ORAL ARGUMENT SET FOR APRIL 8, 2022

Appeal No. 21-5170

United States Court of Appeals for the District of Columbia Circuit

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

Plaintiffs–Appellants,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION,

Defendants–Appellees.

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

Case No. 1:19-cv-03161-RC

REPLY BRIEF OF APPELLANTS MARK MCAFEE & FARM-TO-CONSUMER LEGAL DEFENSE FUND

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Certificate as to Parties, Rulings, and Related Cases

Under D.C. Circuit Rule 28(a)(1), Appellants certify as follows:

A. Parties and Amici

The parties before the district court and in this Court are:

1. Mark McAfee (Plaintiff-Appellant).

2. Farm-to-Consumer Legal Defense Fund—Plaintiff-Appellant Farm-to-Consumer is a Virginia-based grassroots non-profit and §501(c)(4) entity under the Internal Revenue Code. Farm-to-Consumer advocates for the rights of farmers and consumers, with small farm and consumer members nationwide. Farm-to-Consumer has no parent, and no publicly-held company has a 10%-or-greater ownership interest in Farm-to-Consumer.

3. U.S. Food and Drug Administration (Defendant-Appellee).

No amici or intervenors appeared in the district court.

In this Court, the following groups of amici have appeared and filed amicus briefs: (1) the Pacific Legal Foundation; and (2) the Weston A. Price Foundation, Farm & 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 are the final judgment, order, and opinion entered on May 24, 2021 by Judge Rudolph Contreras of the

United States District Court for the District of Columbia. An official reporter citation for Judge Contreras's May 24, 2021 opinion now exists: **541 F. Supp. 3d 21** (D.D.C. 2021). The opinion is also available at 2021 WL 2073402 and 2021 U.S. Dist. LEXIS 97331.

C. Related Cases

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

Respectfully submitted,

Dated: March 11, 2022

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APA	Administrative Procedure Act
DDC	U.S. District Court for the District of Columbia
CDC	Centers for Disease Control and Prevention (U.S.)
EPA	Environmental Protection Agency (U.S.)
FDA	Food and Drug Administration (U.S.)
FDCA	Food, Drug, and Cosmetic Act
FRAP	Federal Rules of Appellate Procedure
HHS	Department of Health and Human Services (U.S.)
USDA	U.S. Department of Agriculture
TSA	Transportation Security Agency (U.S.)

Introduction

When FDA says that a food must be made from a particular ingredient, FDA imposes a standard of identity.

So if FDA were to say that tortillas must be made from corn sprayed with pesticides, FDA would impose a standard of identity for tortillas. This is true regardless of the mandate's objective—for instance, an FDA belief that pesticide-treated corn generally helps to prevent the transmission of communicable diseases. And this is true regardless of the mandate's indirect incorporation of a required manufacturing process (spraying pesticide on corn).

FDA says that butter must be "made from dairy ingredients (milk or milk products) that have all been pasteurized." 21 C.F.R. §1240.61(a). This is a standard of identity for butter, no different from requiring tortillas to be made from pesticide-treated corn. The mandate's intent (prevention of disease transmission) does not change this. Nor does the mandate's indirect incorporation of a required manufacturing process (pasteurization).

FDA's pasteurization mandate for butter (or raw-butter ban) then violates the Food, Drug, and Cosmetic Act. The FDCA states: "[n]o definition and standard of identity … shall be established for … butter." 21 U.S.C. §341. FDA's mandate also violates the Butter Standards Act, which Congress has folded into the FDCA. The Act permits trade in butter "made" from any kind of "milk or cream"—not just *pasteurized* milk or cream. 21 U.S.C. §321a.

These violations explain why FDA's raw-butter ban rests solely on the Public Health Service Act. The Act gives the Surgeon General (whose powers the FDA has inherited) the authority to "provide for … disinfection, sanitation, [and] pest extermination." 42 U.S.C. §264(a). Deeming pasteurization a form of disinfection or sanitation, FDA argues the Act independently enables FDA to say that butter must be made from pasteurized dairy ingredients.

But the Public Health Service Act also directs that "nothing" in the Act "shall be construed as **in any way** affecting, modifying, repealing, or superseding the provisions of the … Food, Drug, and Cosmetic Act." 42 U.S.C. §262(g). Reading the Public Health Service Act as FDA urges would mean that the Act supersedes the FDCA's butter-standard prohibition and the Butter Standards Act's express allowance of butter made from any kind of milk or cream.

FDA's view of the Public Health Service Act also has no limits. Under this view—and contrary to the FDCA—FDA may address the numerous produce outbreaks that FDA has catalogued for years by banning the relevant fruits and vegetables unless cooked (assuring disinfection). FDA admits this, stating if a "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**." FDA.Br.33 (bold added).

This incredible claim, on par with FDA's raw-butter ban, defies the rule of law. The Court should not let either stand.

Argument

I. Raw butter is safe and can be made safely.

Raw butter is butter made from milk or cream that has not been pasteurized. Consumers enjoy raw butter—and farmers like Mark McAfee take pride in making it—because, unlike pasteurized butter, raw butter is "rich in flavor, vitamins, healthy fats, and a naturally 'bright yellow color' from grass-grazing." McAfee.Br.7.

Raw butter is also how farmers and civilizations have made butter for millennia. McAfee.Br.15-16. "Up to the late nineteenth century, cream was separated from raw milk by standing raw milk overnight in bowls. This cream was then separated and churned in wooden bowls without pasteurization." JA.124.

For over two centuries, Americans have safely produced and eaten billions of pounds of raw butter. McAfee.Br.16-17. Modern technology and pathogen testing, in turn, have made raw butter even safer. McAfee's dairy uses distinct lot identifiers to accurately track every batch of milk that goes into raw butter and to further link each batch to the relevant test results. McAfee.Br.6.

McAfee's dairy has subsequently "sold over 2 million pounds of [raw] butter since 2001" without any record of foodborne illness. JA.104. FDA does not dispute this—or the fact that 11 states allow raw butter, including California, which has protected raw butter by law for nearly 60 years without incident. McAfee.Br.7.

FDA nevertheless asserts that raw butter "threatens to spread communicable diseases." FDA.Br.34. But an online FDA database collecting "foodborne outbreaks reported to the CDC since 1998" fails to reveal "even one outbreak" tied "to commercially prepared raw butter during that time period." JA.103-04.

By contrast, in 2018, infected romaine lettuce killed 5 people. Weston.Amici.Br.14. In 2006, infected spinach killed 3 and left 31 with kidney failure. *Id.* And in 2011, infected cantaloupe killed 33. *Id.* FDA did not, however, ban any of these raw foods.

Why, then, has FDA banned interstate commerce in raw butter, millions of pounds of which have been eaten nationwide without a single modern outbreak linked to a commercial producer? The short answer is: because FDA has long believed it can.

From this follows FDA's effort to malign McAfee for "repeated violations of the FDCA and FDA regulations." FDA.Br.9. FDA omits that the regulations concerned labeling and interstate sales. *United States v. Organic Pastures Dairy Co.*, 708 F. Supp. 2d 1005, 1016 (E.D. Cal. 2010). FDA made no showing in *Organic Pastures* that McAfee's products were "adulterated" or "harm … the public." *Id.*

McAfee thereafter petitioned FDA to end its unjust raw-butter ban. JA.94-117. FDA now responds with the "persistent if unspoken message" of "the 'practical advantages' of ignoring the written law." *McGirt v. Oklahoma*, 140 S. Ct. 2452, 2474 (2020). But that is "not the rule of law," as the following analysis shows. *Id.*

II. FDA has many tools for ensuring food safety, but FDA cannot use tools that Congress has expressly withheld from FDA (like a standard of identity for butter).

Congress enacted the Food, Drug, and Cosmetic Act (FDCA)—the heart of FDA's jurisdiction—both to "promot[e] honesty and fair dealing" and to "**safeguard the public health**." H.R. REP. NO. 2139 (75th Cong.) at 2 (1938). In this regard, Congress has granted FDA a wide variety of tools for ensuring food safety nationwide.

One of these tools is emergency permit controls. FDCA, §404, 52 Stat. 1048 (codified at 21 U.S.C. §344). Covering "any class of food," this tool allows FDA to ensure food safety by establishing "conditions governing the manufacture, processing, or packing of … food, for such temporary period of time, as may be necessary to protect the public health." *Id.* (§404(a)).

Congress balanced this tool with certain limits. *Id.* FDA must "find" based on an "investigation" that a class of food "may … be injurious to health" due to "contamination with micro-organisms." *Id.* FDA must also find this risk "cannot be adequately determined" after the food has "entered interstate commerce." *Id.* Finally, FDA may use this tool only for a "temporary period of time." *Id.*

Another tool that Congress has given FDA to ensure food safety is the authority to deem "food … adulterated." FDCA, §402, 52 Stat. 1046 (codified at 21 U.S.C. §342). FDA may deem food adulterated on various grounds, including if food "consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise

unfit for food." *Id.* (§402(a)(3)). FDA may then act on this finding via food seizures, injunction proceedings, and fines. FDCA, §§301-304, 52 Stat. 1042, 1042-45 (codified at 21 U.S.C. §§331–334).

But like permit controls, adulteration findings come with limits. FDA must prove adulteration on a case-by-case basis. For example, in *United States v. 449 Cases Containing Tomato Paste*, the government sought judicial authorization to seize tomato paste as adulterated because testing "disclosed … mold" that "exceed[ed] administrative tolerances." 212 F.2d 567, 568 (2d Cir. 1954).

FDA was reminded of this limit the hard way when it brought injunction proceedings against McAfee's dairy, Organic Pastures. *See Organic Pastures*, 708 F. Supp. 2d at 1013-16. Citing interstate sales of raw milk and mislabeling, FDA sought to enjoin Organic as if FDA had also proven Organic's products were adulterated. *Id.* For example, FDA's proposed injunction decreed a right "to inspect Organic['s] … facilities without prior notice." *Id.* at 1015-16.

The district court condemned this "unprecedented" overreach: "there is no evidence that [Organic's] products are adulterated, contaminated, or that they are causing harm to the public." *Id*. FDA had not even "conducted an inspection." *Id.* at n.12. The court made its displeasure clear: "if [FDA] had found conditions in [Organic's] plant that would cause [FDA] to distrust [Organic's] operations, their sanitation practices, the integrity of the products, this might be justified. But there's no evidence [of] that [here] …."

A third tool that Congress has given FDA to ensure food safety is "standards of identity." FDCA, §401, 52 Stat. 1046 (codified at 21 U.S.C. §341). To "promote honesty and fair dealing in the interest of consumers," FDA may fix "a reasonable definition and standard of identity" for food "under its common or usual name." *Id.* In a given standard, FDA may require ingredients or manufacturing processes that ensure food safety, thus promoting "honesty and fair dealing" with consumers. 38 Fed. Reg. 27924, 27924-25 (Oct. 10, 1973).

Consider cheese. 15 Fed. Reg. 5656 (Aug. 16, 1950). To "promote honesty and fair dealing," FDA decided to include in the "standards of identity [for] … cheese" certain "reasonable precautions to render … finished cheese safe for human consumption." *Id.* at 5658. These precautions included that "cheese be held after it is manufactured for not less than 60 days at temperatures of not less than 35° F" to the extent "the milk used … is not pasteurized." *Id.; e.g.,* 21 C.F.R. §133.113(a) (cheddar standard that includes this rule).

But again, as with permit controls and adulteration findings, Congress has limited FDA's power to impose standards of identity. With the exception of "avocadoes, cantaloupes, citrus fruits, and melons," Congress has generally established that "**no definition and standard of identity** … shall be established for **fresh or dried fruits**" or "**fresh or dried vegetables**." 21 U.S.C. §341.

But this does not mean that Congress has left FDA powerless to ensure the safety of fruits and vegetables. FDA may use adulteration

findings and permit controls. And under FDCA §419, Congress has authorized FDA to impose "science-based minimum standards for the safe production and harvesting of … fruits and vegetables." Pub. L. No. 111-353, tit. I, §105(a), 124 Stat. 3899, 3899-900 (Jan. 4, 2011) (codified at 21 U.S.C. §350h). FDA has used this §419 authority—and not standards of identity, as FDA wrongly asserts—to require that farmers "treat seeds or beans that will be used to grow sprouts" with a "scientifically valid method to reduce microorganisms of public health significance." 80 Fed. Reg. 74547, 74561 (Nov. 27, 2015) (codified at 21 C.F.R. §112.142(e)(1)); FDA.Br.36.

As a result, to conclude that FDA may not use standards of identity to police fruits and vegetables does not "call into question … [FDA] regulations that ensure the safety of fruits and vegetables by setting standards for their growing, harvesting, packing, and holding."[1] FDA.Br.36. Congress has expressly authorized these regulations by statute (like FDCA §419), reinforcing the cardinal rule that "agencies … possess only the authority that Congress has provided." *NFIB v. Dep't of Labor*, 142 S. Ct. 661, 665 (2022).

The same goes for butter. The FDCA dictates "[n]o definition and standard of identity … shall be established for … butter." 21

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[1] Congress has authorized FDA to regulate the "packing" and "holding" of food (including fruits and vegetables) under other FDCA provisions. *See* 21 U.S.C. §350e (sanitary transport practices); *id.* §350g (requiring manufacturers to prevent "hazards that could affect food manufactured, processed, packed, or held").

U.S.C. §321a. But as with fruits and vegetables, Congress has not left FDA powerless to ensure the safety of butter. FDA may use permit controls—which reach all foods—to address any food-safety risks at particular buttermaking facilities. *See* 21 U.S.C. §344(a).

Congress has also expressly authorized FDA to address butter safety through adulteration findings, as FDA admits. FDA.Br.4. The FDCA authorizes FDA to police butter on a case-by-case basis upon finding either: (1) the "raw material" consists "in whole or in part of any filthy, putrid, or decomposed substance"; or (2) the "butter is otherwise unfit for food." Act of Mar. 16, 1950, ch. 61, §3(d), 64 Stat. 21 (codified at 21 U.S.C. §342(e)). With this evidence in hand, FDA may commence proceedings to seize any unsafe butter and to enjoin the producer. *See* 21 U.S.C. §334 (authorizing seizure of adulterated food); *id.* §332 (authorizing injunction proceedings).

What FDA cannot do is throw away the many scalpels that Congress has provided to ensure butter safety in favor of using an axe that Congress has not provided—and in fact expressly denied. *Dominion Energy, Inc. v. City of Warren Police & Fire Retirement Sys.*, 928 F.3d 325, 348 (4th Cir. 2019) (Motz, J., dissenting) ("Congress legislates with a scalpel, not a meat axe."). But that is what FDA has done here in saying that all butter in interstate commerce must be made from only pasteurized dairy ingredients.

III. FDA has adopted an unlawful standard of identity for butter by forbidding interstate commerce in butter unless this food is made from pasteurized dairy ingredients.

A. The Food, Drug, and Cosmetic Act (FDCA)

It is the Supreme Court's duty "to say what a statute means." *Rivers v. Roadway Express, Inc.*, 511 U.S. 298, 312 (1994). And "once the Court has spoken," other courts must "respect" this decision. *Id.* Any other rule would unleash the "dangerous principle" that courts may "give the same statutory text different meanings in different cases." *Clark v. Martinez*, 543 U.S. 371, 386 (2005).

The Supreme Court has said what the FDCA "means" in terms of when FDA actions impose a standard of identity. *62 Cases of Jam v. United States*, 340 U.S. 593, 589 (1951). A "standard of identity" is a "regulation" that "fix[es] the ingredients of any food" such that "a commodity cannot be introduced into interstate commerce which purports to be" that food "unless" the commodity "is composed of the required ingredients." *Id.* (punctuation omitted).

FDA has declared that: "[n]o person shall cause to be delivered into interstate commerce" the "milk product" of butter "**unless … made from dairy ingredients … that have all been pasteurized**." 21 C.F.R. §1240.61(a); *id.* §1240.3(j) ("milk product" includes butter). This regulation dictates that a commodity purporting to be butter cannot be introduced into interstate commerce unless it is composed of the required ingredients (pasteurized milk or cream).

Section 1240.61(a) thus fixes the ingredients of a food (butter), making this regulation a "standard of identity" under the Supreme Court's clear definition of the phrase. *62 Cases of Jam*, 340 U.S. at 589. FDA also does not deny that "[s]tandards of identity provide legal definitions for food products by describing their basic nature and essential characteristics, **such as required ingredients**." FDA.Br.5 (bold added); *see also, e.g.*, 70 Fed. Reg. 29214, 29216 (May 20, 2005) ("FDA food standards vary widely in their content …. Some foods are defined and distinguished by their ingredients.").

Section 1240.61(a) then violates the FDCA's command that "[n]o … standard of identity … shall be established for … butter." 21 U.S.C. §341. FDA tries in the following three ways to overcome this reality. *See* FDA.Br.23-38. None is unavailing.

1. FDA insists §1240.61(a) merely "requires a manufacturing process." FDA.Br.26. This analysis would make sense if §1240.61(a) regulated a butter-making mechanic (McAfee.Br.6)—e.g., requiring butter to be "washed" for a certain period of time.[2] By analogy, FDA imposes a required manufacturing process on cheese in establishing that dairies must hold raw-milk cheeses for "not less than 60 days at temperatures of not less than 35° F." 15 Fed. Reg. at 5658.

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[2] One reason that butter is "washed" is to help prevent disease. *See* EDWARD GUTHRIE, THE BOOK OF BUTTER 174 (1920) ("From the bacteriological viewpoint, the buttermilk should be washed out so that the bacteria will be deprived of it as a food.").

Section 1240.61(a), however, is an ingredient requirement, prohibiting interstate commerce in butter "unless … **made from [pasteurized] dairy ingredients**." This is no different than if FDA prohibited interstate commerce in tuna salad unless made from canned tuna (rather than fresh tuna). An ingredient requirement does not cease to be an ingredient requirement simply because the specified ingredient—be it cream or tuna—undergoes a particular manufacturing process (e.g., pasteurization or canning).

FDA's effort to distinguish a required manufacturing process from a standard of identity is also a distinction without a difference. FDA concedes that "[s]tandards of identity" include FDA-required "manufacturing process[es] when th[e] process has a bearing on the identity of the finished product." FDA.Br.24 (punctuation omitted). Presuming §1240.61(a) enacts a manufacturing process, §1240.61(a) is a standard of identity because required use of pasteurized milk or cream in buttermaking has a bearing on the identity of the finished product: butter that is not "raw." This distinction matters, as state laws regulating butter confirm. *See, e.g.,* CAL. FOOD & AGRIC. CODE §37192 ("Butter … sold to the retail trade shall be labeled with the words 'pasteurized' or 'raw,' as the case may be.").

Perhaps recognizing this, FDA pivots to arguing pasteurization "simply makes butter safer" without changing butter's "distinctive characteristics." FDA.Br.25. But FDA never explains what butter's key characteristics are. For good reason: pasteurization affects many

butter characteristics that matter to consumers, including vitamin content and flavor. *See* Weston.Amici.Br.6-7 ("[P]asteurization kills natural vitamins. … [Consumers] may [also] find the taste [of raw butter] is better than pasteurized butter.").

At bottom, FDA's attempt to minimize what pasteurization means in buttermaking defies common sense. Pasteurization means "heating every particle of milk." 21 C.F.R. §1240.61(b). Pasteurized milk or cream is therefore different from raw milk or cream in the same way that a cooked oyster is different from a raw oyster. While the purpose of applying heat in both cases may be the elimination of pathogens, heated food is not the same as raw (uncooked) food—and food products made from heated ingredients are not the same as food products made from raw (fresh) ingredients.

This analysis clarifies why a raw-butter ban "is beyond FDA's statutory authority" while other possible FDA manufacturing rules to ensure safe raw-butter production are not. FDA.Br.36. Requiring dairies to make butter from pasteurized ingredients exceeds FDA's authority because this requirement "chang[es] the identity of butter from raw to pasteurized." McAfee.Br.25. Other manufacturing rules do not have this effect, leaving the identity of butter alone.

Consider a rule that raw butter must be tested for pathogens before such butter is shipped across state lines. Or a rule that all farm or dairy surfaces that come into contact with raw butter must be sanitized on a regular basis. Or a rule that anyone who handles

or works with raw butter must wear a mask at all times. All these rules ensure the safe production of raw butter while ensuring that raw butter remains raw butter (no change of identity).

FDA may therefore ensure the safe production of raw butter without ever changing the identity of butter. Section 1240.61(a), on the other hand, does change the identity of butter by establishing that butter can be made from only "dairy ingredients that have all been pasteurized." That is an actual or constructive standard of identity for butter—something FDA may not impose no matter how noble FDA's intentions might be. *See* 21 U.S.C. §341.

2. FDA suggests that standards of identity do not concern food safety but only consumer's expectations "when purchasing a product with the name under which it [is] sold." FDA.Br.4-5. To bolster this point, FDA contends that foods "that do not conform to [identity] standards may still be sold to consumers, just not under the product's standardized name." FDA.Br.25.

But nothing in the FDCA's allowance of standards of identity limits the function or operation of these standards to food labeling. FDA's regulation of cheese proves as much. As noted above, FDA has "include[d] in the … standards of identity of … cheese" certain "reasonable precautions to render … finished cheese safe for human consumption." 15 Fed. Reg. at 5658. These reasonable precautions include requiring raw-milk cheeses to "be held … for not less than 60 days at temperatures of not less than 35° F." *Id.*

Now if FDA is correct that standards of identity are nothing more than labeling restrictions, then every dairy in the nation is free to defy FDA's 60-day aging rule for raw-milk cheeses. By the FDA's own logic, cheeses "that do not conform to th[is] standard[] may still be sold to consumers" under a non-standard name. FDA.Br.25. So, to sell raw-milk cheeses aged below 60 days, all dairies need to do is market this cheese under a non-standard name. *Id.*

This reality explains why FDA does not wholly embrace the notion (endorsed by the district court) that standards of identity are just labeling restrictions. FDA recognizes that adopting this notion means giving up the agency's ability to use standards of identity to ensure food safety, as FDA has done with raw-milk cheeses. Section 1240.61(a)'s food-safety function then affords no bar to recognizing that §1240.61(a) imposes a standard of identity for butter.

3. FDA emphasizes that in adopting §1240.61(a), FDA "never purported" to "create a standard of identity for butter." FDA.Br.26. But FDA intentions do not control whether §1240.61(a) is a standard of identity for butter. The question is whether §1240.61(a) meets the Supreme Court's test for what qualifies as a "standard of identity" for FDCA purposes. *See 62 Cases of Jam*, 340 U.S. at 589.

Section 1240.61(a) provides that no food purporting to be butter may enter interstate commerce "unless … composed of the required ingredients"—i.e., pasteurized milk or cream. *Id.* According to the Supreme Court, that is a standard of identity. *Id.* FDA cannot then

alter this reality based on a lack of intent or invocation of the Public Health Service Act. Accepting this idea "would elevate form over substance" and allow FDA to "evade the [FDCA's] requirements." *Allis-Chalmers Corp. v. Lueck*, 471 U.S. 202, 211 (1985).

B. The Butter Standards Act.

The Butter Standards Act, like its statutory precursors, guards the "customary and lawful process of the manufacture of butter." *United States v. 11,150 Pounds of Butter*, 195 F. 657, 660–61 (8th Cir. 1912). The Act defines butter as food "made exclusively from milk or cream, or both." 21 U.S.C. §321a. FDA concedes this plain text allows commerce in butter made from milk or cream that "can be either pasteurized or unpasteurized." FDA.Br.28-29.

In *Federal Security Administrator v. Quaker Oats Co.*, 318 U.S. 218 (1943), the Supreme Court explains that once "legislative" judgment "determine[s] what may be included and what excluded" in a food, such judgment is conclusive. *Id.* at 232-33. No one else may vary this standard, even if one believes the food at issue should be defined by more "wholesome [or] beneficial ingredient[s]." *Id.* Thus, what the Butter Standards Act determines may be included in butter—use of unpasteurized milk or cream—FDA cannot exclude.

FDA offers three unavailing responses:

1. FDA argues §1240.61(a) complies with the Butter Standards Act because the Act authorizes butter to be "made exclusively from

milk or cream" and "[p]asteurized milk and cream" are milk or cream. FDA.Br.25. But §1240.61(a) does not simply allow the use of pasteurized milk or cream to make butter—the regulation also forbids the use of unpasteurized milk or cream.

If that is a proper reading of the Butter Standards Act, then FDA may by the same logic require that all butter be made from sheep's milk and cream (i.e., banning cow's milk and cream)—or require that all butter be made from Wisconsin-farmed milk and cream (i.e., banning dairy from other states). After all, the required ingredients are "still milk and cream." FDA.Br.25.

In the end, FDA cannot by regulation "arbitrarily *constrict*" the Butter Standards Act by "adding limitations found nowhere in its terms." *Food Marketing Inst. v. Argus Leader Media*, 139 S. Ct. 2356, 2364 (2019) (italics-in-original). And that is what FDA has done in making pasteurized milk or cream the only kind of milk or cream that may be used to make butter, arbitrarily constricting the Butter Standards Act's plain, broad text ("milk or cream").

2. FDA argues that *Quaker Oats* is irrelevant. *See* FDA.Br.28. FDA rests this argument on two red herrings. The first is the notion that *Quaker Oats* does "not suggest that a manufacturing process necessarily turns one ingredient into another." *Id.* But that is not the lesson that makes *Quaker Oats* relevant to this case.

In *Quaker Oats*, the Federal Security Administrator established a standard of identity for "enriched farina" that directed "minimum

quantities of vitamin B1, riboflavin, 3 nicotinic acid … and iron" and allowed vitamin D as an "optional" ingredient. 318 U.S. at 222-23. Quaker Oats wanted to sell enriched farina that included vitamin D but excluded the other vitamins due to their cost. *Id.* at 235.

The Supreme Court said 'no': Quaker Oats had to respect the Administrator's entire standard for enriched farina, as opposed to just those parts the company liked. *Id.* at 232 (standards of identity "would be defeated if producers" could depart from them at will). The Court even highlighted the Butter Standards Act as justification for reaching this firm conclusion. *See id.* at 232 n.8.

Quaker Oats then instructs that FDA must respect Congress's entire standard of identity for butter, which allows the use of "milk or cream" whether pasteurized or raw. 21 U.S.C. §321a. FDA cannot honor part of this standard while denying the other part. Otherwise, FDA invites food makers to do the same with respect to FDA's own "280 food standards of identity." 70 Fed. Reg. at 29216.

FDA's other red herring is that *Quaker Oats* does not mean the agency "creates a standard of identity whenever it requires a manufacturing process in the interest of public health." FDA.Br.28. But the point here is that Congress has created a standard of identity for butter, and *Quaker Oats* forbids FDA's piecemeal compliance.

Finally, FDA's red herrings fail on their own terms. Whatever may be said of other manufacturing processes, pasteurization turns one ingredient into another: from raw to pasteurized. If the opposite

were true, pasteurized milk could be advertised as raw milk. Also, FDA does create a standard of identity when the agency imposes a manufacturing rule on food that changes the nature of the food (e.g., aging of cheese), regardless of the rule's justification.

3. FDA disputes McAfee's "hypotheticals." FDA.Br.29. These hypotheticals show that if FDA may rewrite one part of the Butter Standards Act ("milk or cream"), the Act's other terms are forfeit. McAfee.Br.32. For instance, given salt's anti-bacterial properties, FDA could require all butter contain salt despite the Act allowing butter "with or without common salt." 21 U.S.C. §321a.

FDA dismisses such hypotheticals as "far afield." FDA.Br.29. But FDA does not deny that under its view of the Butter Standards Act, FDA could ban unsalted butter and abridge the Act in a dozen other ways—so long as FDA's objective was food safety. *Id.* That is reason enough for the Court to reject FDA's position.

IV. FDA cannot use the Public Health Service Act to evade Congress's limits on FDA's authority to regulate butter.

Since the FDCA and the Butter Standards Act do not allow FDA to limit the content of butter to "dairy ingredients that have all been pasteurized," 21 C.F.R. §1240.61(a), FDA invokes the Public Health Service Act, 42 U.S.C. §264(a). The question then becomes: does the Act permit FDA to "do indirectly what [FDA] cannot do directly." *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1358 n.* (2018).

Careful examination of the Public Health Service Act fails to reveal any grant of authority enabling FDA to impose a standard of identity for butter or otherwise dictate the ingredients of butter. The Act instead forbids "any" view of its terms that would "affect[], modify[], repeal[], or supersed[e]" the FDCA. 42 U.S.C. §262(g). The Act's history reinforces this point, limiting the Act's breadth to infected persons and "animals known to transmit disease." *Ala. Ass'n of Realtors v. HHS*, 141 S. Ct. 2485, 2487-89 (2021).

FDA offers three unavailing responses:

1. FDA argues that the Public Health Service Act authorizes FDA to mandate pasteurized butter because: "[t]he 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.'" FDA.Br.21-22. But this reading of the Act's text actually undercuts FDA's blanket pasteurization mandate.

The key words are "found to be so infected or contaminated." FDA's 1987 adoption of §1240.61(a) lacks any express finding that raw butter is so infected or contaminated as to justify application of the Public Health Service Act. *See* 52 Fed. Reg. 29509 (Aug. 10, 1987). The same goes for FDA's 1992 declaration clarifying that §1240.61(a) includes butter. *See* 57 Fed. Reg. 57343 (Nov. 1, 1992).

To be sure, FDA's 1987 adoption of §1240.61(a) does talk about raw milk. But raw butter is not the same "article" as raw milk. Raw butter is a manufactured product many steps removed from its basic

dairy ingredients. McAfee.Br.5. Raw butter's other distinct qualities, like consisting of at least 80% butterfat, also preclude conflating raw butter with raw milk. JA.105-115; 21 U.S.C. §321a.

FDA's invocation of the Public Health Service Act thus cannot save §1240.61(a), as FDA failed to make any finding in 1987 or 1992 that raw butter is "so infected or contaminated" as to justify FDA's use of the Act's powers. The Act's text also indicates that agency use of the Act's powers—and the required infection finding—must be *particularized* in nature (i.e., directed at specific persons, animals, or articles, rather than reaching all things indiscriminately).

This conclusion stems from the Act's authorization of not only "disinfection" and "sanitation," but also "**destruction** of animals or articles found to be so infected or contaminated." 42 U.S.C. §264(a). A blanket destruction order would raise key due process concerns, precluding farmers from proving that the specific animals or articles to be destroyed were not infected or contaminated.

The same concern then cabins the Public Health Service Act's other powers (like disinfection), leaving no support for §1240.61(a). Indeed, FDA's pasteurization mandate for butter operates as blanket order, without FDA ever having to find that particular raw butter is "so infected or contaminated" as to justify pasteurization. Nor does the mandate allow dairies to prove by testing (or other means) that their raw butter contains no pathogens and thus cannot be found to be so infected or contaminated as to fall under the Act.

2. FDA argues that "[p]rohibiting the interstate sale of raw cream butter" is no different from "other measures that FDA has taken" under the Public Health Service Act. FDA.Br.22. FDA cites Act-based regulations involving shellfish, turtles, parrots, and trash. *Id.* But none of these regulations in any way resembles the one at issue here: a categorical ban on a food (raw butter) that Congress has expressly protected through two other statutes.

The turtle and parrot regulations each ban interstate commerce in certain animals as pets—not food. *See* 40 Fed. Reg. 22543, 22543 (May 23, 1975) (codified at 21 C.F.R. §1240.62) (addressing "certain small pet turtles and viable turtle eggs"); 21 C.F.R. §1240.65(a). The trash regulation is similarly distinguishable. While this regulation bans the feeding of untreated trash to swine, the regulation does so in all cases, including pet swine. 21 C.F.R. §1240.75.

As for the shellfish regulation, this regulation does not ban interstate commerce in raw shellfish or require that all shellfish be cooked (or disinfected) before crossing state lines. *See* 21 C.F.R. §1240.60. Rather, the regulation mandates the sanitary handling of shellfish entering interstate commerce and compliance with certain labeling and certification requirements. *Id.*

FDA's shellfish regulation then cements the incredible nature of FDA's raw-butter ban. Raw shellfish are a key cause of foodborne illness, prompting major FDA investigations. *See* 76 Fed. Reg. 65200 (Oct. 20, 2011). Yet, FDA has never banned or claimed the power to

ban raw shellfish under the Public Health Service Act. Raw butter therefore stands alone under the Act, subject to an FDA ban without precedent and contrary to Congress's express protection of all butter under both the FDCA and the Butter Standards Act.

3. FDA argues McAfee has "forfeited" his analysis showing that "the Public Health Service Act's original meaning does not authorize FDA to regulate butter." FDA.Br.16. Not so, given the district court's ruling that FDA's inability to "alter the standard of identity for butter does not mean … [FDA] cannot regulate butter for other purposes under other statutes." JA.84.

"On appeal, a party may refine and clarify its analysis in light of the district court's ruling, including citing additional support." *In re Harman Int'l Indus., Inc. Sec. Litig.*, 791 F.3d 90, 100 (D.C. Cir. 2015). McAfee's analysis of the Public Health Service Act's original meaning fits this bill. McAfee shows that the purposes of the Public Health Services Act fail to support FDA's raw-butter ban, contrary to the district court's expansive view of these purposes.

FDA's assertion of forfeiture also fails because a party cannot forfeit a law's original meaning. In statutory interpretation cases, the Court's singular job is to enforce "the original meaning of the statute at hand." *New Prime, Inc. v. Oliveira*, 139 S. Ct. 532, 539 (2019). Only Congress may "revise statutes." *Wisc. Cent. Ltd. v. United States*, 138 S. Ct. 2067, 2073-74 (2018). "Until it exercises that power, the people may rely on the original meaning of the written law."

Moving past FDA's assertion of forfeiture, FDA does not offer any substantive rebuttal of McAfee's detailed analysis establishing that "Congress never intended the Public Health Service Act to be a grant of freestanding agency jurisdiction to … regulate a product as important to Congress as butter." McAfee.Br.41. FDA instead offers two minor responses, each of which is self-defeating.

First, FDA stresses that "the Public Health Service Act broadly authorizes FDA" to prevent disease transmission. FDA.Br.39. But using the Act's power to ban a form of butter is a decision of vast national significance. McAfee.Br.28-29. FDA must then show how the Act "speak[s] clearly" in terms of allowing FDA to regulate food or butter. *Id.* FDA does not do this. McAfee, on the other hand, cites the Act's express refusal to displace the FDCA—a statute that does speak clearly about food and butter. McAfee.Br.47.

Second, FDA suggests that a unilateral agency "ban on the interstate sale of raw cream butter" in the middle of World War II "may not have surprised Congress." FDA.Br.41 FDA's sole support for this jaw-dropping claim is that by 1939, San Francisco's elected municipal leadership decided to require pasteurization of all milk. *Id.* But this local decision accords with McAfee's demonstration that at this time (and for generations after), the "nation understood milk sanitation **as a local matter**"—not something that unelected agencies could resolve through a nationwide ban. McAfee.Br.35-36.

V. FDA does not dispute that a raw-butter ban, as a regulation of butter (a matter of vast national significance), falls under—and does not survive—the major questions doctrine.

Under the "major questions doctrine," Congress is bound "to speak clearly if it wishes to assign to an executive agency decisions of vast economic and political significance." *NFIB*, 142 S. Ct. at 667 (Gorsuch, J., concurring) (cleaned up). The doctrine "ensures that the national government's power to make the laws that govern us remains … with the people's elected representatives." *Id.*

FDA sensibly does not dispute that the regulation of butter in America is—and has always been—a question of vast economic and political significance. McAfee.Br.39. FDA instead tries to change the subject, insisting "[t]he Public Health Service Act's text does not include an exception for butter." FDA.Br.39. But under the major questions doctrine, for the Act to reach butter, it must clearly speak to butter—neither silence nor broad terminology suffices.

FDA next argues that it is "irrelevant" whether Congress ever anticipated FDA might use the Public Health Service Act to regulate butter: "[b]y delegating authority in this area, Congress recognized that it could not foresee every public health threat." FDA.Br.40. But FDA made and lost this same basic argument in *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000).

Citing Congress's broad delegation of authority under the FDCA to address public health threats, FDA argued that it could regulate cigarettes as "drug delivery devices" to meet the public

health problems posed by smoking. *Id.* at 125, 131. The Supreme Court disagreed, emphasizing the major questions doctrine and Congress's historic protection of tobacco. *Id.* at 143-56.

FDA finally demands *Chevron* deference. *See* FDA.Br.37. But *Chevron* deference does not apply to "question[s] of deep 'economic and political significance" like butter regulation. *King v. Burwell*, 576 U.S. 473, 486 (2015). FDA's raw-butter ban then fails given FDA's inability to cite any Public Health Service Act provision that clearly gives FDA the power to ban raw butter—a ban that if imposed in 1944 would have devastated American farms nationwide.

VI. FDA presents no effective limiting principles, instead claiming unlimited power to ban any fresh food as FDA deems necessary to prevent disease transmission.

If FDA's raw-butter ban stands, then no limiting principles exist for FDA's exercise of power under the Public Health Service Act as related to fresh food. McAfee.Br.44-48. FDA confirms this, stating that if it views a food as posing a transmission risk, "FDA may regulate the distribution of that [food], **regardless of how it otherwise is defined by statute or regulation**." FDA.Br.33.

FDA argues any "concern[]" here is "overstated" because, in most food-safety cases, the FDCA will afford all the authority that FDA needs. *See* FDA.Br.34. FDA also maintains that *Corbett v. TSA*, No. 21-1074, 2021 U.S. App. LEXIS 36433 (D.C. Cir. Dec. 10, 2021),

forecloses the Court's ability to recognize any limits on the FDA's powers under the Public Health Service Act. FDA.Br.31.

Corbett does not apply here, as that case rejected an effort to infer limits not expressly stated. 2021 U.S. App. LEXIS 36433, *26-27. McAfee relies on express FDCA limits and the Public Health Service Act's express refusal to displace those limits. FDA's imposition of a raw-butter ban heedless of these limits then confirms that McAfee's concerns are anything but overstated. McAfee.Br.44-48.

In sum: FDA's raw-butter ban is "unprecedented." *Ala. Ass'n of Realtors*, 141 S. Ct. at 2489. Even more so is FDA's attempt to use the Public Health Service Act to evade the dictates of the FDCA and the Butter Standards Act. FDA may consider such "improvisation … more expedient than what the law allows," but "lawful ends do not justify unlawful means." *SAS Inst.*, 138 S. Ct. at 1358 n.*.

Conclusion

The Court should reverse the judgment below and remand for proceedings consistent with the Court's opinion.

Respectfully submitted,

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Certificate of Compliance

Counsel for Plaintiffs-Appellants certifies that this reply brief meets the formatting and type-volume requirements set forth under FRAP 32(a) and Circuit Rule 32(e).

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Certificate of Service

Counsel for Plaintiffs-Appellants certifies that on March 14, 2022, he electronically filed this reply brief with the Clerk for the U.S. Court of Appeals for the D.C. Circuit by using the CM/ECF system. Counsel also certifies that counsel-of-record for all case participants are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

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