A at 26a (quoting *Pa. Dep't of Corrections v. Yeskey*, 524 U.S. 206, 212 (1998)); *cf. Bostock*, 140 S. Ct. at 1749 ("But ' "the fact that [a statute] has been applied in situations not expressly anticipated by Congress" ' does not demonstrate ambiguity; instead, it simply ' "demonstrates [the] breadth" ' of a legislative command." (quoting *Sedima, S. P. R. L. v. Imrex Co.*, 473 U. S. 479, 499 (1985)). DSHEA's language broadly encompasses all constituents of botanicals—including those that, like DMAA, appear in plants only in trace quantities and have not previously been extracted for medicinal, cosmetic, or dietary purposes. That should have been dispositive.

The need for this Court to correct the Eleventh Circuit's misinterpretation is paramount, for a great deal is at stake. DSHEA's drafters recognized that dietary supplements are an important food source, and the Eleventh Circuit's decision will stifle innovation in the

industry. The FDA's record in attempting to take Petitioners' DMAA-containing supplements off the market raises serious concerns about regulatory overreach. If this Court does not grant plenary review, it should at least grant certiorari, vacate the Eleventh Circuit's judgment, and remand for further consideration in light of *Bostock*.

OPINIONS BELOW

The Eleventh Circuit's opinion is reported as *United States v. Undetermined Quantities of All Articles of Finished and In-Process Foods*, 936 F.3d 1341 (C.A.11 2019), and reproduced at App. A at 1a–26a. The District Court's unpublished opinion granting the Government summary judgment is reproduced at App. C at 30a–42a. The District Court's unpublished opinion denying Hi-Tech and Jared Wheat's motion for reconsideration is reproduced at App. B at 27a-29a. The Eleventh Circuit's unpublished order denying panel and *en banc* rehearing is reproduced at App. D at 43a–44a.

STATEMENT OF JURISDICTION

The decision under review arose from an *in rem* forfeiture action the United States filed against the dietary supplements at issue here. Hi-Tech and its CEO, Jared Wheat, intervened as claimants in that action. The District Court had jurisdiction under 28 U.S.C. §1345, which gives "the district courts . . . original jurisdiction of all civil actions, suits or proceedings commenced by the United States," and 21 U.S.C. §334(a)(1), which provides that the Government may proceed with Food, Drug, and Cosmetic Act condemnation actions "in any district court of the United States or United States court of a Territory within the jurisdiction of which the article is found."

The District Court entered final judgment, finding the DMAA-containing supplements subject to forfeiture. App. C at 42a; App. B at 27a–29a. Hi-Tech and Wheat took a timely appeal, and the Eleventh Circuit had jurisdiction under 28 U.S.C. §1291. The panel entered final judgment, affirming the summary judgment, on August 30, 2019. *See* App. A at 21a. The Eleventh Circuit denied Hi-Tech and Wheat's timely application for panel rehearing and rehearing *en banc* on April 8, 2020. *See* App. D at 44a.

This Court has jurisdiction under 28 U.S.C. §1254(1). Supreme Court Rule 13 made this petition due on July 7, 2020. This Court's Order of March 19, 2020, extended the deadline to file by 60 days, to September 8, 2020. Hi-Tech and Wheat are filing this petition within that timeframe.

STATUTORY PROVISIONS INVOLVED

The key text from DSHEA states:

> For the purposes of this chapter . . . The term "dietary supplement" – means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: (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).

STATEMENT OF THE CASE

This case arises from the FDA's seizure of millions of dollars' worth of DMAA-containing dietary supplements from Hi-Tech Pharmaceuticals, Inc. The FDA instituted a forfeiture proceeding against the supplements in the Northern District of Georgia, and Hi-Tech and Jared Wheat, the company's principal owner and CEO, intervened as claimants. The FDA's theory as to why these supplements were not marketable shifted throughout the litigation. As explained below, eventually the FDA prevailed on a ground that was distinct from the one the agency first advanced to seize these products.

A. DSHEA's regulatory structure

DSHEA is a 1994 law that reflected Congress's desire to make dietary supplements more available to the public. Before DSHEA, the Food, Drug, and Cosmetic Act ("FDCA") treated dietary supplements like drugs, in the sense that manufacturers had to embark on a costly and time-consuming process of obtaining FDA approval before marketing hem. Among other things, the FDCA required that a manufacturer prove to the FDA that its dietary supplements were safe for public consumption before it could market them. *See* 21 U.S.C. §355 (pre-market approval process for drugs); 21 C.F.R. §§101.13-14; 101.70.

DSHEA changed this landscape by distinguishing dietary supplements from drugs. DSHEA categorizes "dietary supplements" as "foods" rather than "drugs," which allows manufacturers to market them without first going through the FDA preapproval process. 21 U.S.C. §321(ff). The FDA may still remove a dietary

supplement from the market after a manufacturer has begun selling it, but only if the agency meets the demanding burden of proving that the supplement or one of its ingredients "presents a significant or unreasonable risk of illness or injury under conditions of use recommended or suggested in labeling, or if no conditions are suggested or recommended in the labeling, under ordinary conditions of use." *Id.* §342(f)(1)(A)(i)-(ii). DSHEA thus withdrew what Congress deemed to be the "unreasonable regulatory barriers" that treated supplements like drugs. *See* Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, §2(13)-(15)(A), 108 Stat. 4325 (1994).

To this end, DSHEA defines "dietary supplement" expansively, to include any "product" that is "intended to supplement the diet that bears or contains one or more" of a list of "dietary ingredients." 21 U.S.C. §321(ff). Most critically for the purposes of the case, this list includes any "constituent" of an "herb or other botanical." *Id.* Also included are:

- "vitamin[s],"
- "mineral[s],"
- "amino acid[s],"
- "dietary substance[s] for use by man to supplement the diet by increasing the total dietary intake"; and
- "concentrate[s], metabolite[s], constituent[s], extract[s]," or a "combination" of any of the aforementioned ingredients.

Id.

B. DMAA's presence in geranium plants

After DSHEA made dietary supplements containing botanical constituents presumptively marketable, evidence emerged that DMAA—a compound that previously had been synthesized in laboratories for use in nasal decongestants—occurs naturally in geranium plants. DMAA has energy-boosting effects much like caffeine's, and its inclusion in dietary supplements helps people work out harder and lose weight. Based on the evidence showing that DMAA is naturally present in geraniums, manufacturers began including this ingredient in their dietary supplements.

This evidence includes multiple peer-reviewed studies showing that DMAA naturally occurs in plants of the pelargonium genus, including in the oils of those plants. *See* App. A at 6a–7a; App. C at 34a; Thomas D. Gauthier, *Evidence for the Presence of 1,3-Dimethylamylamine (1,3-DMAA) in Geranium Plant Materials,* 8 ANALYTICAL CHEMISTRY INSIGHTS 29-40 (2013), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3682735/); Zang Ping *et al., A Study on the Chemical Constituents of Geranium Oil*, 25 J. GUIZHOU INST. TECH. 82 (1996); J.S. Li *et al.*, *Identification and Quantification of Dimethylamylamine in Geranium by Liquid Chromatography Tandem Mass Spectrometry*, 7 ANALYTICAL CHEMISTRY INSIGHTS 47 (2012); HL Fleming *et al.*, *Analysis and Confirmation of 1,3-DMAA and 1,4-DMAA in Geranium Plants Using High Performance Liquid Chromatography with Tandem Mass Spectrometry at ng/g Concentrations*, 7 ANALYTICAL CHEMISTRY INSIGHTS 59 (2012). These plants have been consumed for hundreds of years in

certain parts of the world, often as a dressing on a salad or dessert.

C. The FDA's shifting positions on DMAA

This case arose when the FDA seized Hi-Tech's DMAA-containing supplements, claiming that they were not presumptively marketable under DSHEA. The FDA then filed an action seeking forfeiture of these supplements in the Northern District of Georgia. But critically and tellingly, the FDA did not premise these enforcement actions on the interpretation of DSHEA that the District Court and Eleventh Circuit majority eventually would adopt: the FDA did not claim that DMAA is not a "constituent" of an "herb or other botanical" even if it naturally occurs in geraniums. The FDA instead contended that DMAA was not a "constituent" of an "herb or other botanical" on the premise that, as a factual matter, the studies discussed above were simply wrong—and that DMAA does not naturally occur in geraniums at all.

But as the forfeiture action proceeded, the FDA's theory fell apart, and was even shown to have been based on fraudulent research. The FDA had relied on one study funded by the United States Anti-Doping Agency ("USADA"), a non-governmental organization that decides which substances American athletes participating in international competitions are permitted to consume. Discovery revealed that USADA had lobbied the FDA to ban DMAA for its own reasons and had funded this study to counter the studies finding DMAA in geraniums. *See* Mahmoud A. ElSohly *et al.*, *Pelargonium Oil and Methyl Hexaneamine (MHA):*

Analytical Approaches Supporting the Absence of MHA in Authenticated Pelargonium Graveolens Plant Material and Oil, J. ANALYTICAL TOXICOLOGY 1 (2012). Discovery also revealed that the researchers who authored USADA's studies had, in fact, found low levels of DMAA in geraniums—but had failed to disclose that finding in their final report after USADA officials told them that a "low level" should not be enough. Doc. 108-4 at p. 565. The final study instead represented that "[n]one of the analyzed oils or the plant material (young and mature, fresh and dried leaves and stems) showed any detectable level of" DMAA. Doc. 108-4 at pp. 572, 585.

Discovery revealed similar flaws in other studies on which the FDA was relying. The FDA had cited a second paper by the same researchers, Mahmoud A. ElSohly *et al.*, *Methylhexanamine is Not Detectable in Pelargonium or Geranium Species and Their Essential Oils: A Multicentre Investigation*, DRUG TESTING & ANALYSIS (2014). But in that study also, the researchers had detected low levels of DMAA in certain geraniums. *See* Doc. 108-5 at pp. 62-67 (email correspondence from Min Yang of the Shanghai Institute of Materia Medica). As with the first study, the authors did not report their findings, and instead used a higher "detection level" to claim that they had detected no DMAA in the plants. Still another study had similar problems. The original version concluded that DMAA naturally occurs in geraniums. *See* Doc. 108-5 at pp. 2-11. But the final version said, without any acknowledgement of the earlier results, that it had

not found DMAA in the geraniums "with a limit of detection of 10 parts per billion." Ying Zhang *et al.*, *1,3 Dimethylamylamine (DMAA) in Supplements and Geranium Products: Natural or Synthetic?*, DRUG TESTING ANALYSIS (2012).

D. The District Court's ruling

After the FDA seized Hi-Tech's dietary supplements and instituted its forfeiture action, Hi-Tech and Wheat intervened, claiming ownership interests in the seized products.[1] Following discovery, both sides moved for summary judgment. The FDA's claim was that, despite the flaws that had been revealed in the studies on which it had relied, the undisputed evidence showed that DMAA does not naturally occur in geraniums and therefore is not a "constituent" of an "herb or other botanical" under DSHEA. Hi-Tech, on the other hand, argued that the undisputed evidence shows that DMAA is naturally in geraniums, and thus is a "constituent" of an "herb or other botanical."

The District Court had little trouble discarding the FDA's theory. The District Court rejected the FDA's assertion that there was "uncontroverted evidence that geraniums cannot make DMAA." App. C at 34a–35a. The District Court instead concluded, based on

[1] After the Government seized these dietary supplements but before it filed the forfeiture action, Hi-Tech filed an action against the FDA and various federal officials in the District Court for the District of Columbia, alleging violations of the Administrative Procedure Act and the Due Process Clause. *See* App. A at 2a–3a. That court transferred the action to the Northern District of Georgia, which consolidated it with the Government's forfeiture action.

the studies cited by Hi-Tech, that there is "fairly substantial evidence that trace amounts of DMAA have been found in a species of a geranium plant." App. C at 34a.

But despite rejecting the FDA's suggestion that the record conclusively resolved the parties' factual dispute, the District Court nonetheless entered summary judgment for the Government—based on an interpretation of DSHEA that the FDA itself had never advanced. The District Court held that the evidence showing DMAA to be present in geranium plants did not establish that it was a dietary ingredient under DSHEA. That was so, in the District Court's estimation, because "to be a botanical, [a] substance must have been extracted from a plant or plant-like organism and used, for example, in or as a medicine." App. C at 36a. "While very small amounts of DMAA might be present in geraniums," the District Court found, "DMAA in the marketplace has never been extracted from geraniums or any other plant." App. C at 36a–37a.[2] While recognizing that DSHEA allows dietary-supplement manufacturers to use synthesized ingredients in their products so long as those ingredients also occur naturally, the District Court found that, for a substance to be a "botanical," there must be "at least

[2] Because the Government had not argued that whether DMAA has a history of being derived from geraniums was relevant, the parties had conducted no discovery on the issue. *See* App. A at 3a. Hi-Tech and Wheat argued in their motion for reconsideration that the District Court should allow them to conduct discovery on this issue. *See* App. A at 3a. The District Court denied that motion, and the Eleventh Circuit affirmed. *See* App. B at 29a; App. A at 17a–19a.

some history of the substance in question having been extracted in usable quantities" from a plant. App. C at 37a. Under that standard—and without considering whether DMAA, if not a botanical, is at least a "constituent" of a botanical—the District Court concluded that "DMAA is not a botanical and thus not a dietary ingredient." App. C at 37a.[3]

Hi-Tech and Wheat filed a motion to reconsider, observing that the District Court had not addressed whether DMAA is, at the very least, a "constituent" of a botanical. The District Court denied the motion, explaining that its analysis applied "by extension" to the question whether DMAA is a botanical "constituent." App. B at 28a.

E. The Eleventh Circuit's decision

Hi-Tech and Wheat appealed, and a divided Eleventh Circuit affirmed. *See* App. A at 2a–26a.

The majority opinion, which was written by Judge Hinkle and joined by Judge Tjoflat, adopted a construction of DSHEA much like the District Court's. The majority acknowledged that a "constituent" of an "herb or other botanical" can be a dietary ingredient even when it is "artificially manufactured" for use in supplements. App. A at 13a. The majority also acknowledged that "this record presents a genuine factual dispute over whether trace amounts of DMAA are naturally contained in geraniums." App. A at 7a. The majority likewise acknowledged that the term

[3] The District Court addressed several other issues that are not pertinent here. *See* App. C at 38a–40a.

"constituent" could mean "anything naturally contained in" and noted also that the term can mean "an essential part." App. A at 10a. Yet after examining the text and ordinary meanings of the terms "constituent" and "botanical," the court declared that "[n]one of this is dispositive." App. A at 11a. It stated that the "safest conclusion" was that "it is unlikely that Congress used the term 'constituent' to mean a substance that is present in a plant in only trace amounts and that has never been derived from a plant for use in any medicinal, cosmetic, or dietary product." App. A at 11a. It reasoned that the "fact that DMAA can be found in trace amounts in geraniums, if true, says absolutely nothing about whether consuming the substance is safe." App. A at 12a–13a.

Judge Jordan dissented in pertinent part. *See* App. A at 22a–26a. Citing various dictionaries, he reasoned that "the word 'botanical' contextually refers to a plant or part of a plant," and the term "constituent" means "a component or element of a whole." App. A at 23a, 24a. He stated that the "statutory text does not provide a basis for the district court's conclusion that a 'constituent' of a 'botanical' must have a history of being extracted in usable quantities, or for the majority's holding that to be a 'constituent' an ingredient must have been derived from a plant for use in a medicinal, cosmetic, or dietary product." App. A at 24a–25a. He argued that "[t]he majority's contrary interpretation" of DSHEA "seems influenced by policy reasons which call for a narrower reading of the statutory text," which he argued were "not ours to consider." App. A at 25a. Instead, he concluded, "[a]lthough the

statutory reading advocated by Hi-Tech is expansive, that reading squares with the broad language Congress chose." App. A at 26a. He therefore would have "remand[ed] for a trial on whether DMAA" does, in fact, naturally occur in geranium plants. App. A at 26a.[4]

Hi-Tech and Wheat petitioned for panel and *en banc* rehearing, which the Eleventh Circuit denied. *See* App. D.

[4] The Eleventh Circuit also addressed several other issues that are not the subject of this petition, including Hi-Tech and Wheat's argument that the District Court at least should have allowed them to conduct discovery on whether DMAA previously had been extracted from geraniums. *See* App. A at 14a–20a.

REASONS THIS COURT SHOULD GRANT CERTIORARI

Shortly after the Eleventh Circuit denied rehearing in this case, this Court decided *Bostock v. Clayton County, Georgia*, 140 S. Ct. 1731 (2020). The context there, and the question presented, were different from the ones now before the Court. But in resolving the specific issue *Bostock* presented, this Court emphasized core principles of statutory interpretation that govern all federal statutes. "When the express terms of a statute give us one answer and extratextual considerations suggest another, it's no contest," this Court explained: "Only the written word is the law, and all persons are entitled to its benefit." *Id.* at 1737. There is no "'canon of donut holes,'" this Court stated, "in which Congress's failure to speak directly to a specific case that falls within a more general statutory rule creates a tacit exception." *Id.* at 1747. "Instead, when Congress chooses not to include any exceptions to a broad rule," this Court stressed, "courts apply the broad rule." *Id.*

Those statements stand as compelling criticisms of the Eleventh Circuit's interpretation of DSHEA—which, though not related to the fundamental civil-rights issue presented in *Bostock*, is important in its own right. In dissenting below, Judge Jordan invoked these same principles. The Eleventh Circuit had given DSHEA a "narrower reading" than its plain text allowed, he observed, App. A at 25a, based on a suspicion that it was "unlikely" Congress would have "mean[t]" for these terms to include substances that appear "only in trace amounts" and do not have a history of being extracted from those plants, App. A at 9a

(majority op.). Out of its concern for what Judge Jordan rightly characterized as "policy reasons," the majority had effectively invoked what this Court in *Bostock* called "the canon of donut holes," carving an exception into the statute that kept DSHEA's broad text from applying in the specific circumstances of this case. App. A at 25a. The result not only runs contrary to the principles set forth in *Bostock*, but also will stifle innovation in the dietary-supplement industry in ways that run contrary to DSHEA's most fundamental purposes. This Court should either grant plenary review or, at least, grant certiorari, vacate the Eleventh Circuit's judgment, and remand for further consideration in light of *Bostock*.

A. The Eleventh Circuit's interpretation of DSHEA is wrong and fundamentally contrary to the principles set forth in *Bostock*

The ordinary understanding of the phrase "constituent" of an "herb or other botanical," as found in DSHEA, encompasses all substances that, like DMAA, naturally occur in geranium plants and their oils. There is no doubt that the geraniums and their oils in which DMAA has been detected are "botanicals" for these purposes. Even the FDA conceded that one definition of "botanical" is a "plant (or part of the plant)." App. A at 23a (Jordan, J., dissenting). And the ordinary meaning of "constituent" is "'an element of a complex whole.'" App. A at 24a (Jordan, J., dissenting) (quoting 1 SHORTER OXFORD ENGLISH DICTIONARY 496 (5th ed. 2002); *see also* App. A at 24a (noting alternative definition as "'a thing, person, or organism that

along with others serves in making up a complete whole or unit'" (quoting WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY OF THE ENGLISH LANGUAGE UNABRIDGED 258 (2002)).

Those considerations mean that DMAA is a "constituent" of a "botanical" so long as it naturally occurs in geraniums and their oils. It is telling that, when the FDA seized these products and sought their forfeiture, it did not contend otherwise. It did not argue that DMAA is not a "constituent" of a "botanical" because it appeared in geraniums only in trace quantities or did not have a history of being extracted from these plants. Its theory was, instead, that DMAA is not a "constituent" of a "botanical" *because it does not naturally occur in geraniums at all*. But discovery revealed that the studies on which the FDA based that theory were flawed and even fraudulent—and that other studies stood as substantial evidence that, as the Eleventh Circuit acknowledged, "trace amounts of DMAA are naturally contained in geraniums." App. A at 7a. The right result, as Judge Jordan's dissent explained, was a remand for a "trial on whether DMAA is," as a factual matter, "a 'constituent' of geraniums." App. A at 26a (Jordan, J., dissenting).

The Eleventh Circuit, like the District Court before it, headed off that result only by writing new words into DSHEA. The statute's text says that a presumptively marketable dietary supplement can contain a "constituent" of an "herb or other botanical." 21 U.S.C. §321(ff)(1). No more, no less. Yet the majority opinion judicially mandated an exception to that text, elimi-

nating the marketability presumption when the constituent is, in the majority's words, "present in a plant in only trace amounts" and has previously "never been derived from a plant for use in any medicinal, cosmetic, or dietary product." App. A at 11a.

That wordsmithing was the Eleventh Circuit's, not Congress's, and the majority opinion did not anchor this verbiage in any part of DSHEA's text. It did point to one dictionary that defines "constituent" as, among other things, an "essential part," and from that definition reasoned that the term's "connotation" is "usually not [as] broad" as the meaning Hi-Tech had argued, which was "anything naturally contained in." App. A at 10a. But the same dictionary also defines "constituent" as "component." *See* "Constituent," MERRIAM-WEBSTER ONLINE DICTIONARY (2019), https://www.merriam-webster.com/dictionary/constituent. And the fact that something appears in small quantities, even trace amounts, does not mean it is not "essential" in any event. Human bodies contain numerous "trace elements" that are present "in only small amounts" but still are "vital for maintaining health." Sukhsatej Batra, *Importance of Trace Elements in the Human Body*, S.F. CHRON. (Dec. 12, 2018), https://healthyeating.sfgate.com/importance-trace-elements-human-body-4864.html. If Congress believed that a certain "essential" amount of a component must be in a plant for it to be a "constituent," DSHEA would have pegged that "essential" amount at a specific number, as statutes do in innumerable contexts. *See, e.g.*, 15 U.S.C. §2697(a)(7)(C) (formaldehyde thresholds in wood products).

Nor did the Eleventh Circuit provide a textual anchor for its requirement that, to count as a "constituent," the plant component must have a prior history of being extracted for "medicinal, cosmetic, or dietary" purposes. App. A at 9a, 11a, 12a. What the Eleventh Circuit meant by this is unclear. The majority emphasized that its ruling did "not mean that DSHEA applies only to products actually derived from plants," and did not doubt that, "[i]f a product is indeed a dietary supplement because it contains a qualifying dietary ingredient—including, for example, an herb or other botanical—a manufacturer may," consistently with DSHEA, either "take the dietary ingredient from nature or produce it artificially." App. A at 13a. Yet the majority held that, before such an ingredient can be considered a "constituent" of a botanical, it must have a history of *previously* being "derived from" that "plant." App. A at 13a.

That reasoning makes no sense and has no textual basis. The components of something are its constituents, regardless of whether they have been physically separated from it in the past. *Cf.* Timothy P. Smith, *Hidden Worlds: Hunting for Quarks in Ordinary Matter* 51 (PRINCETON UNIV. PRESS 2003) (calling quarks "the basic constituents of matter" even though science has "never isolated a quark" and perhaps "never will"). Although the majority suggested it would be "awkward[]" if "constituent" had a "broad[er]" scope than other substances DSHEA makes marketable—substances that are derived directly from plants, App. A at 11a—Judge Jordan rightly observed that "words . . . connect[ed]" in a disjunctive list like this one in

DSHEA "'are to be given separate meanings.'" App. A at 25a (quoting *Loughrin v. United States*, 573 U.S. 351, 357 (2014)).

Much more so than any textual consideration, the majority developed its exception to DSHEA's list of presumptively marketable supplements through the kind of extratextual reasoning this Court rejected in *Bostock*. Chief among the Eleventh Circuit's cited concerns was its belief that it was "unlikely" that Congress "mean[t]" for the term "constituent" to encompass a substance that, like DMAA, is "present in a plant in only trace amounts and that has never been derived from a plant for use in any medicinal, cosmetic, or dietary product." App. A at 11a. Yet the Eleventh Circuit cited no text or legislative history that would support any supposition that Congress had specifically considered the matter, and this Court in *Bostock* emphasized that any surmise that "few in" Congress would have "expected" a result is no reason to deny what "follows ineluctably from the statutory text." *Bostock*, 140 S. Ct. at 1750. As this Court explained, "it is ultimately the provisions of those legislative commands rather than the principal concerns of our legislators by which we are governed." *Id.* (quoting *Oncale v. Sundowner Offshore Servs., Inc.*, 523 U.S. 75, 79 (1998) (internal quotations omitted)).

Of similar effect—and in similar tension with *Bostock*—was the Eleventh Circuit's repeated concern that the ordinary meaning of the words "constituent" and "herb or other botanical" would simply be too "broad." App. A at 10a. In so doing the Eleventh Circuit followed the "'canon of donut holes'" that *Bostock*

firmly rejected, "in which Congress's failure to speak directly to a specific case that falls within a more general statutory rule creates a tacit exception." *Id.* at 1747. As *Bostock* emphasized and Judge Jordan's dissent echoed, that is not how the law works. "[W]hen Congress chooses not to include any exceptions to a broad rule," courts are not to create an exception like the Eleventh Circuit did below, but instead are to "apply the broad rule." *Id.* "'[T]he fact that [a statute] has been applied in situations not expressly anticipated by Congress'" does not demonstrate ambiguity; instead, it simply "'demonstrates [the] breadth'" of a legislative command." *Id.* at 1749 (quoting *Sedima*, 473 U.S. at 499.)

The Eleventh Circuit likewise ran headlong into *Bostock*'s prohibitions when it offered policy justifications for altering the text. According to the majority, it made sense to narrow the list of presumptively marketable supplements because "[t]he fact that DMAA can be found in trace amounts in geraniums, if true, says absolutely nothing about whether consuming the substance is safe." App. A at 12a–13a. But *Bostock* makes clear that this sort of atextual reasoning can play no role when the text is plain. To evade a statute's language on the premise that "undesirable policy consequences would follow" is to abandon "any pretense of statutory interpretation." *Bostock*, 140 S. Ct. at 1753. "[T]hat's an invitation no court should ever take up," this Court pronounced, because "[t]he place to make new legislation, or address unwanted consequences of old legislation, lies in Congress." *Id.* Judge Jordan made the same point: the "policy reasons" that

drove the majority's "narrower reading of the statutory text," he concluded, were not that court's—or any court's—"to consider." App. A at 25a.

Judicially narrowing statutes based on policy calculations of this sort is ill-advised—not only because "people are entitled to rely on the law as written," as *Bostock* observed, but also because a court's "suppositions about" Congress's "intentions" often turn out to be wrong. *Bostock*, 140 S. Ct. at 1749, 1754. The Eleventh Circuit's decision stands as a stark example of that dynamic. Contrary to the Eleventh Circuit's surmise, the DSHEA provision at issue here, which defines which dietary supplements are presumptively marketable, "is *not*," as commentators have emphasized, "a safety provision." Scott Bass *et al.*, *The New Dietary Ingredient Safety Provision of DSHEA: A Return to Congressional Intent*, 31 AM. J.L. & MED. 285, 294-95 (2005). This provision draws the line not between substances that are safe and those that are not, but instead between substances that occur in nature and those that do not. DSHEA does have a safety provision, located in a separate statutory section, that allows the FDA to take products off the market if it can show they "present[] a significant or unreasonable risk of illness or injury." 21 U.S.C. §342(f)(1)(A). But critically, the FDA has never tried to make that showing with respect to DMAA. In light of the evidence showing that DMAA is safe when used in accordance with its intended uses, the FDA would not succeed in any such endeavor. *See* App. A at 16a ("If the issue was whether DMAA is safe, Hi-Tech's evidence would create a genuine issue of fact precluding summary

judgment; neither side's evidence is conclusive."). The Eleventh Circuit's concern over safety not only steered it away from the text's proper interpretation, but also was unjustified in its own right.

The Eleventh Circuit's misguided analysis underscores why, as *Bostock* reiterated, resort to policy considerations is imprudent when the statutory text is broad and plain. "[S]uppositions about intentions or guesswork about expectations" of Congress's are not part of the interpretive process. *Bostock*, 140 S. Ct. at 1754. A court's task is not, as *Bostock* put it, to "point out" any "application" of a statute that it believes to be "both unexpected and important" and to "refer the subject back to Congress." *Id.* at 1750. The court's task is to determine if "the plain terms of the law" cover the situation at hand and, if so, to "enforce" them. *Id.* That is what the Eleventh Circuit should have done below, and it is what the Eleventh Circuit likely would do now if this Court grants review, vacates the judgment, and remands for consideration in light of the intervening decision in *Bostock*.

B. The Eleventh Circuit's rewriting of DSHEA is important and worthy of review

The need for this Court's intervention—and, at the very least, for an instruction that the Eleventh Circuit reconsider the case in light of *Bostock*—is imperative. The issue of DMAA's marketability is a novel one, and as a result there is no division among the lower courts on this question. But the Eleventh Circuit's decision is of tremendous importance to the dietary-supplement industry, and the FDA's pattern of overreach on

DMAA may improvidently prevent further lower-court consideration of this significant issue.

Consider first the effect this decision will have on the industry. DMAA is an important dietary ingredient, and supplements containing it have formed a significant portion of Hi-Tech's business. Yet the Eleventh Circuit's insertion of this language into DSHEA will call into question not only DMAA's continued viability, but also the processes for producing numerous other beneficial dietary ingredients in the future. Pterostilbene, for example, is an antioxidant in blueberries, but in "trace amounts," around 10 parts per million. *See* Denise McCormack *et al.*, *A Review of Pterostilbene Antioxidant Activity and Disease Modification*, OXIDATIVE MEDICINE & CELLULAR LONGEVITY (2013), https://www.hindawi.com/journals/omcl/2013/575482/. Resveratrol is the chemical that makes red wine healthy, but there are only 0.3 to 0.5 milligrams per glass. *See* Ore. State Univ. Linus Pauling Inst., *Micronutrient Info. Ctr.: Resveratrol* (2015) tbl. 1, http://lpi.oregonstate.edu/mic/dietary-factors/phytochemicals/resveratrol. Manufacturers have synthesized these compounds to incorporate them into dietary supplements in larger, more beneficial quantities. *See, e.g.*, James McNulty, *A scalable process for the synthesis of (E)-pterostilbene involving aqueous Wittig olefination chemistry*, SCIENCE DIRECT J. (May 2013); Bob Yirka, *Chemists Figure Out How to Synthesize Compounds from Resveratrol*, PHYSORG.COM (June 23, 2011), https://phys.org/news/2011-06-chemists-figure-compounds-resveratrol.html. Yet even

though the Eleventh Circuit acknowledged that botanical constituents can be included in supplements when they are "artificially manufactured," the limitations the majority wrote into DSHEA—precluding, among other things, constituents found only in "trace amounts"—will call these processes into doubt. App. A at 13a.

The Eleventh Circuit's decision will put the brakes on progress in the dietary-supplement industry in additional ways. The machines used to determine a plant's components are "still evolving to meet the latest demands of biotechnology." John Buie, *Evolution of Mass Spectrometers*, LAB MANAGER (Feb. 27, 2011), https://www.labmanager.com/lab-product/2011/02/evolution-of-mass-spectrometers#.XZomwvZFw2w. Scientists constantly uncover new and beneficial plant compounds. *See, e.g.*, *Scientists Discover a Cancer-Fighting Substance in a Common Wildflower*, SILICON REPUBLIC (Aug. 2, 2019), https://www.siliconrepublic.com/innovation/feverfew-wildflower-cancer-killing-compound. When future technological and scientific leaps reveal these compounds in trace amounts—and the compounds have not previously been derived from the plants at issue—the Eleventh Circuit's decision will preclude their use in presumptively marketable supplements no matter how beneficial they may be. These considerations make it important not to delay resolution of this question—or, at the very least, to give the Eleventh Circuit another opportunity to answer it in light of *Bostock*.

The FDA actions that brought this issue to a head heighten the need for this Court's immediate intervention. When the United States Anti-Doping Agency first approached the FDA about DMAA's marketability, FDA officials took the position that, due to the research showing that "[DMAA] is found in the oil of many geraniums," DMAA "appear[ed] to be a dietary ingredient under [DSHEA] because it is a constituent of another dietary ingredient, (i.e., a plant)." Doc. 108-4 at pp. 290 & 292. It was only after USADA continued to lobby the FDA—and after USADA funded the fraudulent study, discussed above, in which researchers concealed DMAA's presence in geraniums—that the FDA changed its position, and began to claim that DMAA is not in geraniums. *See supra* at 11–13.

In pressing that ultimately unsuccessful claim, the FDA chose enforcement actions that minimized the opportunities for judicial review. The FDA did not, as it has for other dietary supplements, initiate notice-and-comment rulemaking to accept public input on whether DMAA is safe, from which judicial review could have followed. *See, e.g.,* Rule Declaring Dietary Supplements Containing Ephedrine Alkaloids Adulterated, 69 Fed. Reg. 6787 (2004), *upheld on review*, *Nutraceutical Corp. v. Von Eschenbach*, 459 F. 3d 1033, 1043–44 (C.A.10 2006). The FDA instead sent warning letters to eleven of the largest DMAA manufacturers, and those manufacturers all took their products off the market rather than face the risks that their defense would have entailed. *See* Doc. 108-5 at p. 26; Doc. 108-7 at p. 112. Smaller manufacturers, like Hi-Tech, then became subject to individualized

seizures and forfeiture actions like the one at issue here.

But when Hi-Tech and Wheat chose to not wave the white flag as other manufacturers had done, the factual premises for the FDA's actions quickly evaporated. Discovery revealed that USADA had encouraged researchers to fudge their results and to conceal DMAA's presence within geraniums. When that became apparent, the FDA should have dismissed this case. Still, the agency pressed on, and the lower courts rightly held that the FDA "failed to meet its burden of establishing that DMAA has not been found in geraniums." App. C at 36a.

Yet both the District Court and the Eleventh Circuit held that the FDA was entitled to summary judgment, based on their belief that Congress would have wanted the statute's meaning to be "narrower" than even the FDA had believed its plain text to provide. App. A at 9a, 10a. *Bostock* shows that parties like Hi-Tech and Wheat, who have a considerable amount to lose if their products are not marketable, should not have to "fear[] that courts might disregard" the "plain terms" of a statute "based on some extratextual consideration" of this sort. *Bostock*, 140 S. Ct. at 1749. The stakes to Hi-Tech and the rest of the dietary-supplement industry are thus high, and the FDA's actions will likely prevent further percolation of these issues. At the very least, a remand to the Eleventh Circuit is warranted.

CONCLUSION

This Court should either grant plenary review or should grant certiorari, vacate the judgment below, and remand the case to the Eleventh Circuit for further consideration in light of *Bostock*.

Respectfully submitted,

John C. Neiman, Jr.
Counsel of Record
Thomas W.H. Buck, Jr.
Brandt P. Hill
MAYNARD COOPER & GALE, P.C.
1901 Sixth Avenue North
2400 Regions/Harbert Plaza
Birmingham, AL 35213
(205) 254-1228
jneiman@maynardcooper.com
tbuck@maynardcooper.com
bhill@maynardcooper.com

Counsel for Petitioners

September 1, 2020

APPENDIX

APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT, FILED AUGUST 30, 2019

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 17-13376

D.C. Docket No. 1:13-cv-03675-WBH

UNITED STATES OF AMERICA,

Plaintiff-Appellee,

versus

UNDETERMINED QUANTITIES OF ALL ARTICLES OF FINISHED AND IN-PROCESS FOODS, RAW INGREDIENTS (BULK POWDERS, BULK CAPSULES), WITH ANY LOT NUMBER, SIZE, OR TYPE CONTAINER, WHETHER LABELED OR UNLABELED, *et al.*,

Defendants,

HI-TECH PHARMACEUTICALS, INC.,
JARED WHEAT,

Claimants-Appellants.

Appeal from the United States District Court
for the Northern District of Georgia

(August 30, 2019)

Appendix A

Before TJOFLAT and JORDAN, Circuit Judges, and HINKLE,* District Judge.

HINKLE, District Judge:

The Dietary Supplement Health and Education Act of 1994 provides favorable treatment for "dietary supplements," defined to include any "botanical" or "constituent" of a botanical. This case presents the question whether these terms apply to a substance that was invented in a laboratory and is artificially produced for commercial sale but that, entirely coincidentally, may be found in trace amounts in a plant. We hold that the terms do not extend this far.

I. Proceedings

The Food and Drug Administration seized from Hi-Tech Pharmaceuticals, Inc. a substantial quantity of products containing 1,3-dimethylamylamine or "DMAA." DMAA is used in fitness products aimed at bodybuilders and other athletes.

The seizure led to two actions that were consolidated in the district court. One was a forfeiture action filed by the United States against the products. Hi-Tech and its chief executive officer, Jared Wheat, intervened as claimants. Hi-Tech filed the other action against the FDA and other governmental defendants.

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* Honorable Robert L. Hinkle, United States District Judge for the Northern District of Florida, sitting by designation.

Hi-Tech asserted that DMAA is a dietary supplement; that under the Administrative Procedure Act the FDA can properly ban DMAA, if at all, only through rulemaking; and that the seizure of Hi-Tech's DMAA violated the Fifth Amendment's Due Process Clause.

The parties filed cross-motions for summary judgment. The district court granted the FDA's motion, holding the seizure proper both substantively and procedurally. The district court denied a motion to reconsider that included a request to reopen discovery. Hi-Tech and Mr. Wheat have appealed. The appeal has been fully briefed and orally argued.

II. Standard of Review

We review de novo the district court's grant of summary judgment. *See, e.g., Price v. Comm'r, Dep't of Corr.*, 920 F.3d 1317, 1323 (11th Cir. 2019). We review for abuse of discretion the district court's denial of the motion for reconsideration and refusal to reopen discovery. *See, e.g., Corwin v. Walt Disney Co.*, 475 F.3d 1239, 1254 (11th Cir. 2007) (reconsideration); *Artistic Entm't, Inc. v. City of Warner Robins*, 331 F.3d 1196, 1202 (11th Cir. 2003) (reopening discovery).

III. The Statute and the Issues

The Federal Food, Drug, and Cosmetic Act prohibits the introduction of adulterated foods into interstate commerce. 21 U.S.C. § 331(a). The FDA enforces the Act. *Id.* § 393(b)(2)(A). The agency may bring an in rem

forfeiture action in district court to condemn adulterated foods. *Id.* § 334(a)(1). Hi-Tech's DMAA products were adulterated foods if they were "food additives" but not if they were "dietary supplements."

The background is this. The Dietary Supplement Health and Education Act of 1994, commonly referred to as "DSHEA," amended the Federal Food, Drug, and Cosmetic Act to provide favorable treatment for dietary supplements. The statute's definition of "dietary supplement" includes multiple parts. 21 U.S.C. § 321(ff). The only part relevant to Hi-Tech's DMAA is this: a product that is intended to supplement the diet—this includes DMAA—is a dietary supplement if it contains "an herb or other botanical" or "a concentrate, metabolite, constituent, extract, or combination of" an herb or other botanical. *Id.* § 321(ff)(1)(C) & (F). The statute describes these—as well as other substances not at issue here—as "dietary ingredients."

Under DSHEA, and subject to exceptions not relevant here, a dietary supplement can be condemned as adulterated only if the FDA carries the burden of proving that the substance presents a "significant or unreasonable risk of illness or injury" under recommended, suggested, or ordinary conditions of use. *Id.* § 342(f)(1)(A). The FDA did not attempt to make that showing for the DMAA products it seized from Hi-Tech. A ruling that DMAA is a dietary supplement thus would resolve this appeal in Hi-Tech's favor.

On the other hand, a ruling that DMAA is a "food additive" would resolve the dispute in the FDA's favor. A substance intended for human consumption is a food additive if it is not a dietary supplement and is not "generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures . . . to be safe under the conditions of its intended use." *Id.* § 321(s). For a substance in common use in food prior to January 1, 1958—this does not include DMAA—the adequate showing of safety can be made not only by scientific procedures but also by experience. There are other exceptions to this definition of "food additive," but none applies here.

The FDA asserts that DMAA is not a dietary supplement, is not generally recognized as safe, does not meet any other exception, and is therefore a food additive. Hi-Tech insists that DMAA is a dietary supplement and thus is not a food additive, but that even if DMAA is not a dietary supplement, DMAA is generally recognized as safe and thus still is not a food additive.

The issues thus are first, whether Hi-Tech's DMAA products are "an herb or other botanical" or "a concentrate, metabolite, constituent, extract, or combination of" an herb or other botanical, and second, if not, whether the products are generally recognized as safe. Secondary issues are whether the FDA was entitled to seize and forfeit the products without engaging in rulemaking and whether the district court should have reopened discovery.

IV. DMAA

The earliest known identification or use of DMAA occurred in 1944. In that year Eli Lilly & Co. synthesized and patented DMAA for use as a nasal decongestant. For marketing reasons, Eli Lilly asked the FDA to withdraw its approval of this use in 1983. At least insofar as shown by this record, DMAA was not used as a dietary supplement or food additive at that time, and no health concerns had been noted.

DMAA eventually made a resurgence, this time in fitness products aimed at bodybuilders and other athletes. Because of DMAA's noticeable stimulant effect, the compound made its way into pre-workout energy and fat-burner products around the world.

The FDA eventually adopted the position that DMAA is not a dietary supplement but an unsafe food additive. The FDA issued cease-and-desist letters to at least some entities marketing DMAA products. Perhaps unaware of Hi-Tech's marketing of DMAA products, the FDA did not issue a cease-and-desist letter to Hi-Tech.

Around the same time, researchers began to find trace amounts of DMAA in geraniums of the genus pelargonium. A 2013 survey concluded that overall, the studies showed that DMAA "is found naturally in some, but not all, geranium plants and extracted geranium oils." Thomas D. Gauthier, Evidence for the Presence of 1,3-Dimethylamylamine (1,3-DMAA) in Geranium Plant Materials, 8 Analytical Chemistry Insights 29-40

(2013), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3682735/. Indeed, the FDA's own expert had previously participated in a study that found trace amounts of DMAA in geraniums.

Even so, this record presents a genuine factual dispute over whether trace amounts of DMAA are naturally contained in geraniums. On the one hand, studies have found trace amounts of DMAA in geraniums. On the other hand, some fertilizers contain DMAA that could be a source of trace amounts of DMAA in geraniums, and the record includes competent testimony that there is no known pathway by which geraniums could produce DMAA. Either way, it is clear that DMAA is not contained in geraniums in amounts greater than could reasonably be characterized as trace amounts. No study has found a greater amount.

V. "Herb or Other Botanical"

The first rule of statutory construction is to apply the plain meaning of the statutory language. *See, e.g., Bankston v. Then*, 615 F.3d 1364, 1367 (11th Cir. 2010). Here the meaning is not completely clear.

Hi-Tech says DSHEA uses "botanical" to mean all plant life, nothing more and nothing less—that is, to mean flora, without limitation. The suggestion is sensible enough—"botany" is the study of plants. On the other hand, it would be passing strange for a writer wishing to cover the universe of plant life—to mean all flora—to achieve that result through the term "herb or other

botanical." Moreover, the usual connotation of "botanical" when used as a noun, as recognized in dictionaries in use when DSHEA was enacted as well as those is use today, is a substance derived from a plant used for a limited category of purposes.

In 1993, a year before DSHEA became law, Merriam-Webster's defined the noun "botanical" as a "a plant part or extract used esp[ecially] in skin and hair care products." "Botanical," Merriam-Webster's Collegiate Dictionary 134 (10th ed. 1993). The current edition defines the noun "botanical" as a "substance obtained or derived from a plant[,] such as . . . a plant part or extract used especially in skin and hair care products[,] a medicinal preparation derived from a plant[, or] plant material used as a flavoring agent." "Botanical," Merriam-Webster's Online Dictionary 2019, available at https://www.merriamwebster.com/dictionary/botanical. Neither definition suggests that the noun "botanical" includes an artificially produced substance that, entirely coincidentally, may be found in trace amounts in a plant. Nor do they suggest that "botanical" includes all flora.

Both the Supreme Court and the Eleventh Circuit have relied on Merriam-Webster's as an aid in construing statutes. *See, e.g., Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 572 U.S. 545, 553 (2014); *Burlington N. & Santa Fe Ry. Co. v. United States*, 556 U.S. 599, 611 (2009); *United States v. Zuniga-Arteaga*, 681 F.3d 1220, 1224 (11th Cir. 2012); *Arriaga v. Fla. Pac. Farms, LLC*, 305 F.3d 1228, 1242 (11th Cir. 2002). This does not make these cited definitions of "botanical" dispositive; dictionaries are

not controlling and in any event give examples to convey a term's most common uses, not necessarily to suggest limits. But the narrower connotation suggested by the dictionaries is consistent with DSHEA's use of the term "herb or other botanical" rather than a broader term plainly encompassing all plant life.

To be sure, the difference between Hi-Tech's broad view—all flora—and the narrower dictionary definitions is not as stark as might appear at first blush. That a substance derived from a plant is used in a dietary product brings it close to the current dictionary definition, which includes a medicinal preparation derived from a plant.

Still, the use of "herb or other botanical" in the statute, together with the dictionary definitions of a botanical as "derived from a plant," supports a much narrower construction than Hi-Tech proposes. Had Congress meant all plants and anything contained in them, it could have said so. It did not. At the least, the com/dictionary/botanical. Neither definition suggests that the statutory language and dictionary definitions support a conclusion that would be reasonable anyway: it is unlikely that Congress used the term "herb or other botanical" to mean a substance invented in a laboratory and artificially produced, that can be found in a plant only in trace amounts, only coincidentally, and that has never been derived from a plant for use in any medicinal, cosmetic, or dietary product.

VI. "Constituent"

The statutory definition of a dietary supplement extends not only to an "herb or other botanical" but also to "a concentrate, metabolite, constituent, extract, or combination of" an herb or other botanical. 21 U.S.C. § 321(ff)(1)(F). Hi-Tech asserts "constituent" means anything naturally contained in. The word could be given that meaning, but the connotation is usually not so broad. Indeed, both the 1993 edition and the current edition of Merriam-Webster's define "constituent" as "an essential part." "Constituent," Merriam-Webster's Collegiate Dictionary 248 (10th ed. 1993); "Constituent," Merriam-Webster Online Dictionary 2019, *available at* https://www.merriam-webster.com/dictionary/constituent. This definition suggests a connotation much narrower than proposed by Hi-Tech and too narrow to include the DMAA—if there is any—contained in geraniums.

For its part, the FDA says Hi-Tech's proposed definition of "constituent" would render superfluous the statute's inclusion of the word "extract." The FDA says the meaning of "constituent" must be informed by the other words in the statutory list, under the canon *noscitur a sociis*. *See In re Piazza*, 719 F.3d 1253, 1263 n.4 (11th Cir. 2013) (discussing this canon); Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* ("*Reading Law*") 195-98 (2012) (same). The "most common effect of the canon is not to establish which of two totally different meanings applies but rather to limit a general term to a subset of all the things or actions that it covers—but only according to its ordinary meaning." *Reading Law* at 196.

A concentrate or extract of a product is derived from the product in usable form or amount. So is a combination of the product with another substance. A metabolite, too, is physically derived from a product. If, as Hi-Tech asserts, constituent means anything contained in, the word is both markedly different from the others in the list and awkwardly placed—the broadest term in a five-item list but placed not first or last but in the center.

None of this is dispositive. The safest conclusion is this: it is unlikely that Congress used the term "constituent" to mean a substance that is present in a plant in only trace amounts and that has never been derived from a plant for use in any medicinal, cosmetic, or dietary product.

VII. The Reason for the Statutory Presumption

As set out above, DSHEA gives a preference to dietary supplements. The FDA can condemn a dietary supplement as adulterated only on a showing that it presents a "significant or unreasonable risk of illness or injury" under recommended, suggested, or ordinary conditions of use. 21 U.S.C. § 342(f)(1)(A). This is, in effect, a rebuttable presumption that the product is safe when used as intended.

A principal reason for rebuttable presumptions, whether in statutes or other legal constructs, is administrative convenience. When a proposition is usually true, it sometimes makes sense to presume it is true, subject only to rebuttal in the occasional instance when it is not true. Perhaps more importantly, at least in the regulatory context, a presumption can avoid unnecessary

expense and delay—a person or entity can go forward with proposed action without awaiting regulatory approval. This approach works best when a proposition is usually true and when the rebuttable presumption is clear and easily applied—otherwise the unnecessary expense and delay is not likely to be avoided.

DSHEA well illustrates this approach. Congress thought it better to have a clear, administrable rule—dietary supplements are presumed safe, subject only to a contrary showing—than to require a particularized inquiry in every case. *See* S. Rep. No. 103-410, at 21-22 (1994). A fair inference is that herbs and other botanicals and their constituents made the list of favored dietary ingredients because consuming them is ordinarily safe.

Consuming most herbs or other botanicals, though surely not all, is safe. The same is true even for most plants, and people have been consuming plants for as long as there have been people. Congress reasonably could choose to treat any product derived from a plant as adulterated only on a showing that it is unsafe. A rebuttable presumption for anything derived from a plant would serve administrative convenience and avoid delay in introducing a product to the market.

It is a stretch, though, to apply the same reasoning to a substance invented in a laboratory and artificially produced, that can be found in a plant, if at all, only in trace amounts, only coincidentally, and that has never been derived from a plant for use in any medicinal, cosmetic, or dietary product. The fact that DMAA can be found

in trace amounts in geraniums, if true, says absolutely nothing about whether consuming the substance is safe.

Nor does applying a rebuttable presumption to a substance of this kind serve administrative convenience. It is easy enough to identify plants or substances actually derived from plants. But as this case illustrates, it is not always easy to determine whether a product invented in a laboratory and artificially manufactured can be found in trace amounts in some plant somewhere in the world.

There is no reason to believe that when it adopted DSHEA, Congress intended to put in place a rebuttable presumption that such a product is safe. We hold that DSHEA does not go that far.

This does not mean that DSHEA applies only to products actually derived from plants, not those artificially manufactured. If a product is indeed a dietary supplement because it contains a qualifying dietary ingredient—including, for example, an herb or other botanical—a manufacturer may take the dietary ingredient from nature or produce it artificially. But there must be a qualifying dietary ingredient. The ability to create a substance in a laboratory and manufacture it artificially does not give a substance that status. Nor does coincidentally identifying the substance in trace amounts in some plant somewhere in the world.

VIII. Generally Recognized as Safe

Hi-Tech says DMAA is generally recognized as safe—or, to quote the statute's more exacting standard, DMAA is "generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures . . . to be safe under the conditions of its intended use." 21 U.S.C. § 321(s). The FDA's rule on this concludes that a substance meets this standard only when, based on "common knowledge throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food," there is "reasonable certainty that the substance is not harmful under the conditions of its intended use." 21 C.F.R. § 170.30(a).

As the statutory requirement for general recognition makes clear, the issue is not whether, as an original matter, the factfinder in a legal proceeding would evaluate the evidence and conclude that a substance is safe. The issue is only whether the substance is *generally recognized* as safe among qualified experts based on adequate studies. To establish the contrary, the FDA "need only show the lack of the proper reputation . . . for safety of the [substance] among the appropriate experts, or that what reputation there is, is not based on adequate studies." *United States v. Articles of Food & Drug Consisting of Coli-Trol 80, F4C-60 Feed Grade, Entrol-S Medicated, Entrol-P*, 518 F.2d 743, 746 (5th Cir. 1975). As a pre-*Bonner* decision of the Fifth Circuit, *Coli-Trol* remains binding in this court. *See Bonner v. City of Prichard*, 661 F.2d 1206, 1207 (11th Cir. 1981) (en banc). Other circuits, too, have enforced the

requirement for general recognition. *See United States v. Article of Food*, 752 F.2d 11, 15 n.4 (1st Cir. 1985); *Premo Pharmaceutical Labs., Inc. v. United States*, 629 F.2d 795, 803-05 (2d Cir. 1980).

The FDA made the required showing. Multiple sources, including in peer-reviewed publications, call into question DMAA's safety. Among their conclusions: DMAA may cause increases in blood pressure and hemorrhagic stroke; individuals with blood pressure of 120/80 mmHg or higher (much of the American population) should avoid DMAA; use of DMAA has been associated with multiple adverse events, including deaths; and DMAA may inhibit activity of liver enzymes and cause liver toxicity.

After four soldiers died with DMAA in their systems, the Department of Defense removed all DMAA products from military exchanges and commissioned a Safety Review Panel. The Panel issued a report finding that "deaths, hepatic failure, myocardial infarction, heat stroke and rhabdomyolysis, seizure and stroke" were temporally associated with service members' "use of [DMAA-containing] products." U.S. Dep't of Def., Report of the Department of Defense 1,3 Dimethylamylamine (DMAA) Safety Review Panel 9 (2013). The report said this suggested that some individuals "may be predisposed to severe health consequences after using DMAA." *Id.* The report said there appeared to be "significant association of DMAA use, particularly high frequency DMAA use, and multiple adverse events." *Id.* And the report concluded that "the available evidence supports an elevated health risk associated with the use of DMAA-containing products."

Id. The Department continued its ban on DMAA products at military exchanges. *Id*. at 10-11.

With this track record, it is hardly surprising that the FDA's expert in food chemical risk management determined that DMAA is not generally recognized as safe by qualified experts.

Hi-Tech asserts, though, that the studies and reports on which the FDA relies involve DMAA use in doses greater than Hi-Tech recommends. Hi-Tech says that use of DMAA as intended does not present the same risks. Hi-Tech cites studies and presents expert testimony concluding that DMAA is safe at the recommended doses.

Hi-Tech's submissions are far from conclusive. The studies use small sample sizes and look at short-term results. None measure the effect of DMAA in high-risk populations or on individuals with elevated blood pressure. And while some but not all of the FDA's cited studies involve high doses of DMAA, it seems unlikely that all the adverse events suffered by military personnel and others resulted from abnormal or unintended use. Correlation is not causation, but neither must correlation be ignored.

If the issue was whether DMAA is safe, Hi-Tech's evidence would create a genuine issue of fact precluding summary judgment; neither side's evidence is conclusive. *See Sparling v. Doyle*, No. EP-13-CV-323-DCG, 2015 WL 4528759 at *20 (W.D. Tex. July 27, 2015) ("It 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."). But the issue is not whether DMAA is safe; the issue is only whether DMAA is *generally recognized* as safe. It plainly is not. On the issue of general recognition, the FDA was entitled to summary judgment.

IX. The Motion to Reopen Discovery

The district court provided ample time for discovery—the full amount the parties requested. The parties submitted cross-motions for summary judgment without asking for more time or asserting that any further discovery was needed. But after the court granted summary judgment for the FDA, Hi-Tech moved to reconsider, taking issue with the court's legal analysis and asserting the court should reopen discovery. Hi-Tech said it needed more discovery because the court's legal analysis did not match up with the position argued by either side.

Ours is an adversary system. When, as here, there are two sides, each side is afforded the opportunity to argue its position. But the court is not limited to choosing one side's position or the other's. The court's role is to get it right, not to choose which side's argument is better and adopt it lock, stock, and barrel. *See, e.g., United States v. Baston*, 818 F.3d 651, 663 (11th Cir. 2016) (concluding that on a disputed legal issue, "[n]either party is correct," and applying the correct standard that neither party advocated); *see also Colburn v. Odom*, 911 F.3d 1110 (11th Cir. 2018) (resolving an appeal on a ground not addressed in either side's brief but essential to proper resolution of the dispute). Were it otherwise, there would be no plain-error doctrine.

Thousands of cases could be cited illustrating this principle. Indeed, the principle is so well settled that it is rarely mentioned. When a court adopts a view of the law that is not precisely in line with either side's argument, the court usually sets out its view of the law without citing authority for the proposition that it may do so. The Supreme Court has explained it this way: "[w]hen an issue or claim is properly before the court, the court is not limited to the particular legal theories advanced by the parties, but rather retains the independent power to identify and apply the proper construction of governing law." *U.S. Nat'l Bk. of Oregon v. Independent Ins. Agents of Am., Inc.*, 508 U.S. 439, 446 (1993) (quoting *Kamen v. Kemper Fin. Servs., Inc.*, 500 U.S. 90, 99 (1991)).

Hi-Tech is correct that the district court did not simply accept either side's view of the facts and law. Nor should the court have done so; neither side had it just right. Similarly, on appeal, we have not simply chosen one side's view or the other's; we have considered the arguments and provided the analysis we believe is correct. One would expect nothing less.

Hi-Tech says, though, that it was blindsided when the district court emphasized that DMAA has never actually been derived from geraniums for use in any product. Hi-Tech says it needs more discovery to fully present its position on this issue—to attempt to find evidence that DMAA has in fact been derived from geraniums.

The assertion misses the mark for two reasons, either of which would be sufficient standing alone.

First, Hi-Tech could not have been surprised that the court considered whether DMAA has actually been derived from geraniums. The question leaps off the page at anyone first considering the issues in this case. Hi-Tech asserts it does not matter whether DMAA has actually been derived from geraniums—a colorable position—but Hi-Tech could not have missed the possibility that a court would disagree.

Second, regardless of whether Hi-Tech recognized or should have recognized that a court might find actual derivation critical, Hi-Tech had every incentive to fully develop the facts on this during the original discovery period. An intensely disputed issue was whether DMAA was contained in geraniums. Hi-Tech said yes; the FDA said no. The best support Hi-Tech could have garnered for its position on this issue—as Hi-Tech surely knew—was evidence that DMAA had actually been derived from geraniums. The reason one can't get blood from a turnip is that there is no blood in a turnip. The reason one *can* get juice from an orange is that oranges are full of juice. The reason Hi-Tech found no evidence during the original discovery period that DMAA had actually been derived from geraniums was not because Hi-Tech didn't know to look; it was because no such evidence existed. Or perhaps because, despite every incentive to do so, Hi-Tech couldn't find it in the ample time it requested—and the court provided—for discovery. Hi-Tech is not entitled to more time.

The district court did not abuse its discretion when it declined to reopen discovery.

X. The Absence of Rulemaking

Hi-Tech faults the FDA for bringing a forfeiture action rather than proceeding through rulemaking. But it is "well established" that "agencies have discretion to choose whether to proceed by rulemaking or adjudication." *RTC Transp. Inc. v. ICC*, 731 F.2d 1502, 1505 (11th Cir. 1984). Not surprisingly, then, we have upheld a forfeiture judgment in favor of the FDA against a food additive without requiring rulemaking. *See United States v. Articles of Food & Drug Consisting of Coli-Trol 80, F4C-60 Feed Grade, Entrol-S Medicated, Entrol-P*, 518 F.2d 743, 746 (5th Cir. 1975); *see also United States v. Article of Food*, 752 F.2d 11, 15-16 (1st Cir. 1985). The FDA was not required to engage in rulemaking but could elect instead to proceed through a forfeiture action against Hi-Tech's DMAA products.

Proceeding in this manner did not violate the Constitution. The governing statute provides notice that unapproved food additives are subject to forfeiture. 21 U.S.C. § 334(a)(1). The statute is not unconstitutionally vague, and Hi-Tech doesn't claim it is. As part of the forfeiture proceeding, Hi-Tech was afforded the full range of procedural due process available in a federal court. The issues were joined and fully adjudicated on the merits. Due process requires nothing more.

XI. Conclusion

DMAA is not an "herb or other botanical." It is not a "constituent" of an herb or other botanical. And it is not

generally recognized by qualified experts, as adequately shown through scientific procedures, to be safe under the conditions of its intended use. The district court properly so ruled. The decision is

AFFIRMED.

Appendix A

JORDAN, Circuit Judge, concurring in part and dissenting in part.

This is a difficult case, and in my opinion there is no "right" or "wrong" answer to the principal statutory question we confront. The majority opinion sets out one plausible interpretation of 21 U.S.C. § 321(ff)(1)(C) & (F), but I read the statute differently. So, although I join Parts I–IV and VIII–X of the majority opinion, I respectfully dissent from Parts V–VII.

* * * * *

As relevant here, § 321(ff)(1)(C) & (F) provides that a product is a "dietary ingredient"—and therefore can be marketed without FDA pre-approval—if it contains "an herb or other botanical" or a "concentrate, metabolite, constituent, extract, or combination of any ingredient" in an "herb or other botanical." Hi-Tech contends that DMAA satisfies these definitions because it is a "constituent" of a geranium plant and therefore a "constituent" of a "botanical." *See* Br. for Appellant at 8. So we need to figure out what the words "herb," "botanical," and "constituent" mean.

The principal dictionary definition for the word "herb" concerns its status as flora: a plant whose stem is not woody and persistent, and which generally dies at the end of its flowering or growing season. *See* The American Heritage Dictionary of the English Language 820 (4th ed. 2009); Webster's Third New International Dictionary of the English Language Unabridged 1058 (2002); 1 Shorter

Oxford English Dictionary 1228 (5th ed. 2002). It is also, but secondarily, defined as a part of a plant that is useful for food or medicine. *See id.* ("A . . . plant used for flavoring or scent, in medicine, etc.").

Some dictionary definitions of the noun "botanical" refer to a drug, medicinal preparation, or similar substance obtained or derived from a plant or several plants. *See* The American Heritage Dictionary of the English Language 215 (4th ed. 2009); The Random House College Dictionary 157–58 (1973). Some even refer to the drug or preparation as crude, or maintaining the ingredient more or less in its natural state. *See* Webster's Third New International Dictionary of the English Language Unabridged 258 (2002); McGraw-Hill Dictionary of Scientific and Technical Terms 272 (6th ed. 2003). But as the FDA concedes, see Br. for Appellee at 16, "botanical" also is defined as the plant (or part of the plant) itself. *See, e.g.,* Merriam-Webster's Collegiate Dictionary 134 (10th ed. 1994) ("a plant part or extract used sp. in skin and hair care products"); The American Heritage Dictionary of the English Language 298 (3d ed. 1993) ("of or relating to plants or plant life").

The statute uses "other botanical" in conjunction with "herb." It therefore seems to me that the word "botanical" contextually refers to a plant or part of a plant, and not a drug or medicinal preparation derived from a plant. *See generally Dole v. United Steelworkers of America*, 494 U.S. 26, 36 (1990) (explaining that "words grouped in a list should be given related meaning") (internal quotation marks and citation omitted). And a geranium is certainly a plant.

That leaves the word "constituent." It means a component or element of a whole, and—significantly—not all dictionaries require the component or element to

be "essential." *See, e.g.*, 1 Shorter Oxford English Dictionary 496 (5th ed. 2002) ("an element of a complex whole"); The American Heritage Dictionary of the English Language 394 (4th ed. 2009) ("[s]erving as part of a whole; component"); Webster's Third New International Dictionary of the English Language Unabridged 258 (2002) ("a thing, person, or organism that along with others serves in making up a complete whole or unit").

As the majority acknowledges, there is evidence that geraniums contain a trace amount of DMAA. *See* Maj. Op. at 7–8. There is also evidence, however, that some fertilizers contain DMAA—which could be the source of trace amounts in geraniums—and that geraniums have no known pathways of producing DMAA. *Id.* Viewing the record in the light most favorable to Hi-Tech, there is a genuine issue of material fact as to whether DMAA—even in trace amounts—is a "constituent" (i.e., a component or element) of geraniums.

* * * * *

In my view, the statutory text does not provide a basis for the district court's conclusion that a "constituent" of a "botanical" must have a history of being extracted in usable quantities, or for the majority's holding that to be a "constituent" an ingredient must have been derived from a plant for use in a medicinal, cosmetic, or dietary

product. Indeed, reading "constituent" to mean something that has been taken out of a plant in usable amounts may make "extract"—another statutory term—surplusage.

The statute lists "constituent" among several other words: "a concentrate, metabolite, constituent, extract, or combination thereof." § 321(ff)(1)(F). When Congress uses "or" to separate several words in a list, that term's "ordinary use is almost always disjunctive, that is, the words it connects are to be given separate meanings." *Loughrin v. United States,* 573 U.S. 351, 357 (2014). As a noun, the term "extract" means "something extracted . . . a preparation obtained by evaporation (as of a solution of a drug or the juice of a plant)." Webster's Third New International Dictionary of the English Language Unabridged 806 (2002). Again, "constituent" is broadly defined as a part of something else, and ascribing a more narrow definition would eliminate any independent meaning Congress intended by using "extract." *See Yates v. United States*, 135 S. Ct. 1074, 1085 (2015) (explaining that courts should "avoid ascribing to one word a meaning so broad that it is inconsistent with its accompanying words") (internal quotation omitted).

The majority's contrary interpretation of § 321(ff)(1)(C) & (F) seems influenced by policy reasons which call for a narrower reading of the statutory text. *See* Maj. Op. at 13–14. I do not challenge those reasons, but believe they are not ours to consider. See *Sturges v. Crowninshield*, 17 U.S. 122, 202 (1819) (we should not "infer from extrinsic circumstances, that a case for which the words of an instrument expressly provide, shall be exempted from

its operation"). Although the statutory reading advocated by Hi-Tech is expansive, that reading squares with the broad language Congress chose. As the Supreme Court has told us, "the fact that a statute can be applied in situations not expressly anticipated by Congress does not demonstrate ambiguity. It demonstrates breadth." *Pa. Dept. of Corrections v. Yeskey*, 524 U.S. 206, 212 (1998) (internal quotation marks and citation omitted).

* * * * *

As I read the statute and the record, the FDA was not entitled to summary judgment. I would remand for a trial on whether DMAA is a "constituent" of geraniums.

APPENDIX B — ORDER DENYING RECONSIDERATION IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF GEORGIA, ATLANTA DIVISION, FILED JUNE 2, 2017

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

CIVIL ACTION NO. 1:13-CV-3675-WBH

June 2, 2017, Decided
June 2, 2017, Filed

UNITED STATES OF AMERICA,

Plaintiff,

v.

QUANTITIES OF FINISHED
AND IN-PROCESS FOODS, *et al.,*

Defendants.

ORDER

On April 3, 2017, this Court entered an order granting the Government's motion for summary judgment and directing the Clerk to enter judgment in the Government's favor. [Doc. 140]. Hi-Tech Pharmaceuticals, Inc., and its CEO (collectively Hi-Tech) have now filed a motion for reconsideration. [Doc. 142].

Appendix B

In its motion, Hi-Tech first argues that this Court improperly "encroached on the policy making prerogative of Congress," [Id. at 14], by determining that in using the term "botanical" in 21 U.S.C. § 321(ff), "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." [Doc. 140 at 9]. This Court disagrees. As noted in the order, there is nothing in the statutory scheme, the legislative history, or the case law that provides even the slightest guidance of congressional intent regarding the use of "botanical." Accordingly, this Court turned to the standard canons of statutory construction to determine what Congress meant by first looking at the term's ordinary meaning. Under that meaning, a botanical — and by extension, a constituent of a botanical — is something that comes from a plant, and none of the DMAA ever placed in a product for sale has come from a plant. This Court thus concluded that DMAA is not a botanical, and whether or not the Government advocated that interpretation is of no moment.[1]

Hi-Tech's next argument is based on its incorrect interpretation of this Court's order. This Court did not conclude that DMAA was not a botanical because there is no evidence that DMAA can be extracted in a usable quantity. Rather, this Court held that, in order for a substance to be a botanical, there must be some *history* of its having been so extracted. As stated, the DMAA in the marketplace has never come from a plant.

1. In response to Hi-Tech's footnote 4, [Doc. 142 at 17-18 n.4], this Court did not state, or even suggest, that geraniums are an obscure plant.

As to Hi-Tech's argument that, until this Court issued the order, it did not know that "the ability to extract DMAA from geraniums in a 'usable quantity'" was in dispute, [Doc. 142 at 22], this Court again points out that the *ability* to extract usable quantities of DMAA from geraniums is not the issue. The question is whether someone has extracted DMAA from geraniums or some other plant and placed that DMAA in a product, and it is obvious from the record that no one has done that. If someone had, there would not have been a dispute regarding whether DMAA was a botanical in the first instance.

For the reasons discussed, Hi-Tech's motion for reconsideration, [Doc. 142], is **DENIED**, and its motion for a stay, [Doc. 143], is **DENIED** as moot.

IT IS SO ORDERED, this 2 day of June, 2017.

/s/ Willis B. Hunt, Jr.
WILLIS B. HUNT, JR.
UNITED STATES
DISTRICT JUDGE

APPENDIX C — ORDER OF THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF GEORGIA, ATLANTA DIVISION, FILED APRIL 3, 2017

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

CIVIL ACTION NO. 1:13-CV-3675-WBH

April 3, 2017, Decided
April 3, 2017, Filed

UNITED STATES OF AMERICA,

Plaintiff,

v.

QUANTITIES OF FINISHED AND IN-PROCESS FOODS, et al.,

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. 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,

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.

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 is arbitrary and not entitled to deference under *Chevron, U.S.A., Inc. v. Nat. Resources Def. Council, Inc.*, 467 U.S. 837, 104 S. Ct. 2778, 81 L. Ed. 2d 694 (1984).

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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

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.oxforddictionaries.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 U.S. Dist. LEXIS 99962, 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 U.S. Dist. LEXIS 97204, 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 HiTech 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.

Appendix C

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.

/s/ Willis B. Hunt, Jr.
WILLIS B. HUNT, JR.
Judge, U. S. District Court

APPENDIX D — ORDER DENYING REHEARING IN THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT, FILED APRIL 8, 2020

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 17-13376-JJ

UNITED STATES OF AMERICA,

Plaintiff-Appellee,

versus

UNDETERMINED QUANTITIES OF ALL ARTICLES OF FINISHED AND IN-PROCESS FOODS, RAW INGREDIENTS (BULK POWDERS, BULK CAPSULES), WITH ANY LOT NUMBER, SIZE, OR TYPE CONTAINER, WHETHER LABELED OR UNLABELED, *et al.*,

Defendants,

HI-TECH PHARMACEUTICALS, INC.,
JARED WHEAT,

Claimants-Appellants.

Appeal from the United States District Court
for the Northern District of Georgia

Appendix D

ON PETITION(S) FOR REHEARING AND PETITION(S) FOR REHEARING EN BANC

BEFORE: JORDAN and TJOFLAT, Circuit Judges, and HINKLE,* District Judge.

PER CURIAM:

The Petition for Rehearing En Banc is DENIED, no judge in regular active service on the Court having requested that the Court be polled on rehearing en banc. (FRAP 35) The Petition for Rehearing En Banc is also treated as a Petition for Rehearing before the panel and is DENIED. (FRAP 35, IOP2)

*Honorable Robert L. Hinkle, United States District Judge for the Northern District of Florida, sitting by designation.

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