Case No. 20-10677

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

URI MARRACHE,
Plaintiff-Appellant,

v.

BACARDI U.S.A., Inc., et al.,
Defendant-Appellee.

On Appeal from the United States District Court
for the Southern District of Florida
Case No. 1:19-cv-23856-RNS

BRIEF OF *AMICI CURIAE* CENTER FOR FOOD SAFETY, CENTER FOR SCIENCE IN THE PUBLIC INTEREST, CLEAN AND HEALTHY NEW YORK, ENVIRONMENTAL DEFENSE FUND, AND ENVIRONMENTAL HEALTH STRATEGY CENTER IN SUPPORT OF NEITHER PARTY

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CORPORATE DISCLOSURE STATEMENT AND CERTIFICATE OF INTERESTED PERSONS

Pursuant to Fed. R. App. P. 26.1 and Fed. R. App. P. 29(a)(4)(A), *Amici Curiae* Center for Food Safety, Center for Science in the Public Interest, Clean and Healthy New York, Environmental Defense Fund, and Environmental Health Strategy Center each certify that they have no parent corporation and no publicly held corporation owns more than 10% of their stock. In addition, pursuant to Eleventh Circuit Rule 29-2, *amici* certify that the following persons, associations of persons, or corporations may have an interest in the outcome of this case:

1. Andiman, Alexis; counsel for *amici curiae*;
2. Apfel, Carrie; counsel for *amicus curiae*;
3. Center for Food Safety, *amicus curiae*;
4. Center for Science in the Public Interest, *amicus curiae*;
5. Clean and Healthy New York, *amicus curiae*;
6. Earthjustice, law firm for *amicus curiae*;
7. Environmental Defense Fund, *amicus curiae*;
8. Environmental Health Strategy Center, *amicus curiae*;
9. Gartner, Eve; counsel for *amicus curiae*;
10. Gregor, Ashley; counsel for *amicus curiae*;
11. Lehner, Peter; counsel for *amicus curiae*;
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INTERESTS OF *AMICI CURIAE*[1]

Amici are nonprofit, nonpartisan public-interest organizations that advocate for a safe and healthy food system. Collectively, *amici* represent over one million people nationwide. Together with their members and supporters, *amici* have a strong interest in preserving states' authority to enact laws and regulations that reduce exposures to unsafe chemical substances in food.

Amicus **Center for Food Safety ("CFS")** works to protect human health and the environment by curbing the use of harmful food production technologies and promoting sustainable agriculture. Among other projects, CFS focuses on reducing industry influence over the federal government's food additives approval process. CFS has 970,000 members across the country.

Amicus **Center for Science in the Public Interest ("CSPI")** is a leading independent, science-based consumer advocacy organization. On behalf of its 450,000 members, CSPI pursues a clear and ambitious agenda for improving the food system to support healthy eating. As part of this agenda, CSPI works to reform the federal government's flawed food ingredient approval process.

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[1] All parties have consented to the filing of this brief. No party's counsel authored any part of the brief. Neither did any party, any party's counsel, or any person other than *amici* and *amici*'s counsel contribute money intended to fund the preparation of this brief.

Amicus **Clean and Healthy New York ("CHNY")** works to get toxic chemicals out of daily life, by changing laws, shifting the marketplace, and helping people make changes in their homes, businesses, and childcare settings. CHNY recently completed a decade-long campaign culminating in the adoption of New York State's Child Safe Products Act, which requires manufacturers to disclose chemicals of concern in children's products and phases out some of the most toxic chemicals, such as benzene and asbestos. CHNY helps to ensure a safe and healthy food system by advocating for and overseeing the implementation of state policies restricting the use of hazardous chemicals in food and food packaging.

Amicus **Environmental Defense Fund ("EDF")** tackles urgent threats with practical solutions, guided by science and economics. EDF's Health Program works to protect American families—including EDF's 463,000 members across the United States—by reducing exposures to hazardous chemicals hidden in food and other everyday items. EDF employs attorneys and scientists with significant experience identifying shortcomings in the federal government's oversight of chemicals added to our food.

Amicus **Environmental Health Strategy Center ("EHSC")**—based in Portland, Maine—works to create a world where all people are healthy and thriving, with equal access to safe food and drinking water, and products that are toxic-free and climate-friendly. EHSC has a strong interest in protecting states'

authority to adopt laws and regulations that are more protective than federal standards governing substances used in food. Among other projects, EHSC has developed policies and led legislative campaigns to ensure that food-contact materials are free from hormone-disrupting chemicals.

STATEMENT OF THE ISSUE[2]

Do the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. §§ 301–399i, and a regulation published by the U.S. Food and Drug Administration ("FDA"), which lists "grains of paradise" among spices, natural seasonings, and flavorings that are "generally recognized as safe," *see* 21 C.F.R. § 182.10, preempt a Florida statute providing for the punishment of any person who "adulterates, for the purpose of sale, any liquor, used or intended for drink, with . . . grains of paradise . . . or any other substance which is poisonous or injurious to health," Fla. Stat. § 562.455?

INTRODUCTION AND SUMMARY OF ARGUMENT

Courts apply a strong presumption *against* preemption of state law by federal laws and regulations, especially with respect to matters within states'

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[2] On April 2, 2020, this Court issued a jurisdictional question, asking "whether the amended complaint, which limited the proposed class to Florida citizens who purchased Bombay Sapphire gin, divested the district court of subject matter jurisdiction." *Amici* take no position on this jurisdictional question. Neither do *amici* take any position on the plaintiff-appellant's claims alleging a violation of the Florida Deceptive and Unfair Trade Practices Act and unjust enrichment.

traditional authority. States enjoy broad authority to protect the health of people living within their borders, including by regulating the safety of food. In light of significant gaps in the federal government's approach to ensuring food safety, this authority remains vitally important today.

Thousands of chemical substances currently used in food have *never* been analyzed for safety by FDA. Others have not been reexamined for decades, even as new scientific information and new methods for evaluating safety have become available. Manufacturers use many of these substances pursuant to a narrow exception in the FFDCA, which FDA has converted into a loophole allowing manufacturers to determine the safety of substances they wish to use in food—and add those substances to food—*in secret*, without notice to FDA or the public.

The district court erred in determining that the FFDCA and FDA's implementing regulations preempt Florida's prohibition on the use of grains of paradise in alcohol. A decision affirming this preemption finding would run counter to binding legal precedent and severely limit states' authority to adopt protective food safety standards. Whether Florida's law, enacted in 1868, continues to offer meaningful public health protection—or any other benefit—is a question best left to the people and legislature of Florida; it does not bear on preemption. For the reasons set forth below, this Court must find that neither the FFDCA nor FDA's regulations preempt Florida's law. And, even if this Court

determines that the FFDCA and FDA's regulations may in some cases preempt more protective state laws governing food safety, which they cannot, *amici* urge the Court to clarify that preemptive effect does not extend to secret and potentially flawed "safety" determinations made by manufacturers.[3]

LEGAL FRAMEWORK

The federal government and state governments share an interest in ensuring the safety of food. Although the FFDCA and FDA's regulations govern the safety of substances used in food, they leave open significant gaps. States have helped to fill these gaps by adopting more protective laws and regulations to preserve the health and safety of people living within their borders.

The Federal Food, Drug, and Cosmetic Act

The FFDCA directs FDA to "protect public health by ensuring that . . . foods are safe." 21 U.S.C. § 393(b)(2)(A). Faced with the increasing prevalence of potentially unsafe substances in food, Congress amended the Act in 1958 to

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[3] As this Court has recognized, "federal courts should avoid reaching constitutional questions," including federal preemption of state law, "if there are other grounds upon which a case can be decided." *BellSouth Telecomms., Inc. v. Town of Palm Beach*, 252 F.3d 1169, 1176 (11th Cir. 2001). The district court appeared to identify alternative grounds for dismissal, including the plaintiff-appellant's failure to state a claim under the Florida Deceptive and Unfair Trade Practices Act ("FDUTPA"). *See Marrache v. Bacardi U.S.A., Inc.*, 2020 WL 434928, *2–*3 (S.D. Fla. 2020); *see also* Fla. Stat. § 501.212(1) (stating that the FDUTPA "does not apply to . . . [a]n act or practice . . . specifically permitted by federal . . . law"). *Amici* take no position on the availability of alternative grounds for dismissal.

"prohibit the use in food of additives which have not been adequately tested to establish their safety." Food Additives Amendment of 1958, Pub. L. 85-929, 72 Stat. 1784, 1784. As amended, the FFDCA defines the phrase "food additive" broadly to include "indirect" additives that leach into food from packaging and other materials, as well as "direct" additives used to flavor, preserve, and otherwise enhance the characteristics of food. *See* 21 U.S.C. § 321(s). The FFDCA commands that *any* additive "shall . . . be deemed to be unsafe" unless it is used "in conformity with[] a regulation . . . prescribing the conditions under which such additive may be safely used." *Id*. § 348(a)(2).

The FFDCA establishes a rigorous process for the premarket review of *some* substances used in food. *See id*. § 348. But the FFDCA and FDA's implementing regulations have important gaps. *First*, as relevant here, the FFDCA allows substances to bypass review if they fall within an exception to the statutory definition of "food additive," applicable to any substance that is:

> generally recognized, among experts qualified by scientific training and experience to evaluate its safety, 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 under the conditions of its intended use.

Id. § 321(s). Because the substances that fall within this "generally recognized as safe" or "GRAS" exception must be safe *by definition*, Congress did not require them to undergo premarket safety review.

Although FDA has published regulations listing *some* GRAS substances, including grains of paradise, *see* 21 C.F.R. § 182.10 (identifying grains of paradise and other spices as GRAS), many other GRAS substances are not identified by regulation. For at least twenty-five years, FDA has allowed manufacturers to self-certify even newly-synthesized chemical substances as GRAS *in secret*, without any notice to FDA or the public. *See, e.g.*, *id*. § 170.205 ("Any person *may* notify FDA of a view that a substance" is GRAS) (emphasis added); Substances Generally Recognized as Safe, 81 Fed. Reg. 54,960, 55,043 (Aug. 17, 2016) (explaining that FDA has "establishe[d] a *voluntary* administrative procedure for notifying FDA" that a substance is GRAS) (emphasis added).[4] Experts estimate

[4] FDA published a proposed rule setting forth procedural and substantive requirements for identifying GRAS substances in 1997 and instructed manufacturers to comply with that proposed rule immediately. *See* Substances Generally Recognized as Safe, 62 Fed. Reg. 18,938, 18,954 (Apr. 17, 1997) (directing interested parties to comply with an "interim policy," which was essentially identical to FDA's proposed new policy, "[b]etween the time of publication of th[e] proposal and any final rule based on th[e] proposal"). FDA then delayed for nearly twenty years before issuing a final rule that effectively made permanent the interim policy. *See* 81 Fed. Reg. 54,960, 54,968–70 (summarizing distinctions between the proposed and final rule, none of which are significant). Because of this unusual history, even though FDA did not publish its most recent final rule governing GRAS substances until 2016, manufacturers have been self-certifying substances as GRAS without FDA oversight for at least twenty-five years. *Amici* CFS and EDF currently are challenging FDA's final rule in U.S. District Court for the Southern District of New York. *See Ctr. for Food Safety et al. v. Azar et al.*, 1-17-cv-03833-VSB (S.D.N.Y. filed May 22, 2017).

that manufacturers have exploited this loophole to self-certify approximately 3,000 substances as GRAS; at least 1,000 of these self-certifications occurred without any notice to FDA. *See* Pew Charitable Trusts, *Fixing the Oversight of Chemicals Added to Our Food* 5 (Nov. 2013), https://www.pewtrusts.org/en/research-and-analysis/reports/2013/11/07/fixing-the-oversight-of-chemicals-added-to-our-food (follow "Downloads: Food Additives Capstone Report" hyperlink) ("Pew Report"). FDA has admitted that it cannot vouch for the safety of GRAS substances "because companies are not required to . . . inform FDA of their GRAS determinations, and FDA officials cannot estimate the number of determinations that occur about which they are not notified." GAO, *FDA Should Strengthen Its Oversight of Food Ingredients Determined to Be Generally Recognized as Safe (GRAS)* 13 (2010), https://www.gao.gov/new.items/d10246.pdf ("GAO Report").

Second, the FFDCA does not expressly direct FDA to revisit past safety determinations for food additives or GRAS substances in light of emerging scientific evidence, and FDA routinely fails to do so. For example, the FFDCA prohibits the use of any food additive found to induce cancer in humans or animals. *See* 21 U.S.C. § 348(c)(3)(A). But FDA does not monitor credible scientific findings of carcinogenicity—even those made by the National Toxicology Program, FDA's sister agency at the U.S. Department of Health and Human Services—to determine whether those findings require FDA to rescind existing

approvals for food additives or GRAS substances *now* known to cause cancer. As a result, FDA fails to take prompt action to prevent manufacturers from continuing to use those carcinogenic substances in food. Recently, FDA partially granted a petition submitted by public-interest organizations, including several *amici*, urging the Agency to rescind approval for several carcinogenic flavors; FDA's decision, prompted by a lawsuit, came more than two years after its response to the petition was due and, for one flavor at issue, more than *three decades* after evidence of carcinogenicity. *See* Food Additive Regulations; Synthetic Flavoring Agents and Adjuvants, 83 Fed. Reg. 50,490-01 (Oct. 9, 2018). Experts estimate that "thousands of chemicals approved before 1980 have not been reassessed for safety." Pew Report at 10.

State Food Safety Laws

In connection with their traditional authority to protect public health, states long have "supervis[ed] the readying of foodstuffs for market." *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 144 (1963) ("*Florida Lime*"). Thus, for example, numerous states have enacted laws and regulations governing foods of particular local concern. Wisconsin and Michigan regulate smoked fish, Wis. Admin. Code ATCP § 70.46; Mich. Admin. Code r. 285.569.10; Alabama has set minimum nutritional requirements for grits, Ala. Code § 20-1-73; and Florida has adopted numerous provisions governing citrus fruits and juices. *See, e.g.*, Fla.

Admin. Code Ann. r. 20-52.001 (establishing minimum juice contents for grapefruits, according to size); *id*. r. 20-13.009(3)(a)(1) (providing that tangelos are mature only when "yellow color predominat[es] on not less than 50% of the fruit's surface in the aggregate"); *id*. r. 20-49.003(3) (prohibiting additives in certain citrus juices).

Given significant gaps in federal oversight of food safety—both historical and continuing—many states also have adopted laws and regulations that are more protective than federal standards governing the safety of food. For instance, Washington banned caffeinated alcoholic drinks after those drinks were linked to multiple deaths, but before FDA took any action.[5] *See* Wash. Admin. Code § 314-20-022. New York imposed limits on the use of sulfite preservatives, amid concerns that FDA's regulations did not go far enough to protect people with potentially deadly allergies. *Compare* N.Y. Agric. & Mkts. Law § 199-d (prohibiting retail and wholesale distributors from adding sulfiting agents to foods)

[5] Although FDA warned certain manufacturers that caffeinated alcoholic drinks pose a "public health concern," FDA has not prohibited these drinks, and they remain available in several states. Alexander Kacala, *Here's How to Get Pabst Blue Ribbon's 'Hard Coffee' Alcoholic Beverage with Caffeine*, Newsweek (July 5, 2019), https://www.newsweek.com/heres-how-get-pabst-blue-ribbons-hard-coffee-alcoholic-beverage-caffeine-1447861 (explaining that one alcoholic coffee drink "is currently available in Pennsylvania, Maine, New Jersey, Florida, and Georgia").

with, e.g., 21 C.F.R. § 182.3616 (declaring most uses of potassium bisulfite to be GRAS). Maryland has adopted a restriction on the presence of certain carcinogenic disinfectants in bottled water that is eight times *stricter* than FDA's regulatory limit. *Compare* Md. Code Ann., Health-Gen. § 21-336 (providing that bottled water may not exceed 10 parts per billion of total trihalomethanes) *with* 21 C.F.R. § 165.110 (limiting total trihalomethanes in bottled water to 0.08 milligrams per liter, or 80 parts per billion). Iowa and Washington prohibit the use of formaldehyde in food. *Compare* Iowa Code § 190.3e *and* Wash. Rev. Code § 69.40.020 *with* 21 C.F.R. § 173.340 (permitting the use of formaldehyde in "defoaming agents"). And Florida makes it a felony to adulterate liquor with "grains of paradise . . . or any other substance which is poisonous or injurious to health," or to sell liquor that has been adulterated in this way.[6] Fla. Stat. § 562.455. At least sixteen states have enacted laws authorizing the adoption of

[6] According to the *Miami Herald*, Florida's law—enacted in 1868—sought to punish unscrupulous distillers and salesmen, who took advantage of Civil War-era shortages to sell liquor adulterated with sulfuric acid, then known as "vitriol," and other dangerous substances. *See* David Ovalle, *Using a 150-Year-Old Law, Miami Lawyer Sues over a Once Notorious Spice in a Popular Gin*, Miami Herald (Sept. 30, 2019), https://www.miamiherald.com/news/business/article235474017.html. Historically, distillers relied on spices, including grains of paradise, to mask the flavor of adulterated liquor. *Id*. *Amici* have no reason to suppose that manufacturers currently use grains of paradise for nefarious purposes.

regulations that are more protective than federal standards governing substances in food.[7]

ARGUMENT

I. The FFDCA and FDA's GRAS Regulation Governing Grains of Paradise Do Not Preempt Florida's Law.

Courts recognize three circumstances in which federal law may preempt state law, none of which are present here. *See Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992). *First*, Congress may *expressly* preempt state law by stating its intent to preempt in the text of the statute. *Id*. *Second*, Congress may impliedly preempt state law by enacting a federal statute that "so thoroughly occupies a legislative field as to make reasonable the inference that Congress left no room for the States to supplement it." *Id*. (internal quotation marks and citation omitted). And *third*, Congress may impliedly preempt state law "[w]here state law is in

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[7] *See* Fla. Stat. § 500.13(2) (authorizing the Florida Department of Agriculture and Consumer Services "to adopt, amend, or repeal regulations *whether or not in accordance with regulations promulgated under the* [*FFDCA*], prescribing therein tolerances for any added poisonous or deleterious substances, for food additives," and for other substances used in or on food) (emphasis added); *see also* Cal. Health & Safety Code § 110085; Colo. Rev. Stat. Ann. § 25-5-413; Haw. Rev. Stat. Ann. § 328-21; 410 Ill. Comp. Stat. Ann. 620/13; Ind. Code Ann. § 16-42-2-5; Kan. Stat. Ann. § 65-663; Md. Code Ann., Health-Gen. § 21-239; Mich. Comp. Laws Ann. § 289.7112; Mont. Code Ann. § 50-31-108; N.H. Rev. Stat. Ann. § 146:21; N.D. Cent. Code Ann. § 19-02.1-12; S.C. Code Ann. § 39-25-130; Tex. Health & Safety Code Ann. § 431.244; Utah Code Ann. § 4-5-104; Va. Code Ann. § 3.2-5121.

actual conflict with federal law . . . or where it stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Id*. at 545 (internal quotation marks and citation omitted).

In each of these circumstances, courts are "guided by two cornerstones of pre-emption jurisprudence." *Wyeth v. Levine*, 555 U.S. 555, 565 (2009). *First*, "the purpose of Congress is the ultimate touchstone in every pre-emption case." *Id*. (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)). *Second*, '"[i]n all pre-emption cases, and particularly in those in which Congress has 'legislated . . . in a field which the States have traditionally occupied,' [courts] start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'" *Id*. (quoting *Lohr*, 518 U.S. at 485).

As the U.S. Supreme Court has recognized, Congress enacted the FFDCA "primarily to protect the health and safety of the public at large." *POM Wonderful LLC v. Coca-Cola Co*., 573 U.S. 102, 108 (2014) ("*POM*"). Congress amended the Act in 1958 "[t]o protect the public health by . . . prohibit[ing] the use in food of additives which have not been adequately tested to establish their safety." Pub. L. 85-929, 72 Stat. 1784, 1784. In seeking to protect public health by promoting food safety, the FFDCA and the 1958 amendment touch upon matters traditionally occupied by the states. *See Lohr*, 518 U.S. at 475 ("Throughout our history the

several States have exercised their police powers to protect the health and safety of their citizens."); *Florida Lime*, 373 U.S. at 143–44 (recognizing that "the supervision of the readying of foodstuffs for market has always been deemed a matter of peculiarly local concern"). Accordingly, a strong presumption *against* preemption applies in the present situation and, for the reasons set forth below, neither the FFDCA nor FDA's GRAS regulation governing grains of paradise preempt Florida's law.

A. The FFDCA Does Not Expressly Preempt More Protective State Laws Governing Food Safety.

With respect to the preemptive effect of federal statutes containing *limited* express preemption provisions, such as the FFDCA, the Supreme Court has recognized that "Congress' enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not pre-empted." *Cipollone*, 505 U.S. at 517. In other words, courts recognize that "Congress could have applied [a] pre-emption clause to the entire [F]FDCA." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 327 (2008). Congress' failure to do so serves as "powerful evidence" of its intent to confine the scope of preemption. *Wyeth*, 555 U.S. at 575.

In drafting the FFDCA, "Congress [took] care to mandate express pre-emption of *some* state laws." *POM*, 573 U.S. at 114. The Act includes provisions that expressly preempt certain state laws governing medical devices, drugs, and cosmetics. *See* 21 U.S.C. §§ 360k(a), 379t(a), 379s(a). In addition, Congress has

amended the FFDCA to add express preemption provisions pertaining to food labeling and pesticide residues in or on food. *See* Pub. L. 101-535, 104 Stat. 2353, 2362–63 (codified at 21 U.S.C. § 343-1(a)); Pub. L. 104-170, 110 Stat. 1489, 1530–31 (codified at 21 U.S.C. § 346a(n)(4)). But Congress *never* has approved any provision expressly preempting state food safety laws.[8]

The fact that the FFDCA does not expressly preempt state laws governing food safety—even though it expressly preempts other state laws—is powerful evidence that Congress did not intend for federal law to preempt state law in this area. *See Wyeth*, 555 U.S. at 575. So too is the fact that Congress has amended the FFDCA to expressly preempt some state laws, but repeatedly has *rejected* amendments that would expressly preempt state laws governing food safety. "The purpose of Congress is the ultimate touchstone in every pre-emption case," *Wyeth*, 555 U.S. at 565 (quoting *Lohr*, 518 U.S. at 485), and Congress has made clear that it does *not* intend for the FFDCA to preempt state food safety laws.

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[8] Lawmakers repeatedly have introduced—but failed to enact—legislation that would expressly preempt state food safety laws. *See, e.g.*, National Uniformity for Food Act of 2005, H.R. 4167, 109th Cong. (2005) (seeking to amend the FFDCA to prohibit states from enacting provisions not identical to, among other things, federal standards governing food additives and GRAS substances). These proposals have drawn opposition from many stakeholders, including a majority of state attorneys general. *See* Letter from Nat'l Ass'n of Attys Gen. to Members of Congress, Mar. 2, 2006, https://www.centerforfoodsafety.org/files/letteruniformitynaag_3206.pdf.

B. The FFDCA Does Not Preempt More Protective State Food Safety Laws By Occupying the Field.

Courts do not lightly infer field preemption, even when confronted with a comprehensive statutory scheme. *See N.Y. State Dep't of Soc. Servs. v. Dublino*, 413 U.S. 405, 415 (1973). To the contrary, the Supreme Court has recognized that "[t]he subjects of modern social and regulatory legislation often by their very nature require intricate and complex responses from the Congress, but without Congress necessarily intending its enactment as the exclusive means of meeting the problem." *Id*; *see also Hillsborough Cty., Fla. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 717 (1985) (explaining that courts "are even more reluctant to infer [field] pre-emption from the comprehensiveness of regulations than from the comprehensiveness of statutes"). Thus, as in all preemption analyses, courts investigating field preemption are guided by congressional purpose and a strong presumption *against* preemption, especially in areas of traditional state authority. *See Wyeth*, 555 U.S. at 565 (quoting *Lohr*, 518 U.S. at 485).

Although the FFDCA and FDA's implementing regulations governing food additives and GRAS substances are voluminous, they are far from comprehensive. *Cf. POM*, 573 U.S. at 108 (recognizing that FDA plays a "less extensive role . . . in the regulation of food than in the regulation of drugs"). Indeed, as explained above, the FFDCA and FDA's regulations contain significant gaps that put food safety and public health at risk. States have helped to fill these gaps by exercising

their authority to protect food safety; in so doing, they have advanced the purposes of the FFDCA.

Many state laws and regulations governing food and food safety, including the Florida law at issue, predate Congress' 1958 amendment to the FFDCA. *See, e.g.*, Ala. Code § 20-1-73 (adopted in 1943); Fla. Stat. § 562.455 (adopted in 1868); Wash. Rev. Code § 69.40.020 (adopted in 1905). In enacting that amendment, Congress surely was aware that states had adopted provisions in connection with their authority to "supervis[e] the readying of foodstuffs for market." *Florida Lime*, 373 U.S. at 144. Had Congress intended to displace these provisions, it would have made its purpose clear. Congress' silence on the issue strongly suggests that it did not intend FDA oversight to be the exclusive means of ensuring food safety. *See Wyeth*, 555 U.S. at 575.

C. The Florida Statute Is Not Conflict Preempted.

As this Court has explained, "[c]onflict preemption . . . arises in instances where (1) 'compliance with both federal and state regulations is a physical impossibility,' or (2) 'the challenged state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Fresenius Med. Care Holdings, Inc. v. Tucker*, 704 F.3d 935, 939 (11th Cir. 2013) (quoting *Arizona v. U.S.*, 567 U.S. 387, 399 (2012)). "The mere fact that state laws . . . overlap to some degree with federal [laws] does not even begin to make a case

for conflict preemption." *Kansas v. Garcia*, 140 S. Ct. 791, 806 (2020); *see also Graham v. R.J. Reynolds Tobacco Co.*, 857 F.3d 1169, 1186 (11th Cir. 2017) ("A party asserting conflict preemption faces a high bar."). Here, the district court concluded that Florida's law "frustrates the purposes and objectives of the FFDCA and its implementing FDA regulations, which establish that grains of paradise is generally regarded as safe." *Marrache*, 2020 WL 434928 at *2. As explained below, the district court's conclusion is inconsistent with binding precedent, which long has supported states' ability to exceed federal protections for public health.

i. Florida's Law Does Not Render Impossible Compliance with the FFDCA or FDA's GRAS Regulation.

"Impossibility pre-emption is a demanding defense." *Wyeth*, 555 U.S. at 573. If it is "a *physical impossibility* for one engaged in interstate commerce" to comply with both federal and state laws or regulations, impossibility preemption is "inescapable." *Florida Lime*, 373 U.S. at 142–43 (emphasis added). However, as this Court has explained, impossibility preemption does *not* arise in situations like this one, in which state law "prohibits and penalizes what federal regulation permits." *Fresenius Med. Care Holdings*, 704 F.3d at 940 (finding that a federal law prohibiting most physician self-referrals did not preempt a similar Florida law with fewer exceptions); *see also Florida Lime*, 373 U.S. at 142–43 (finding that a federal regulation governing the marketing of avocados did not preempt a California law seeking to ensure the maturity of avocados sold in that state, even

though the California law excluded from sale some avocados deemed marketable under federal law).

In the present situation, the FFDCA and FDA's regulations merely *permit* manufacturers to add grains of paradise to alcohol, and Florida's law prohibits this practice. Because manufacturers can satisfy both regimes—for example, by choosing not to add grains of paradise to alcohol or choosing not to sell alcohol with grains of paradise in Florida—dual compliance is not physically impossible. Therefore, the FFDCA and FDA's regulations do not preempt Florida's law through impossibility.

ii. Florida's Law Does Not Frustrate the Purposes and Objectives of the FFDCA or FDA's GRAS Regulation.

In determining whether state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress, courts focus on the language of the federal statute purported to have preemptive effect "and the 'statutory framework' surrounding it.'" *Graham*, 857 F.3d at 1186 (quoting *Lohr*, 518 U.S. at 486); *W. Va. Univ. Hosp. v. Casey*, 499 U.S. 83, 98 (1991) ("The best evidence of th[e] purpose [of a statute] is the statutory text adopted by both Houses of Congress and submitted to the President."). Here, as explained above, Congress enacted the FFDCA "to protect the health and safety of the public at large," *POM*, 573 U.S. at 108, and amended it in 1958 "[t]o protect the public health by . . . prohibit[ing] the use in food of additives which have not

been adequately tested to establish their safety." Pub. L. 85-929, 72 Stat. 1784, 1784. Florida's law, which provides for the punishment of anyone who adulterates liquor with grains of paradise or any other substance "poisonous or injurious to health," although apparently outdated, is nonetheless entirely consistent with these purposes.

The purpose of the 1958 amendment is set out clearly in its text. *See* Pub. L. 85-929, 72 Stat. 1784, 1784 (stating that the purpose of the amendment is "[t]o protect the public health by amending the [FFDCA] to prohibit the use in food of additives which have not been adequately tested to establish their safety"). Instead of grappling with this purpose, the district court relied on a secondary goal, which appears only in the amendment's legislative history: "to advance food technology by permitting the use of food additives at safe levels." *Marrache*, 2020 WL 434928 at *2 (quoting Cong. Rec. 17,413 (daily ed. Aug. 13, 1958)). In so doing, the court ran afoul of the well-established presumption against preemption. *See English v. Gen. Elec. Co.*, 496 U.S. 72, 90 (1990) ("The 'teaching of this Court's decisions . . . enjoin[s] *seeking out* conflicts between state and federal regulation where none clearly exists.'") (quoting *Huron Portland Cement Co. v. Detroit*, 362 U.S. 440, 446 (1960)) (emphasis added).

In addition, the district court failed to construe the 1958 amendment's secondary goal in its proper historical context. Prior to the amendment's passage,

federal law prohibited manufacturers from adding *any* poisonous or deleterious substances to food, even in amounts that pose no risk to human health. *See Cont'l Chemiste Corp. v. Ruckelshaus*, 461 F.2d 331, 340 (7th Cir. 1972). By permitting the use of food additives at safe levels, Congress intended to devise a system in which "the benefits of [an] additive were to be evaluated rather than merely its potential for harm." *Cont'l Chemiste Corp.*, 461 F.2d at 340. There is no evidence, however, that Congress intended for FDA's safety assessments to override states' traditional role in providing public health protections. *See Florida Lime*, 373 U.S. at 145 ("Congressional regulation of one end of the stream of commerce does not, ipso facto, oust all state regulation at the other end. Such a displacement may not be inferred automatically from the fact that Congress has regulated production and packing of commodities for the interstate market.").

Indeed, as the Supreme Court has recognized, it is "a well-settled proposition that a State may impose upon imported foodstuffs 'a higher standard demanded . . . for its consumers.'" *Id*. at 144 n.13; *see also id.* at 144 (explaining that a state may, for example, "confiscate or exclude from market . . . processed butter which had complied with all the federal processing standards," but which failed to satisfy the state's *higher* standard). "It is one of the happy incidents of the federal system that a single courageous state may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest

of the country." *Graham*, 857 F.3d at 1190 (quoting *New State Ice Co. v. Liebmann*, 285 U.S. 262, 386–87 (1932) (Brandeis, J., dissenting)). Thus, as explained above, at least sixteen states have enacted laws authorizing regulations that are more protective than federal standards governing substances used in food. *See supra* note 7. New York has adopted stricter limits on the use of sulfite preservatives, N.Y. Agric. & Mkts. Law § 199-d, and Washington has elected to ban caffeinated alcoholic drinks within its borders. *See* Wash. Admin. Code § 314-20-022. In a variety of analogous contexts, courts have concluded that states can impose additional restrictions on products deemed "safe" by federal agencies. *See, e.g.*, *Wyeth*, 555 U.S. at 573 (refusing to find that federal law preempted a state-law duty to provide stronger warnings about the risks of administering a certain drug); *Wis. Pub. Intervenor v. Mortier*, 501 U.S. 597, 614 (1991) (refusing to find that federal law preempted local restrictions on pesticide use); *In re Bisphenol-A (BPA) Polycarbonate Plastic Products Liability Litigation*, 2009 WL 3762965, *4 (W.D. Mo. 2009) (explaining that "FDA's approval of BPA as safe without labeling requirements establishes only a regulatory minimum").

Finally, contrary to the district court's conclusion, this case is *not* "comparable to recent court decisions finding state law claims stemming from the use of partially hydrogenated oils ('PHOs') in food were preempted because they conflicted with the FFDCA, which deemed PHOs to be safe." *Marrache*, 2020

WL 434928 at *2. *First*, the FFDCA does *not* deem PHOs to be safe. To the contrary, in 2015, FDA determined that "there is no longer a consensus among qualified experts that PHOs . . . are safe for human consumption." Final Determination Regarding Partially Hydrogenated Oils, 80 Fed. Reg. 34,650-01, 34,651 (June 17, 2015). Accordingly, FDA revoked PHOs' GRAS status and ordered manufacturers who wished to continue using PHOs to obtain federal approval by June 18, 2018. *See id. Second*, Congress took specific action with respect to PHOs, by declaring that "[n]o partially hydrogenated oils . . . shall be deemed unsafe . . . until the compliance date as specified in [FDA's] order (June 18, 2018)." Consolidated Appropriations Act, 2016, Pub. L. No. 114-113, § 754, 129 Stat. 2242, 2284 (2015). *Third*, courts finding preemption in this context did not rely on FDA's determination concerning PHOs' safety (or lack thereof) but, instead, found that the congressionally-mandated compliance period preempted premature enforcement. *See, e.g.*, *Beasley v. Conagra Brands, Inc.*, 374 F. Supp. 3d 869, 876 (N.D. Cal. 2019) (concluding that "plaintiff's California state law claims regarding the use of PHOs in food *prior to June 18, 2018* are conflict preempted by federal law") (emphasis added); *Backus v. General Mills, Inc.*, 2018 WL 6460441, *4 (N.D. Cal. 2018) ("Congress has been clear that no liability can arise for use of PHOs *before the June 18, 2018 compliance date*") (emphasis added). In the present situation, FDA has not established a deadline by which

manufacturers must begin to comply with any federal determination about grains of paradise, and Congress has taken no specific action to endorse that deadline. Thus, cases concerning PHOs are entirely inapposite.

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In sum, the FFDCA and FDA's regulations do not preempt Florida's law. Although the FFDCA expressly preempts some state laws, Congress repeatedly has declined to adopt amendments that would expressly preempt more protective state laws governing food safety. The FFDCA and FDA's regulations do not occupy the entire legislative field but, instead, leave open gaps that states have helped to fill. And, Florida's law neither renders compliance with the FFDCA and FDA's regulations physically impossible, nor obstructs Congress' purpose to protect the health and safety of the public at large. To the contrary, Florida's law is altogether consistent with this purpose.

II. Even if FDA's GRAS Regulations Could Preempt More Protective State Laws, Which They Cannot, That Principle Cannot Extend to Manufacturers' GRAS Self-Certifications.

The substance at issue in this litigation—grains of paradise—is unusual among GRAS substances, insofar as FDA has issued a *regulation* confirming its GRAS status. *See* 21 C.F.R. § 182.10. Many other purportedly GRAS substances are unknown even to FDA. *See* GAO Report at 13 (reporting that FDA is unable to track all substances added to food "because companies are not required to . . .

inform FDA of their GRAS determinations, and FDA officials cannot estimate the number of determinations that occur about which they are not notified"). Indeed, as explained above, for at least twenty-five years, FDA has allowed manufacturers to determine the GRAS status of substances they wish to use in food—and add those substances to food—*in secret*, without notice to FDA or the public. Even if this Court were to determine that *FDA's* GRAS regulations preempt more protective state laws, which they do not, it must make clear that *manufacturers'* GRAS determinations have no preemptive effect. *See Lohr*, 518 U.S. at 485 (explaining that the presumption against preemption also supports a narrow interpretation of "the *scope* of [Congress'] intended invalidation of state law"). A decision extending preemptive effect to manufacturers' GRAS determinations would conflict with binding precedent and common sense for at least three reasons.

First, a decision extending preemptive effect to manufacturers' GRAS determinations would run directly counter to the well-established presumption against preemption. If manufacturers' GRAS determinations had preemptive effect, private companies could invalidate state law at will. And, because manufacturers need not disclose their GRAS determinations to FDA or the public, states could not tailor their food safety laws to avoid preemption. Indeed, they might not even *discover* that their laws were preempted until a conflict arose. Congress cannot have intended such an absurd result.

Second, a decision extending preemptive effect to manufacturers' GRAS determinations would signal a return to the dangerously inadequate system of addressing public health crises caused by unsafe substances in food only *after* those crises occur. If manufacturers' secret GRAS determinations could preempt state law, states could not proactively protect public health by prohibiting the use of unsafe substances in food and, thus, would have to rely on post-injury enforcement. But this is precisely the problem that Congress sought to avoid when it amended the FFDCA in 1958. *See* H.R. Rep. No. 2284 at 1–2 (1958) (explaining that, before the 1958 amendment, the government could prohibit the use of unsafe additives only by *proving* that they were poisonous or deleterious—a process that "require[d] approximately 2 years or more of laboratory experiments," during which time manufacturers could continue to use the additives in food). Reverting to a food safety system that relies on post-injury enforcement is flatly inconsistent with Congress' purpose.

Third, a decision extending preemptive effect to manufacturers' GRAS determinations almost certainly would *increase* "the use in food of additives which have not been adequately tested to establish their safety," Pub. L. 85-929, 72 Stat. 1784, 1784, raising yet another conflict with the 1958 amendment. Manufacturers' safety assessments often are unreliable. For instance, according to one analysis, "financial conflicts of interest [a]re ubiquitous" in manufacturers' GRAS

determinations. Thomas G. Neltner et al., *Conflicts of Interest in Approvals of Additives to Food Determined to Be Generally Recognized as Safe: Out of Balance*, 173 J. Am. Med. Ass'n E1, E4 (2013). And manufacturers have self-certified substances as GRAS *even after* FDA raised concerns about the safety of those substances. *See* Tom Neltner et al., *Generally Recognized as Secret: Chemicals Added to Food in the United States* (2014), https://www.nrdc.org/sites/default/files/safety-loophole-for-chemicals-in-food-report.pdf. Unreliable GRAS determinations put food safety and public health at risk. Congress cannot have intended to bring about a result that so clearly undermines its purpose in adopting the 1958 amendment.

CONCLUSION

For these reasons, *amici* respectfully ask this Court to reverse the district court's ruling on preemption and clarify that preemptive effect cannot extend to manufacturers' secret GRAS determinations.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I certify that the following statements are true:

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a) because it contains 6,499 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).
2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in 14-point Times New Roman.

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CERTIFICATE OF SERVICE

I hereby certify that on May 4, 2020, I electronically filed this brief with the Clerk of the Court for the U.S. Court of Appeals for the Eleventh Circuit by using the appellate CM/ECF system. I certify that the foregoing document is being served this day on all counsel of record, and that service will be accomplished by the appellate CM/ECF system.

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