**[ORAL ARGUMENT NOT SCHEDULED]**

**No. 21-5170**

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**IN THE UNITED STATES COURT OF APPEALS**
**FOR THE DISTRICT OF COLUMBIA CIRCUIT**

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MARK MCAFEE; FARM-TO-CONSUMER LEGAL DEFENSE FUND,

Plaintiffs-Appellants,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION,

Defendant-Appellee.

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On Appeal from the United States District Court
for the District of Columbia

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# BRIEF FOR APPELLEE

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## CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to D.C. Circuit Rule 28(a)(1), the undersigned counsel certifies as follows:

### A. Parties and Amici

Plaintiffs-appellants are Mark McAfee and Farm-to-Consumer Legal Defense Fund. Defendant-appellee is the United States Food and Drug Administration. There were no amici or intervenors in the district court. Amici in this Court include Pacific Legal Foundation, the Weston A. Price Foundation, Farm and Ranch Freedom Alliance, Red Acre Center, Food Freedom Foundation, National Health Freedom Coalition, and National Health Freedom Action.

### B. Rulings Under Review

The rulings under review (issued by Judge Rudolph Contreras) are the final judgment, order, and opinion entered on May 24, 2021. The opinion is available at 541 F. Supp. 3d 121 (D.D.C. 2021). There is no official citation for the final judgment and order.

### C. Related Cases

This case has not previously been before this Court or any other court. To counsel's knowledge, there are no related cases within the meaning of D.C. Circuit Rule 28(a)(1)(C).

*/s/ Cynthia A. Barmore*
Cynthia A. Barmore

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## GLOSSARY

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|---|---|
| FDA | Food and Drug Administration |
| FDCA | Federal Food, Drug, and Cosmetic Act |

## INTRODUCTION

For several decades, Food and Drug Administration (FDA) regulations have prohibited butter and other milk products from being sold in interstate commerce unless they are pasteurized or made from pasteurized dairy ingredients. These regulations protect consumers from diseases caused by pathogens, such as *Listeria*, *E. coli*, *Salmonella*, and *Staphylococcus*, found in unpasteurized milk products.

Mark McAfee and Farm-to-Consumer Legal Defense Fund (together, McAfee) filed a rulemaking petition asking FDA to change its longstanding regulations to permit the interstate sale of butter made from unpasteurized cream. McAfee claimed that FDA never had statutory authority to require pasteurization. But the Public Health Service Act plainly gives FDA that authority by empowering it to "make and enforce such regulations as in [its] judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases." 42 U.S.C. § 264(a). That statute contains no exception for butter. Nor, contrary to McAfee's claim, do provisions about butter in the Federal Food, Drug, and Cosmetic Act curtail FDA's separate statutory authority to protect the public from communicable diseases.

Accordingly, FDA denied McAfee's petition for rulemaking, and the district court upheld that reasonable decision. The district court's judgment should be affirmed.

## STATEMENT OF JURISDICTION

McAfee invoked the district court's jurisdiction under 28 U.S.C. §§ 1331, 1361. JA 10. On May 24, 2021, the district court entered final judgment in favor of FDA. JA 74. McAfee filed a timely notice of appeal on July 23, 2021. JA 93; *see* Fed. R. App. P. 4(a)(1)(B) (60-day time limit). This Court has appellate jurisdiction under 28 U.S.C. § 1291.

## STATEMENT OF THE ISSUE

Whether FDA reasonably concluded that it has statutory authority to retain its longstanding regulations prohibiting the interstate sale of butter made from unpasteurized dairy products.

## PERTINENT STATUTES AND REGULATIONS

Pertinent statutes and regulations are reproduced in the addendum to this brief.

## STATEMENT OF THE CASE

### A. Statutory And Regulatory Background

**1.** FDA has statutory authority to prevent the spread of communicable diseases. The Public Health Service Act authorizes the agency "to make and enforce such regulations as in [its] judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases … from one State or possession into any other State or possession." 42 U.S.C. § 264(a). "For purposes of carrying out and enforcing such regulations," the agency may, among other things, provide for "disinfection," "sanitation," and "destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in [its] judgment may be necessary." *Id.* Although the statute originally conferred this authority on the Surgeon General, it was reassigned to the Secretary of Health and Human Services, *see* Reorganization Plan No. 3 of 1966, 31 Fed. Reg. 8855 (June 25, 1966), *reprinted in* 80 Stat. 1610 (1966); Department of Education Organization Act, Pub. L. No. 96-88, 93 Stat. 668 (1979); Act of Oct. 19, 1984, Pub. L. No. 98-532, 98 Stat. 2705, and ultimately delegated to FDA with respect to food and other

products, *see* 21 C.F.R. § 1240.30; 65 Fed. Reg. 49,906, 49,907 (Aug. 16, 2000).

FDA has promulgated a variety of regulations pursuant to this authority. The agency has prohibited "the import or sale of animals known to transmit disease," *Alabama Ass'n of Realtors v. Department of Health & Human Servs.*, 141 S. Ct. 2485, 2487 (2021) (per curiam) (citing ban on small turtles known to be carriers of *Salmonella*, 21 C.F.R. § 1240.62), and has regulated products such as shellfish, 21 C.F.R. § 1240.60, milk, *id.* § 1240.61, parrots, *id.* § 1240.65, and food waste used to feed swine, *id.* § 1240.75.

**2.** Congress separately has given FDA authority to regulate food products in the Federal Food, Drug, and Cosmetic Act (FDCA). For instance, FDA may regulate "adulterated" foods that contain "poisonous or deleterious substance[s]" that may render them "injurious to health." 21 U.S.C. § 342(a); *id.* § 371 (authorizing the agency to "promulgate regulations for the efficient enforcement" of the FDCA). The FDCA specifies that "butter" is adulterated if it is "unfit for food." *Id.* § 342(e).

The FDCA also generally authorizes FDA to set "a reasonable definition and standard of identity" for "any food" to "promote honesty

and fair dealing in the interest of consumers." 21 U.S.C. § 341. Standards of identity provide legal definitions for food products by describing their basic nature and essential characteristics, such as required ingredients or production processes that bear on their identity. *See* 70 Fed. Reg. 29,214, 29,216 (May 20, 2005); JA 462. For example, the standard of identity for "fruit jam" lists the minimum amount of fruit and sugar that jam must contain, 21 C.F.R. § 150.160, while the standard of identity for "cottage cheese" describes how that product is prepared, *id.* § 133.128. By requiring products to conform to standards of identity, FDA ensures that consumers receive the product they "expected to receive when purchasing a product with the name under which it was sold." *See Federal Sec. Adm'r v. Quaker Oats Co.*, 318 U.S. 218, 230–31 (1943).

Congress prohibited FDA from creating a standard of identity for butter or most fresh or dried fruits and vegetables. 21 U.S.C. § 341. Butter instead is defined by statute as "the food product usually known as butter, and which is made exclusively from milk or cream, or both, with or without common salt, and with or without additional coloring

matter, and containing not less than 80 per centum by weight of milk fat, all tolerances having been allowed for." *Id.* § 321a.

**3.** In 1972, FDA first proposed to prohibit unpasteurized milk and cream from being sold in interstate commerce. 37 Fed. Reg. 18,392, 18,393 (Sept. 9, 1972). The final rule required pasteurization in order to "assure[] the destruction of pathogenic bacteria that may be present" in milk and cream and thereby "promote honesty and fair dealing in the interest of consumers." 38 Fed. Reg. 27,924, 27,924–25 (Oct. 10, 1973). The rule relied on the agency's statutory authority, discussed above, to define food products under the FDCA, 21 U.S.C. §§ 341, 371. 38 Fed. Reg. at 27,925. The agency thus banned unpasteurized milk and cream from interstate commerce by changing the definition of milk and cream to require pasteurization. *Id.* at 27,926–29. The rule did not change the standard of identity for butter or otherwise prevent the sale of butter made from unpasteurized cream (known as raw cream butter).

FDA stayed the 1973 rule as it applied to certified raw milk (*i.e.*, unpasteurized milk that meets production standards set by a private trade organization) pending a public hearing. 39 Fed. Reg. 42,351, 42,351 (Dec. 5, 1974). Objectors had argued that the FDCA did not

authorize FDA "to promulgate a standard of identity solely for health reasons." *Id.* The agency responded in its stay order that "pasteurization is appropriately required" under not only the FDCA, but also the Public Health Service Act, and "added" a "citation to this authority." *Id.* For the next decade, FDA studied the connection between diseases and certified raw milk, ultimately concluding that consumption of "all forms of raw milk and raw milk products was linked to the outbreak of serious disease." *See Public Citizen v. Heckler* (*Public Citizen II*), 653 F. Supp. 1229, 1232 (D.D.C. 1986). In 1982, FDA began drafting a regulation to ban all raw milk and raw milk products from interstate commerce. *Id.*

Several years later, FDA's inaction on raw milk became the subject of litigation. In 1984, an organization filed a petition asking FDA to ban all domestic sales of raw milk and raw milk products. *See Public Citizen v. Heckler* (*Public Citizen I*), 602 F. Supp. 611 (D.D.C. 1985). In 1985, a court held that the agency had unreasonably delayed responding to the petition, concluding that under "both the Public Health Service Act's authorization for regulations to control communicable diseases" and "the [FDCA]'s provisions for the control of

adulterated foods," the Secretary has "the authority and the heavy responsibility to act to protect the nation's health in situations such as this one." *Id.* at 613. After further delays, in 1986, the court ordered FDA to promulgate a rule "banning the interstate sale of all raw milk and all raw milk products." *Public Citizen II*, 653 F. Supp. at 1242.

In 1987, FDA banned the interstate distribution of "any milk or milk product" that "has not been pasteurized." 52 Fed. Reg. 29,509, 29,514 (Aug. 10, 1987); 21 C.F.R. § 1240.61 (1988). The rule provided an exception for "milk and milk products for which an alternative to pasteurization is established in a standard of identity regulation." 52 Fed. Reg. at 29,513. FDA relied on the Public Health Service Act as providing "the legal basis for the final rule." *Id.* at 29,510, 29,514 (citing 42 U.S.C. §§ 216, 243, 264, 271). The agency also noted that the FDCA's provisions authorizing FDA to control adulterated or contaminated foods provided "[a]dditional support for the final rule." *Id.* at 29,510 (citing 21 U.S.C. §§ 342(a)(1), (3), (4), 371(a)).

In 1992, following notice and comment, FDA issued a "technical amendment" clarifying the meaning of "milk" and "milk products" for purposes of the 1987 pasteurization rule. 57 Fed. Reg. 57,343, 57,343

(Dec. 4, 1992). FDA specified that "milk products" includes butter. *Id.* at 57,343–44. As amended, the rule currently bans from interstate commerce "any milk or milk product … unless the product has been pasteurized or is made from dairy ingredients (milk or milk products) that have all been pasteurized, except where alternative procedures to pasteurization are provided for by regulation." 21 C.F.R. § 1240.61(a); *id.* § 1240.3(j) (defining "[m]ilk products" to include "butter"). The amended rule identifies the Public Health Service Act as providing statutory authority. 57 Fed. Reg. at 57,344 (citing 42 U.S.C. §§ 216, 243, 264, 271 as providing authority for 21 C.F.R. pt. 1240); 62 Fed. Reg. 51,512, 51,521 (Oct. 1, 1997) (same).

### B. Factual Background

Mark McAfee is the founder of Organic Pastures Dairy Company, which produces and sells raw dairy products in California. JA 97. Since 2010, Mark McAfee and Organic Pastures, due to their repeated violations of the FDCA and FDA regulations, have been subject to an injunction prohibiting them from selling unpasteurized dairy products in interstate commerce. *See United States v. Organic Pastures Dairy Co.*, 708 F. Supp. 2d 1005, 1007–09, 1017–18 (E.D. Cal. 2010). Farm-to-

Consumer Legal Defense Fund is a non-profit organization dedicated to agricultural issues. JA 97.

In June 2016, McAfee filed a petition for rulemaking requesting that FDA amend its regulations to allow the interstate sale and shipment of raw cream butter. JA 94–117. McAfee asked FDA to exclude butter from the definition of milk products in 21 C.F.R. § 1240.3(j) and to exempt butter from the pasteurization requirement in 21 C.F.R. § 1240.61. JA 96. McAfee argued that FDA lacked both statutory authority to require pasteurization and a "sound scientific basis" for doing so. JA 100–02. In support of his statutory argument, he argued only that the FDCA prohibited FDA from banning the interstate sale of raw cream butter, notwithstanding FDA's otherwise broad authority under the Public Health Service Act. *Id.* In December 2016, FDA informed McAfee that limited agency resources and competing priorities had delayed a decision on his petition. JA 457. In October 2019, McAfee filed suit in district court to compel a response. Dkt. 1. The parties agreed to a stay and FDA committed to respond by February 28, 2020. Dkt. 7, at 2.

On February 27, 2020, FDA denied McAfee's petition. JA 475. The agency concluded that the petition neither "contain[ed] facts demonstrating any reasonable grounds for amending 21 CFR 1240.61" nor "substantially show[ed] that [the] proposal is in the public interest and will promote the objectives" of the agency. *Id.*; *see* 21 C.F.R. § 10.40(a)(2).

FDA first determined that it had statutory authority under the Public Health Service Act to prohibit the interstate sale of raw cream butter. JA 460–62. FDA acknowledged that the FDCA prevented it from establishing a standard of identity for butter. JA 462. But the agency concluded that requiring pasteurization under the Public Health Service Act did not conflict with that limitation. *Id.* FDA explained that standards of identity serve a different purpose than food safety regulations, and it concluded that the pasteurization requirement did "not purport to be a standard of identity rulemaking" and "did not serve to operate as one in practice either." JA 461–62.

FDA also concluded that requiring pasteurization is scientifically justified to prevent the spread of communicable diseases. JA 462–74. Cream is the main ingredient in butter and FDA found that raw cream

may contain pathogens capable of causing disease. JA 464. It further found that pasteurization, unlike other steps in the butter manufacturing process, eliminates those pathogens. *Id.* Finally, the agency considered and rejected McAfee's contrary scientific evidence as unconvincing. *Id.*

### C. Prior Proceedings

In May 2020, McAfee amended his complaint in district court to claim that FDA's denial of his petition violated the Administrative Procedure Act. JA 29. He claimed that the denial was "contrary to or prohibited by law" on the ground that FDA lacked statutory authority to prohibit the interstate transportation of raw cream butter. JA 27–28. He also claimed that the denial was arbitrary and capricious. JA 28–29. Both parties moved for summary judgment. JA 69–72.

The district court granted summary judgment to FDA. JA 74. The court first held that the agency's decision was a "straightforward" exercise of its statutory authority under the Public Health Service Act. JA 78–84. McAfee did "not dispute that, on its own, the [Public Health Service Act] would seem to give the FDA authority to mandate pasteurization." JA 79. "Nor could" he: That Act empowers FDA "to

protect the public against the spread of communicable diseases." *Id.* (quoting *Louisiana v. Mathews*, 427 F. Supp. 174, 176 (E.D. La. 1977)). Pasteurization serves that purpose by "eliminat[ing] 'numerous … harmful microorganisms' that transmit infectious diseases." JA 79–80. And the Public Health Service Act's text makes no exception for butter. *See* JA 82.

The court rejected McAfee's argument that the FDCA nevertheless "prohibits any mandate that butter be pasteurized." JA 80. The court acknowledged that the FDCA defines butter and prohibits FDA from establishing a standard of identity for butter. *Id.* But the court saw no conflict between those FDCA provisions and the Public Health Service Act. JA 81. Standards of identity "are meant to ensure that consumers know what foods they are buying," while the Public Health Service Act "is concerned with containing the spread of infectious diseases." JA 81–82. "Rarely do statutes with such different purposes and scopes conflict." JA 82. The court further rejected as supported only by a "misreading of history" the "false premise" that "the pasteurization rule works a change to butter's standard of identity." *Id.* The court concluded that the Public Health Service Act "grants the FDA authority

to combat infectious diseases apart from the authority the FDCA gives the agency to set standards of identity" and "[t]hose separate authorities do not conflict here." JA 84. "Absent a conflict with the FDCA, the [Public Health Service Act] comfortably authorizes the pasteurization rule." *Id.*

The court also held that FDA's decision was not arbitrary and capricious. JA 84–92. FDA properly "articulated the basic rationale behind its pasteurization rule," "put forth a great deal of scientific evidence in support of its judgment," and "rejected each of the substantive grievances that [McAfee] raised in [his] petition." *Id.* "At bottom, there is little doubt that pasteurization minimizes the 'documented risks' posed by pathogens in dairy products like butter." JA 90.

## SUMMARY OF ARGUMENT

**I.** The Public Health Service Act gives FDA statutory authority to prohibit the interstate sale of butter made with unpasteurized cream. That Act empowers FDA "to make and enforce such regulations as in [its] judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases," such as "disinfection" and

"sanitation" of "articles found to be so infected or contaminated as to be sources of dangerous infection to human beings." 42 U.S.C. § 264(a). Pasteurization provides for disinfection and sanitation, in that it is a processing control that prevents the spread of communicable diseases by eliminating pathogens like *Listeria*, *Salmonella*, *Staphylococcus*, and *E. coli* that otherwise could be found in butter. *See, e.g.*, JA 464–65.

McAfee mistakenly claims that the FDCA prohibits FDA from excluding raw cream butter from interstate commerce. The FDCA simply exempts butter from FDA's authority to create definitions and standards of identity for food products. A standard of identity typically establishes the permitted ingredients for a food product to ensure that the product matches consumer expectations. FDA has never established a standard of identity for butter, either de jure or de facto. Instead, FDA required pasteurization by exercising its separate authority under the Public Health Service Act to prevent the spread of communicable diseases. *See* 52 Fed. Reg. at 29,510, 29,514; 57 Fed. Reg. at 57,344; 62 Fed. Reg. at 51,521. There is no conflict between these two statutes; they serve different purposes, and this Court can give effect to both by allowing FDA to regulate butter for public health

purposes while prohibiting FDA from altering Congress's definition of butter to match consumer expectations.

**II.** McAfee forfeited his remaining arguments, which are in any event without merit.

McAfee claims for the first time on appeal that the Public Health Service Act's original meaning does not authorize FDA to regulate butter, and that FDA cannot be delegated authority to issue regulations under that Act. These arguments are doubly forfeited, as they were raised neither before the agency nor before the district court. In any case, these arguments are meritless. The Public Health Service Act's text contains no exception for butter, and FDA was entitled to respond to scientific evidence by issuing a regulation within its statutory mandate. And the regulation requiring pasteurization of milk and milk products that McAfee challenges was signed by the Secretary of Health and Human Services, and in any event McAfee provides no basis to invalidate the longstanding delegation of regulatory authority to FDA.

Finally, McAfee failed to develop his arbitrary and capricious challenge in his opening brief. Regardless, his arguments are meritless and do not provide a "compelling cause" to overturn FDA's refusal to

initiate the rulemaking requested in his petition. *See WildEarth Guardians v. U.S. Envtl. Prot. Agency*, 751 F.3d 649, 653 (D.C. Cir. 2014) (quoting *National Customs Brokers & Forwarders Ass'n of Am. v. United States*, 883 F.2d 93, 97 (D.C. Cir. 1989)). As FDA reasonably concluded, butter is made from cream; raw cream can contain dangerous pathogens; and pasteurization protects the public from communicable diseases by eliminating those pathogens. *See* JA 464.

## STANDARD OF REVIEW

This Court "will overturn an agency's decision not to initiate a rulemaking only for compelling cause, such as plain error of law or a fundamental change in the factual premises previously considered by the agency." *WildEarth Guardians v. U.S. Envtl. Prot. Agency*, 751 F.3d 649, 653 (D.C. Cir. 2014) (quoting *National Customs Brokers & Forwarders Ass'n of Am. v. United States*, 883 F.2d 93, 97 (D.C. Cir. 1989)). The Court will defer to an agency's reasonable interpretation of its statutory authority, *Pharmaceutical Research & Mfrs. of Am. v. Federal Trade Comm'n*, 790 F.3d 198, 206 (D.C. Cir. 2015), and will reject an arbitrary and capricious challenge if the agency's decision is reasoned, *American Horse Prot. Ass'n v. Lyng*, 812 F.2d 1, 4–5 (D.C. Cir.

1987). FDA receives "a high level of deference" for its "scientific analysis of the evidence before it." *Pharmaceutical Mfg. Research Servs., Inc. v. FDA*, 957 F.3d 254, 262 (D.C. Cir. 2020) (quoting *Rempfer v. Sharfstein*, 583 F.3d 860, 867 (D.C. Cir. 2009)).

## ARGUMENT

### I. FDA Has Statutory Authority To Prohibit The Interstate Sale Of Raw Cream Butter

McAfee claims that FDA lacks statutory authority to prohibit the interstate sale of butter made with unpasteurized cream, but the Public Health Service Act plainly gives FDA that authority.

#### A. The Public Health Service Act Authorizes FDA To Prevent The Spread Of Communicable Diseases

The Public Health Service Act authorizes FDA[1] "to make and enforce such regulations as in [its] judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases." 42 U.S.C. § 264(a). The district court correctly held that banning raw cream butter from interstate commerce falls squarely within this grant of authority. JA 79–80. As FDA reasonably found, pasteurization is

[1] As noted, although the statute refers to the Surgeon General, this authority has been delegated to FDA with respect to food and other products. *See supra* pp. 3–4; *infra* pp. 42–43.

necessary to prevent the spread of communicable diseases: "The main ingredient in butter is cream" and "[r]aw cream may be contaminated with pathogens capable of causing disease." JA 464. These pathogens, which include *Listeria*, *Salmonella*, *Staphylococcus*, and *E. coli*, can cause serious illness. JA 465. For example, *Listeria* can cause listeriosis, which has a high hospitalization and fatality rate. JA 596.

Another district court recognized these health risks when, in 1986, it ordered FDA to promulgate a rule "banning the interstate sale of all raw milk and all raw milk products." *See Public Citizen II*, 653 F. Supp. 1229, 1242 (D.D.C. 1986). The court cited "overwhelming evidence" that "conclusively" showed the dangers of consuming raw milk. *Id.* at 1238, 1241; *see also Public Citizen I*, 602 F. Supp. 611, 612 (D.D.C. 1985) (recognizing that raw milk is linked to outbreaks of "campylobacteriosis and salmonellosis, which typically produce bloody diarrhea, usually lasting several days but sometimes several months," and on rare occasions, "result in death").

Pasteurization reduces these risks to human health by "heating milk to a specific temperature for a set period of time" in order to "kill[] harmful bacteria." *See* JA 460, 464; JA 90 ("At bottom, there is little

doubt that pasteurization minimizes the 'documented risks' posed by pathogens in dairy products like butter."); 52 Fed. Reg. at 29,512 ("All information available to the agency documents that pasteurization … effectively eliminates *S. dublin* as well as numerous other harmful microorganisms."). In contrast, other steps in the butter manufacturing process do "not destroy pathogens that may be present in the cream," which may then "end up in the finished butter product." JA 464, 469. FDA originally considered alternatives to pasteurization, such as labeling or screening technologies. *See* 52 Fed. Reg. at 29,513. But the agency rejected those alternatives as inadequate because many consumers would not fully understand the risks identified in labeling and no existing test could "simultaneously and instantaneously screen" for the many pathogens that may be present in raw dairy products. *See id.*

The Supreme Court's recent decision in *Alabama Ass'n of Realtors v. Department of Health & Human Services*, 141 S. Ct. 2485 (2021) (per curiam), supports FDA's exercise of statutory authority. There, the Court concluded that 42 U.S.C. § 264(a) did not provide authority to impose an eviction moratorium for "all residential properties

nationwide." 141 S. Ct. at 2486. The Court held that the statute instead authorized measures that "directly relate to preventing the interstate spread of disease by identifying, isolating, and destroying the disease itself." *See id.* at 2488. A requirement to pasteurize milk products readily meets that description, as it uses heat to destroy the infectious pathogens that otherwise might appear in milk products.

The Supreme Court reasoned that the Public Health Service Act's examples of the "kinds of measures that could be necessary" to prevent the spread of communicable diseases "informs the grant of authority." *Alabama Ass'n of Realtors*, 141 S. Ct. at 2488. Those examples encompass pasteurization. The statute expressly permits "disinfection" and "sanitation" of "articles found to be so infected or contaminated as to be sources of dangerous infection to human beings." *See* 42 U.S.C. § 264(a). Pasteurization of butter's ingredients is a method to "disinfect[]" and "sanit[ize]" butter, an "article" that otherwise risks spreading *Listeria*, *Salmonella*, *Staphylococcus*, and *E. coli*. *See Disinfect*, Webster's New International Dictionary of the English Language 748 (2nd ed. 1942) ("To free from infection, esp. by destroying disease germs or other harmful microorganisms."); *Disinfected*, Black's

Law Dictionary 590 (3d ed. 1933) ("Made free from injurious or contagious diseases."); *Sanitation*, Black's Law Dictionary 1581 (3d ed. 1933) ("Devising and applying of measures for preserving and promoting public health; removal or neutralization of elements injurious to health[.]").

Prohibiting the interstate sale of raw cream butter is also akin to other measures that FDA has taken to prevent the spread of communicable diseases. *See Alabama Ass'n of Realtors*, 141 S. Ct. at 2487 (citing 40 Fed. Reg. 22,543 (May 23, 1975) (banning small turtles known to be carriers of *Salmonella*)); *see also* 21 C.F.R. § 1240.60 (establishing sanitation requirements for molluscan shellfish); *id.* § 1240.61 (requiring pasteurization of milk and milk products); *id.* § 1240.75 (requiring heat treatment of food waste used to feed swine); *id.* § 1240.65 (limiting transportation of parrots). Accordingly, FDA properly relied on the Public Health Service Act for authority to retain its regulations prohibiting the interstate sale of raw cream butter. *See* JA 460–61.

### B. The FDCA Does Not Prevent FDA From Regulating Butter Under The Public Health Service Act

McAfee did not dispute before the agency or in district court that the Public Health Service Act, by its terms, authorizes FDA to prohibit the distribution of raw cream butter in interstate commerce. Instead, he argued that provisions of a different statute, the FDCA, prevent FDA from requiring pasteurization under the Public Health Service Act. Specifically, McAfee noted that while the FDCA generally authorizes FDA to create definitions and standards of identity for food products to "promote honesty and fair dealing in the interest of consumers," 21 U.S.C. § 341, there is an exception for butter, *id.*, which instead is defined by statute, *id.* § 321a. Because FDA did not amend the standard of identity for butter, the district court correctly rejected these arguments. *See* JA 80–84.

**1.** Standards of identity provide legal definitions for food products by describing their basic nature and essential characteristics. *See* 70 Fed. Reg. at 29,216; JA 462. Standards of identity typically "fix the ingredients" of the product. *62 Cases, More or Less, Each Containing Six Jars of Jam v. United States*, 340 U.S. 593, 598 (1951); JA 461. For

example, the standard of identity for "fruit jam" lists the minimum amount of fruit and sugar that jam must contain. *See* 70 Fed. Reg. at 29,216 (citing 21 C.F.R. § 150.160).

Standards of identity also may "describe the manufacturing process when that process has a bearing on the identity of the finished food." 70 Fed. Reg. at 29,216; JA 462 n.4. For example, the standards of identity for various cheeses specify manufacturing processes to distinguish one cheese from another, because those products "owe their distinctive characteristics to the manner in which they are produced." *See* 70 Fed. Reg. at 29,216 (citing 21 C.F.R. pt. 133). "Cottage cheese," for instance, is "soft uncured cheese prepared by mixing cottage cheese dry curd with a creaming mixture." 21 C.F.R. § 133.128(a).

Products that do not conform to these standards may still be sold to consumers, just not under the product's standardized name. *See* 70 Fed. Reg. at 29,216; 21 U.S.C. § 343(g) (misbranding). For example, a fruit product with too little fruit or sugar may not be sold as "fruit jam," but it may be sold as "fruit topping." 70 Fed. Reg. at 29,216. Standards of identity thus ensure that consumers receive the product they "expected to receive when purchasing a product with the name under

which it was sold." *See Federal Sec. Adm'r v. Quaker Oats Co.*, 318 U.S. 218, 230–31 (1943) (explaining that standards of identity "eliminate a source of confusion" among consumers who may have difficulty "determin[ing], solely on the basis of informative labeling, the relative merits of a variety of products superficially resembling each other"); *see also Nemphos v. Nestle Waters N. Am., Inc.*, 775 F.3d 616, 621–22 (4th Cir. 2015) (similar).

**2.** McAfee claims (at 24–28) that FDA amended the standard of identity for butter by changing the ingredients of butter to include only pasteurized milk or cream. But the pasteurization requirement does not add to or subtract from the ingredients that constitute butter. By statute, "butter" is "made exclusively from milk or cream." 21 U.S.C. § 321a. Pasteurized milk and cream are still milk and cream. Nor does the pasteurization requirement impose a manufacturing process that "has a bearing on the identity of the finished food." *See* 70 Fed. Reg. at 29,216. Pasteurization may be a manufacturing process, but it is not one that gives butter its distinctive characteristics; pasteurization simply makes butter safer by heating its ingredients to kill bacteria that otherwise risk spreading communicable diseases. *See* JA 460.

FDA has never purported to change butter's statutory definition or create a standard of identity for butter, whether to include a pasteurization requirement or otherwise. Instead, FDA invoked the Public Health Service Act to prohibit the interstate sale of raw cream butter. 52 Fed. Reg. at 29,510, 29,514; 57 Fed. Reg. at 57,344; 62 Fed. Reg. at 51,521. That is entirely consistent with FDA's food safety mission. And while FDA required pasteurization of milk and cream in 1973 as part of those products' standards of identity, 38 Fed. Reg. at 27,924–29, it took a different course when it required pasteurization for all milk products in 1987, 52 Fed. Reg. at 29,510, 29,514, determining that the Public Health Service Act provided a "more uniform and efficient regulatory mechanism than a standard of identity proceeding." *See Public Citizen II*, 653 F. Supp. at 1233; *supra* pp. 6–9.

FDA also has not created a de facto standard of identity for butter. FDA does not create a standard of identity every time it requires a manufacturing process. Often a manufacturing process will have no bearing on a product's identity, as is the case for butter, which does not "owe [its] distinctive characteristics" to the pasteurization of its ingredients. *See* 70 Fed. Reg. at 29,216. And even if pasteurization

could be required as part of a standard of identity (as with milk and cream), FDA is free to use different tools to accomplish its objectives, provided that the chosen option is "authorized by the agency's organic statutes." *See Friends of Animals v. Bernhardt*, 961 F.3d 1197, 1208–09 (D.C. Cir. 2020). Congress gave FDA multiple tools to create manufacturing requirements, many of which can be used to safeguard public health. *See, e.g.*, 21 U.S.C. § 341 (standards of identity); *id.* § 342 (adulterated foods); *id.* § 350g (food hazards); *id.* § 350h (produce safety); *id.* § 371 (authority to promulgate regulations for efficient enforcement of the FDCA); 42 U.S.C. § 264(a) (Public Health Service Act). "That there is overlap" among these "provisions is not surprising," and the agency may "pick the enforcement mechanism" that best fits the situation. *See DeNaples v. Office of Comptroller of Currency*, 706 F.3d 481, 487 (D.C. Cir. 2013); *Helicopter Ass'n Int'l, Inc. v. Federal Aviation Admin.*, 722 F.3d 430, 434–35 (D.C. Cir. 2013). Just because FDA uses one authority does not mean it simultaneously uses them all.

McAfee's reliance (at 25–27) on the Supreme Court's decision in *Quaker Oats* is thus misplaced. *Quaker Oats* upheld FDA's regulation establishing standards of identity for "farina" and "enriched farina," two

highly refined wheat products resembling flour. 318 U.S. at 224. The standards of identity listed ingredients for "farina" that did not include vitamin D, and included vitamin D along with other vitamins as ingredients in "enriched farina." *Id.* at 222–23. The Court held that a product with only vitamin D could not be sold as either "farina" or "enriched farina" because the addition or omission of ingredients rendered the product inconsistent with its standard of identity. *Id.* at 224. The Court did not suggest that a manufacturing process necessarily turns one ingredient into another. Nor did it imply that FDA creates a standard of identity whenever it requires a manufacturing process in the interest of public health.

**3.** Relatedly, McAfee argues that the pasteurization requirement conflicts with the statutory definition of butter. But Congress did not specify the method of production for butter as part of the definition. *See* 21 U.S.C. § 321a. It required that butter be made from "milk or cream," which, as noted, can be either pasteurized or unpasteurized. *See id.*; *supra* p. 25. McAfee urges (at 27) that milk and cream would not have been "presume[d]" to be pasteurized when Congress defined butter in 1923, but neither would those ingredients have been understood to be

unpasteurized: As McAfee acknowledges (at 27 n.50), pasteurization of milk and cream was increasing as early as 1915. JA 463. In short, raw cream butter is still "butter"—it just cannot be sold in interstate commerce for reasons unrelated to the standard of identity. *See* JA 82 (rejecting the "false premise" of McAfee's argument "that the pasteurization rule works a change to butter's standard of identity").

McAfee's own recitation of the history and motivation for the statutory standard of identity underscores the errors in his argument: As McAfee points out (at 18, 21), Congress was concerned about whether oleomargarine could be treated as butter despite the absence of milk and cream, or whether the Executive Branch could regulate the fat content of butter. Congress thus required that butter be made from milk and cream, with or without salt and coloring, and with at least 80 percent milk fat. 21 U.S.C. § 321a. The pasteurization requirement does not disturb that definition of "butter," and McAfee's hypotheticals (at 32) that contradict the statutory definition by prohibiting unsalted butter or changing the required fat content are far afield from this case.

**4.** McAfee also argues (at 47) that FDA cannot regulate products like butter under the Public Health Service Act because it cannot create

a standard of identity for them under the FDCA. In his view, the FDCA is the more specific statute and so should control the scope of FDA's authority under the Public Health Service Act.

A court faced with two statutes "allegedly touching on the same topic" must "strive to give effect to both." *Epic Sys. Corp. v. Lewis*, 138 S. Ct. 1612, 1624 (2018) (quotation marks omitted). McAfee thus bears "the heavy burden of showing a clearly expressed congressional intention" that the FDCA displaces the agency's authority under the Public Health Service Act to regulate butter. *See id.* (quotation marks omitted). And the rule McAfee invokes, that "specific statutory language should control more general language when there is a conflict between the two," does not apply when "there is no conflict." *See National Cable & Telecomms. Ass'n v. Gulf Power Co.*, 534 U.S. 327, 335–36 (2002) ("The specific controls but only within its self-described scope."); *Adirondack Med. Ctr. v. Sebelius*, 740 F.3d 692, 698–99 (D.C. Cir. 2014) (similar).

The district court correctly determined that there is no conflict here between two separate statutes that serve different purposes. *See* JA 81–82; *Radzanower v. Touche Ross & Co.*, 426 U.S. 148, 157 (1976).

The Public Health Service Act and the FDCA do not even "touch[] on the same topic." *See Epic Sys. Corp.*, 138 S. Ct. at 1624. The purpose of the Public Health Service Act is to "prevent[] the interstate spread of disease." *See Alabama Ass'n of Realtors*, 141 S. Ct. at 2488. In contrast, standards of identity ensure that consumers receive the product they "expected to receive when purchasing a product with the name under which it was sold." *See Quaker Oats*, 318 U.S. at 230–31. It is possible to "give effect to each" statute while "preserving their sense and purpose": FDA can regulate butter to prevent the spread of communicable diseases, even if it cannot define butter to ensure that consumer expectations are met. *See Watt v. Alaska*, 451 U.S. 259, 267 (1981).

This Court recently rejected a similar attempt to "apply limiting constructions to provisions plainly granting [an agency] broad authority to act by drawing on entirely separate provisions" in the U.S. Code. *See Corbett v. Transportation Sec. Admin.*, 19 F.4th 478, 489 (D.C. Cir. 2021). *Corbett* held that the Transportation Security Administration's broad statutory authority to ensure transportation security allowed it to require that masks be worn in airports, on commercial aircraft, and on

surface transportation. *Id.* at 486. This Court rejected petitioner's argument that these "broad grants of authority" were "constrained" by other statutory provisions related to, *e.g.*, passenger screening: "There is no viable canon of construction that endorses this interpretive approach." *Id.* at 489.

Moreover, the FDCA elsewhere makes clear that FDA can regulate butter safety even though it cannot define butter. Congress authorized FDA to control "adulterated" foods that may be "injurious to health" or "unfit for food"—including "butter" that is "unfit for food." 21 U.S.C. § 342(a), (e); *id.* § 371 (authorizing the agency to "promulgate regulations for the efficient enforcement" of the Act); *see Public Citizen I*, 602 F. Supp. at 613 (recognizing that "the [FDCA's] provisions for the control of adulterated foods," in addition to the Public Health Service Act, give FDA "legal authority" to require pasteurization). Congress did the same for fruits and vegetables that likewise are exempt from FDA's definitional authority. *See* 21 U.S.C. § 341 (prohibiting standards of identity for most fresh or dried fruits and vegetables); *id.* § 350h (requiring FDA to create "minimum standards for the safe production and harvesting" of raw "fruits and vegetables" to "minimize the risk of

serious adverse health consequences or death"). And more generally, the FDCA "as a whole was designed primarily to protect consumers from dangerous products." *United States v. Sullivan*, 332 U.S. 689, 696 (1948). It is implausible that Congress intended in the FDCA to prevent FDA from regulating butter for public health purposes when, in that very statute, Congress expressly authorized FDA to regulate butter for public health purposes.

Because there is no conflict between the Public Health Service Act and the FDCA, McAfee's remaining citations are inapposite. For instance, he notes (at 47) that the Public Health Service Act should not be construed as "affecting, modifying, repealing, or superseding" the provisions of the FDCA, 42 U.S.C. § 262(g), but requiring pasteurization does not conflict with any provision of that Act. *See supra* pp. 25–33.

**5.** McAfee warns (at 30–32, 44–48) that FDA's interpretation would lead to serious consequences, allowing FDA to evade procedural requirements for amending standards of identity, revise the statutory definition of butter, and ban any unprocessed food from interstate commerce. He argues (at 31–32) that the provisions governing standards of identity must carry meaningful regulatory consequences.

These concerns are overstated. The Public Health Service Act provides authority to make and enforce regulations only where "necessary" to prevent the spread of communicable diseases. 42 U.S.C. § 264(a). That authority is further informed by the Act's examples of the "kinds of measures that could be necessary," which, like pasteurization, "directly relate to preventing the interstate spread of disease by identifying, isolating, and destroying the disease itself." *Alabama Ass'n of Realtors*, 141 S. Ct. at 2488. Decisions under that authority are subject to arbitrary and capricious review. 5 U.S.C. § 706(2)(A). In the vast majority of cases, no action will be necessary to prevent the spread of communicable diseases, and the two regulatory regimes will not overlap. But where, as here, a particular food product threatens to spread communicable diseases, FDA may regulate the distribution of that product, regardless of how it otherwise is defined by statute or regulation. *See Corbett*, 19 F.4th at 489 (rejecting similar argument that authority to issue security regulations would grant "essentially unlimited" power to agency).

Furthermore, McAfee provides no support for his assertion (at 31) that FDA could issue new regulations without providing notice and an

opportunity to comment. The Administrative Procedure Act requires notice and comment unless an exception applies. 5 U.S.C. § 553. Indeed, the underlying regulations at issue in this case were issued following notice and comment. 52 Fed. Reg. at 29,510; 57 Fed. Reg. at 57,343.

McAfee's reliance (at 31–32) on this Court's decision in *Genus Medical Technologies, LLC v. FDA*, 994 F.3d 631 (D.C. Cir. 2021), is misplaced. There, this Court held that because the FDCA's definition of "device" was "encompassed by, but narrower than," the definition of "drug," and because drugs and devices were subject to different regulatory schemes, FDA could not regulate as drugs those products that qualified as devices. *Id.* at 638. The Court was concerned that FDA claimed discretion to choose how to regulate a product that fit both definitions, when the two schemes created mandatory, incongruent regulatory requirements. The case did not suggest that there could not be two distinct, but overlapping, statutory schemes conferring different authority for different purposes that might happen to affect the same product. Unlike in *Genus*, there is no need to select one of two competing regulatory pathways for butter, given that butter made from

pasteurized milk and cream complies with both the statutory definition of butter and FDA's pasteurization requirement.

McAfee also ignores the consequences of his approach. McAfee's position would upend FDA's ability to ensure the safety of any product that is exempt from the agency's authority to create standards of identity. *See* 21 U.S.C. § 341 (exempting butter and most fresh or dried fruits and vegetables). McAfee does not explain why, in his view, requiring pasteurization is beyond FDA's statutory authority but requiring other manufacturing processes "to ensure safe production of raw butter" would not be, Br. 47. By his logic, any production rules would create a standard of identity by changing butter's ingredients from "milk and cream" to "safely processed milk and cream." That interpretation likewise would call into question myriad regulations that ensure the safety of fruits and vegetables by setting standards for their growing, harvesting, packing, and holding. *See, e.g.*, 21 C.F.R. pt. 112; *id.* § 112.142(e) (invoking the Public Health Service Act and the FDCA to require that seeds used to grow sprouts be treated in order to destroy dangerous microorganisms). Under his view, such production

requirements would create standards of identity for fruits and vegetables, contrary to the FDCA's exemption for those products.

At a minimum, FDA's interpretation of its statutory authority is reasonable and entitled to deference. *See Pharmaceutical Research & Mfrs. of Am. v. Federal Trade Comm'n*, 790 F.3d 198, 206 (D.C. Cir. 2015) (citing *City of Arlington v. Federal Commc'ns Comm'n*, 569 U.S. 290, 296–97 (2013)) ("[A]s the Supreme Court has made clear, a court must defer under *Chevron* to an agency's reasonable interpretation of a statutory ambiguity that concerns the scope of the agency's statutory authority."). FDA reasonably interpreted the Public Health Service Act to authorize the agency to prohibit the interstate sale of raw cream butter. *See* JA 460–61; *supra* pp. 18–22. FDA also reasonably interpreted the FDCA not to conflict with or curtail the agency's Public Health Service Act authority to regulate butter, concluding that the pasteurization requirement does not establish a standard of identity for butter under the FDCA. *See* JA 461–62; *Mylan Labs., Inc. v. Thompson*, 389 F.3d 1272, 1279–80 (D.C. Cir. 2004) (deferring to FDA's interpretation of the FDCA); *supra* pp. 23–37.

## II. McAfee Forfeited His Remaining Arguments, Which Are In Any Event Without Merit

McAfee's remaining arguments are not properly presented on appeal and are in any event meritless.

**A.** McAfee contends (at 41) for the first time on appeal that the Public Health Service Act does not provide "a grant of freestanding agency jurisdiction to regulate dairy products." But McAfee did not present this argument in his petition for rulemaking or in his summary judgment briefing. Instead, McAfee's only argument regarding the agency's statutory authority was the one discussed above: that provisions in the FDCA limit FDA's authority under the Public Health Service Act to regulate butter. *See* JA 98–102 (petition); SA 15–20 (district court brief); JA 79 (recognizing that McAfee did "not dispute that, on its own, the [Public Health Service Act] would seem to give the FDA authority to mandate pasteurization").

This argument is thus doubly forfeited. Arguments cannot be raised in court without first being raised in agency proceedings, and "agencies have no obligation to anticipate every conceivable argument about why they might lack … statutory authority." *Koretoff v. Vilsack*, 707 F.3d 394, 398 (D.C. Cir. 2013) (per curiam). Particularly given that

this case arises from a petition to rescind a rule, FDA surely was under no obligation to rescind its rule for reasons that were never expressed to it. *See Professional Drivers Council v. Bureau of Motor Carrier Safety*, 706 F.2d 1216, 1217 n.2 (D.C. Cir. 1983) (limiting judicial review of substantive challenges to the "narrow issues as defined by the denial of the petition for rulemaking"). And in addition, "[a]bsent exceptional circumstances, a party forfeits an argument by failing to press it in district court." *Government of Manitoba v. Bernhardt*, 923 F.3d 173, 179 (D.C. Cir. 2019).

McAfee's belated argument is in any event without merit. As discussed above, the Public Health Service Act broadly authorizes FDA to "make and enforce such regulations as in [its] judgment are necessary to prevent the … spread of communicable diseases." 42 U.S.C. § 264(a); *see supra* pp. 18–22. That language squarely authorizes requirements like pasteurization that "directly relate to preventing the interstate spread of disease by identifying, isolating, and destroying the disease itself." *See Alabama Ass'n of Realtors*, 141 S. Ct. at 2488. The Public Health Service Act's text does not include an exception for butter, much less for all dairy products. Nor does McAfee

identify language in the statute that means "one thing today" but "might have meant something else at the time of its adoption." *See Bostock v. Clayton County*, 140 S. Ct. 1731, 1750 (2020).

Instead, McAfee argues that Congress would have been surprised by a ban on raw cream butter in 1944. But "'in the context of an unambiguous statutory text,' whether a specific application was anticipated by Congress 'is irrelevant.'" *Bostock*, 140 S. Ct. at 1751. "[M]any, maybe most, applications" of a statutory provision with "broad language" may have been "'unanticipated' at the time of the law's adoption." *Id.* at 1752. By delegating authority in this area, Congress recognized that it could not foresee every public health threat that might arise. Instead, Congress empowered the agency to address those threats as scientific developments reveal both new problems and new solutions. "[W]hen Congress delegates broad authority to an agency to achieve a particular objective, agency action pursuant to that delegated authority may extend beyond the specific manifestations of the problem that prompted Congress to legislate in the first place." *Corbett*, 19 F.4th at 488 (quoting *Cablevision Sys. Corp. v. Federal Commc'ns Comm'n*, 649 F.3d 695, 707 (D.C. Cir. 2011)).

Thus, regardless of Congress's expectations in 1944, prohibiting the interstate sale of raw cream butter falls squarely within FDA's statutory authority to prevent the spread of communicable diseases. *See supra* pp. 18–22. At most, McAfee's argument suggests that it might have been arbitrary and capricious to require pasteurization in 1944, which does not suggest that the statute provides no such authority but instead provides an alternative explanation for why the agency did not do so until scientific evidence and common practices evolved. And in any case, a ban on the interstate sale of raw cream butter may not have surprised Congress as much as McAfee suggests. *See Natural Milk Producers Ass'n v. City & County of San Francisco*, 317 U.S. 423, 423–24 (1943) (per curiam) (recognizing that by 1939, all milk sold in San Francisco was required to be pasteurized).

**B.** McAfee next argues (at 42–43) that the Public Health Service Act prohibits the Secretary of Health and Human Services from delegating regulatory authority to FDA. This argument, too, has not been previously raised and is doubly forfeited. *See* JA 98–102 (petition); SA 15–20 (district court brief); JA 79.

It is also mistaken on the merits. McAfee has no basis whatsoever to challenge the 1987 regulation requiring pasteurization of milk and milk products, which he concedes (at 43 n.69) that the Secretary of Health and Human Services signed. *See* 52 Fed. Reg. at 29,514. The Secretary's personal approval of that rule renders irrelevant any dispute about whether FDA could have relied on a delegation of authority, and there is no basis for McAfee's suggestion—without citation—that the Secretary was "simply reaffirming his delegation to FDA." The 1992 regulation was merely a clarification that the prior regulation, signed by the Secretary, extended to butter. *See* 57 Fed. Reg. at 57,343 (making "explicit that which was implicit in the original rule").

Regardless, on its own terms, McAfee's cursory challenge relies on the fact that the provision that originally authorized the delegation of certain powers by the Surgeon General to officials in the Public Health Service—which now refers to the Secretary of Health and Human Services—contains an exception for "the making of regulations." *See* 42 U.S.C. § 203. But the reorganization plan that transferred the Surgeon General's functions to the Secretary—which was ratified by Congress—

authorized the Secretary to delegate "any" of those functions to "any" agency of the Department. *See* 31 Fed. Reg. at 8855 (transferring functions of the Surgeon General to the Secretary of Health, Education, and Welfare and authorizing the Secretary to "make such provisions as he shall deem appropriate authorizing the performance of any of the functions transferred to him … by any officer, employee, or agency … of the Department of Health, Education, and Welfare"); Pub. L. No. 96-88, § 509, 93 Stat. at 695 (redesignating the Secretary of Health, Education, and Welfare as the Secretary of Health and Human Services); Pub. L. No. 98-532, § 1, 98 Stat. at 2705 (ratifying past reorganization plans). McAfee does not identify any infirmity in that reorganization plan or in the subsequent delegation of authority to FDA. *See* 65 Fed. Reg. at 49,907 (retaining FDA's delegated "regulatory authority … with respect to animals and other products that may transmit or spread communicable diseases"); 21 C.F.R. § 1240.30 (authorizing FDA to "take such measures to prevent such spread of [communicable] diseases as he deems reasonably necessary"). Nor does McAfee identify any court that has ever questioned this longstanding delegation to FDA (or the

Secretary's similar delegation to the Centers for Disease Control and Prevention, 65 Fed. Reg. at 49,906).[2]

**C.** In his Opening Brief, McAfee identifies (at 3) two issues for appeal: whether FDA exceeded its statutory authority and whether FDA's decision was arbitrary and capricious. He forfeited the second issue by failing to develop the argument in his Opening Brief. *See City of Waukesha v. Environmental Prot. Agency*, 320 F.3d 228, 250 n.22 (D.C. Cir. 2003) (per curiam) (holding that arguments "raised in the opening brief only summarily, without explanation or reasoning," are forfeited); *Haughton v. District of Columbia*, 819 F. App'x 1, 3 (D.C. Cir. 2020) (holding that argument included in "statement of issues" was "forfeited" where appellant "failed to develop it in the body of his brief"). McAfee invokes (at 44–48) arbitrary and capricious review only to support his statutory argument that the FDCA limits FDA's authority under the Public Health Service Act: In his view, such "highly

[2] Constitutional arguments raised by amicus Pacific Legal Foundation also were not raised by McAfee before the agency, the district court, or this Court, and are not properly presented on appeal. *See MetLife, Inc. v. Financial Stability Oversight Council*, 865 F.3d 661, 666 n.4 (D.C. Cir. 2017) (amicus may not "expand an appeal's scope to sweep in issues that a party has waived").

deferential" review is not an adequate "check" on FDA's Public Health Service Act authority. McAfee does not, however, argue that FDA's decision should be overturned as arbitrary and capricious.

In any case, FDA's denial of McAfee's rulemaking petition was not arbitrary and capricious. The denial was based on a wealth of evidence that pasteurization of butter's dairy ingredients prevents the spread of communicable diseases. *See supra* pp. 18–20. That decision was "reasonable and reasonably explained." *See Department of Commerce v. New York*, 139 S. Ct. 2551, 2571 (2019). FDA "examined the data before it, considered alternatives in light of the comments received and its statutory mandate, and offered reasoned explanations for both its conclusion and its rejection of viable alternatives." *See Hispanic Affairs Project v. Acosta*, 901 F.3d 378, 395 (D.C. Cir. 2018). FDA is entitled to substantial deference for its "scientific analysis of the evidence before it." *See Pharmaceutical Mfg. Research Servs., Inc. v. FDA*, 957 F.3d 254, 262 (D.C. Cir. 2020).

On appeal, McAfee criticizes (at 44–46) just one element of FDA's decision: its reliance on a list of outbreaks linked to butter. McAfee notes (at 45) that the list did not indicate whether the butter at issue in

each outbreak was made from unpasteurized milk or cream. But McAfee ignores the purpose of this table, which FDA provided in response to McAfee's argument that "*all butter* … poses a very low risk of foodborne illness." *See* JA 90, 103, 463 (emphasis added). The table provides ample basis to reject that assertion. *See* JA 463, 476. And as the district court recognized, the list of outbreaks "was just one source of evidence" that FDA relied on to deny McAfee's petition. JA 91; *see* JA 462–74 (considering the scientific evidence and rejecting McAfee's arguments). The agency "also rested its denial on numerous studies that showed how raw butter could host pathogens in high enough levels to be dangerous or that linked outbreaks to other raw dairy products." JA 91.[3]

More fundamentally, McAfee has not presented a "compelling cause" to overturn FDA's decision not to initiate rulemaking, such as a "fundamental change in the factual premises" underlying FDA's longstanding regulations. *See WildEarth Guardians v. U.S. Envtl. Prot.*

[3] Coalition amici are wrong (at 11) to suggest that FDA relied solely on the district court's decision in *Public Citizen II* to justify the pasteurization requirement. In any case, their arguments are all made in support of an arbitrary and capricious challenge that has not been properly presented on appeal. *See supra* pp. 44–45.

*Agency*, 751 F.3d 649, 653 (D.C. Cir. 2014) (quoting *National Customs Brokers & Forwarders Ass'n of Am. v. United States*, 883 F.2d 93, 97 (D.C. Cir. 1989)). "[L]ess than perfect" data is not grounds to overturn FDA's decision as arbitrary and capricious. *See Hispanic Affairs Project*, 901 F.3d at 392 (quoting *District Hosp. Partners, L.P. v. Burwell*, 786 F.3d 46, 61 (D.C. Cir. 2015)). Under these circumstances, "[r]eweighing even a mixed bag of scientific evidence is inappropriate when there is plenty to support the agency's decision." JA 92.

## CONCLUSION

The judgment of the district court should be affirmed.

Respectfully submitted,

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## CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 9,171 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Microsoft Word 2016 in Century Schoolbook 14-point font, a proportionally spaced typeface.

*/s/ Cynthia A. Barmore*
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## CERTIFICATE OF SERVICE

I hereby certify that on February 7, 2022, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the District of Columbia Circuit by using the appellate CM/ECF system. Service will be accomplished by the appellate CM/ECF system.

*/s/ Cynthia A. Barmore*
Cynthia A. Barmore

# ADDENDUM

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**42 U.S.C. § 264. Regulations to control communicable diseases**

**(a). Promulgation and enforcement by Surgeon General**

The Surgeon General, with the approval of the Secretary, is authorized to make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. For purposes of carrying out and enforcing such regulations, the Surgeon General may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in his judgment may be necessary.

….

**21 U.S.C. § 341. Definitions and standards for food**

Whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, or reasonable standards of fill of container. No definition and standard of identity and no standard of quality shall be established for fresh or dried fruits, fresh or dried vegetables, or butter, except that definitions and standards of identity may be established for avocadoes, cantaloupes, citrus fruits, and melons. In prescribing any standard of fill of container, the Secretary shall give due consideration to the natural shrinkage in storage and in transit of fresh natural food and to need for the necessary packing and protective material. In the prescribing of any standard of quality for any canned fruit or canned vegetable, consideration shall be given and due allowance made for the differing characteristics of the several varieties of such fruit or vegetable. In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the Secretary shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on

the label. Any definition and standard of identity prescribed by the Secretary for avocadoes, cantaloupes, citrus fruits, or melons shall relate only to maturity and to the effects of freezing.

**21 C.F.R. § 1240.61. Mandatory pasteurization for all milk and milk products in final package form intended for direct human consumption.**

(a) No person shall cause to be delivered into interstate commerce or shall sell, otherwise distribute, or hold for sale or other distribution after shipment in interstate commerce any milk or milk product in final package form for direct human consumption unless the product has been pasteurized or is made from dairy ingredients (milk or milk products) that have all been pasteurized, except where alternative procedures to pasteurization are provided for by regulation, such as in part 133 of this chapter for curing of certain cheese varieties.

….