[PUBLISH]

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)

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.

* 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.merriam-webster.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

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.

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).

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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.