United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued April 8, 2022 Decided June 10, 2022

No. 21-5170

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

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION,
APPELLEE

Appeal from the United States District Court
for the District of Columbia
(No. 1:19-cv-03161)

Mahesha P. Subbaraman argued the cause for appellants. With him on the briefs was *Samantha J. Ellingson*.

Aditya Dynar was on the brief for *amicus curiae* Pacific Legal Foundation in support of appellants.

Marisa C. Maleck was on the brief for *amici curiae* The Weston A. Price Foundation, et al. in support of appellants.

Cynthia A. Barmore, Attorney, U.S. Department of Justice, argued the cause for appellee. With her on the brief

were *Brian M. Boynton*, Acting Assistant Attorney General, and *Daniel Tenny*, Attorney.

Before: SRINIVASAN, *Chief Judge*, TATEL* and PILLARD, *Circuit Judges*.

Opinion for the Court filed by *Circuit Judge* PILLARD.

PILLARD, *Circuit Judge*: Dairy farmer Mark McAfee sells raw, unpasteurized butter within his home state of California. Looking to expand his market, McAfee petitioned the FDA to revoke the agency's decades-old rule under the Public Health Service Act (PHSA) that bars the interstate sale of raw butter and replace it with a rule that allows such sale. McAfee told the FDA that his proposed rule was legally required because the Food, Drug, and Cosmetic Act (FDCA) exhaustively defines "butter" without describing it as pasteurized. In McAfee's view that makes the FDA's rule banning raw butter sales an unlawful change to butter's statutory definition. The FDA denied McAfee's petition. It concluded that the PHSA authorizes the agency to require pasteurization, that substantial evidence justified doing so, and that regulating butter for safety does not contravene its FDCA definition. McAfee challenged the FDA's action in court, and on cross motions for summary judgment the district court ruled in the agency's favor.

On appeal, McAfee raises only one preserved claim: that a rulemaking is necessary because the FDA's regulation banning interstate sale of raw butter violates the FDCA's definition of butter. Because we agree with the district court that challenge is meritless, and because McAfee has forfeited his other claims by failing to raise them below, we affirm.

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* Judge Tatel assumed senior status after this case was argued and before the date of this opinion.

I.

An agency decision to deny a petition for rulemaking is subject to only "extremely limited and highly deferential" review, *Massachusetts v. EPA*, 549 U.S. 497, 527-28 (2007) (internal quotation marks omitted), under which we may reverse the agency's choice "only for compelling cause, such as plain error of law or a fundamental change in the factual premises previously considered by the agency," *Nat'l Customs Brokers & Forwarders Ass'n of Am., Inc. v. United States*, 883 F.2d 93, 97 (D.C. Cir. 1989). *See generally WildEarth Guardians v. EPA*, 751 F.3d 649, 653 (D.C. Cir. 2014); Harry T. Edwards & Linda A. Elliott, Federal Standards of Review: Review of District Court Decisions and Agency Actions 195-96 (3d ed. 2018).

McAfee's rulemaking petition turns on the interaction of two statutes. The first is the Public Health Service Act, which provides the statutory basis for the FDA's pasteurization requirement. That Act authorizes the Surgeon General "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." 42 U.S.C. § 264(a). It includes a non-exhaustive list of appropriate ways to do so, including through "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 [the Surgeon General's] judgment may be necessary." *Id*.

The FDA today exercises that authority as it relates to food and other products. *See, e.g.*, 21 C.F.R. § 1240.62 (banning certain turtles known to carry salmonella); *id.* § 1240.60

(regulating shellfish). The FDA determined that raw cream may contain dangerous bacteria and that pasteurization disinfects and sanitizes it by killing those bacteria. Accordingly, the agency exercised its PHSA authority to require that milk products, including butter, be pasteurized. *Id.* § 1240.61.

The second relevant statutory provision is a food-naming power in the FDCA, 21 U.S.C. § 341, designed to prevent confusion and ensure that consumers know what they are buying. *See Fed. Sec. Adm'r v. Quaker Oats Co.*, 318 U.S. 218, 230-32 (1943). That provision authorizes the FDA to set "a reasonable definition and standard of identity" for "any food, under its common or usual name," to "promote honesty and fair dealing in the interest of consumers." 21 U.S.C. § 341. The agency thus delineates the basic characteristics of foods associated with their common or usual names. For example, products labeled "fruit jam" must contain a certain amount of fruit, 21 C.F.R. § 150.160; those labeled "maple syrup" (or "maple sirup") must contain a certain amount of maple sap, *id.* § 168.140; and so on.

Importantly, however, Congress exempted butter and most fruits and vegetables from the FDA's naming power and instead set those definitions itself in the statute. In 1938, Congress set the standard of identity of butter 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." 21 U.S.C. § 321a. At the same time, Congress specified that "[n]o [other] . . . standard of identity . . . shall be established for . . . butter . . . ." *Id.* § 341.

The FDA in 1987 banned the interstate distribution of "any milk or milk product" that has not been pasteurized. 21 C.F.R. § 1240.61. It did so following a district court ruling that the FDA had unreasonably delayed responding to a national consumer group's petition for such a ban, which emphasized that the "overwhelming evidence of the risks associated with" consuming raw milk products supported a pasteurization requirement. *Pub. Citizen v. Heckler*, 653 F. Supp. 1229, 1238 (D.D.C. 1986); *see id.* at 1242 (ordering FDA to promulgate "a rule banning the interstate sale of all raw milk and all raw milk products"). The FDA confirmed in 1992 that "milk product" includes "butter," and that the Public Health Service Act is the statutory authority for the pasteurization rule. Control of Communicable Diseases; Definition of Milk and Milk Products, 57 Fed. Reg. 57,343, 57,343 (Dec. 4, 1992).

McAfee's 2016 petition for a rulemaking to exclude butter from the rule requiring pasteurization of milk products—and thereby allow interstate sale of "raw" butter—argued that the FDA lacked sound legal or scientific grounds for its ban. Petition for Rulemaking at 1-24, J.A. 94-117. After some delay, the FDA denied the petition. FDA Denial of McAfee/FTCLDF Citizen Petition, dated Feb. 27, 2020 (FDA 1072-1093) [hereinafter Denial Letter] at 1-17, J.A. 459-75. It reasoned that the pasteurization rule does not conflict with or change the statutory definition of butter, which does not mention pasteurization; "manufacturing controls intended to ensure safety," it wrote, "may exist independent of any standards of identity." Denial Letter at 4, J.A. 462. The FDA addressed McAfee's arguments and the relevant scientific literature and concluded they did not alter the agency's conclusion that the ban on raw butter helps prevent the spread of communicable diseases. Denial Letter at 4-17, J.A. 462-75.

The district court sustained the FDA's denial of McAfee's Rulemaking petition on the ground that the agency's raw butter ban was a "straightforward" exercise of its PHSA authority, *McAfee v. U.S. Food & Drug Admin*, 541 F. Supp. 3d 21, 27 (D.D.C. 2021), and that such food safety regulation posed no conflict with the standard of identity of butter in the FDCA, *id.* at 29. "Just because the FDA cannot alter the standard of identity for butter," the court reasoned, "does not mean the agency cannot regulate butter for other purposes under other statutes." *Id*. The district court also rejected McAfee's arbitrary-and-capricious challenges: Given the "great deal of scientific evidence" the FDA presented in support of its judgment, *id*. at 34, the district court held these challenges "completely miss[ed] the mark" and were a "nonstarter," *id*. at 32-33.

McAfee timely appealed. We have jurisdiction over this appeal from the district court's final order under 28 U.S.C. § 1291, and McAfee has standing as a raw butter manufacturer. He does not directly challenge the FDA's 1987 or 1992 pasteurization rules, but instead challenges the agency's denial of his petition for a rulemaking to repeal the raw butter ban and allow interstate sale of unpasteurized butter.

II.

McAfee's only preserved challenge is that a rulemaking is necessary because the FDA's regulation under the Public Health Service Act barring interstate sale of raw butter violates the FDCA's definition of butter. When Congress set the standard of identity for butter, it explicitly prevented the FDA from altering that definition. *See* 21 U.S.C. § 341. But, McAfee argues, the agency's pasteurization requirement under the FDCA does just that. That is incorrect: The pasteurization rule did not amend the statutory standard of identity for butter,

either formally or functionally. Raw-cream butter, though unpasteurized, is still "butter" notwithstanding the FDA's determination that its interstate sale would threaten public health. As the district court succinctly observed, McAfee's argument "rests on the false premise that the pasteurization rule works a change to butter's standard of identity." *McAfee*, 541 F. Supp. 3d at 28. Particularly given our very limited review, we have no basis to overturn the FDA's denial of McAfee's request for rulemaking resting on that false premise.

The absence of the conflict McAfee perceives follows from the distinct roles of the food-naming and public-health provisions. Congress and the FDA's standards of identity under the FDCA ensure consumers know what they are buying. Recall, for instance, that a product labeled "fruit jam" must contain a certain amount of fruit. 21 C.F.R. § 150.160. Products containing a lower fruit content are not unsafe; they just must be marketed under a different name, such as "fruit topping." *See* Food Standards; General Principles and Food Standards Modernization, 70 Fed. Reg. 29,214, at 29,216 (May 20, 2005). Here, the statutory definition setting butter's standard of identity determines only what may be marketed as "butter." Products not meeting that definition may well be safe but must be called something else.

Altogether separate is the FDA's authority under the Public Health Service Act, which authorizes the agency to require processes including "inspection, fumigation, disinfection, [and] sanitation" to ensure that the food supply is safe and does not spread communicable diseases. 42 U.S.C. § 264(a). Those public health requirements do not alter a food's definition or standard of identity. Indeed, the FDA acknowledges that both pasteurized and unpasteurized butter are "butter," Appellee Br. at 25, since each "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." 21 U.S.C. § 321a. For safety reasons, however, the agency disallowed interstate sale of some (specifically, unpasteurized) butter. Even though raw cream butter may accurately be labeled "butter" at a local farmers' market, the FDA has deemed it too dangerous to be sold interstate. Accordingly, the FDA permissibly concluded that the raw butter ban did "not purport to be a standard of identity rulemaking" and "did not serve to operate as one in practice either." Denial Letter at 4, J.A. 462.

McAfee offers no persuasive response. He insists that the FDA has at least functionally amended the definition of butter by adding a safety requirement—pasteurization—not found in 21 U.S.C. § 321a. But as already discussed, the FDA did not alter the statutory definition because the FDA's public health regulatory authorities are distinct from, serve different purposes than, and do not conflict with its standard-of-identity rules. To be sure, we need not rule out the possibility that in an unusual case a food-safety control might be so integral to a food's identity that altering it would functionally amend how that food is defined under the FDCA. The FDA recognized that "sometimes standards of identity may also designate the manner in which products are produced when the manufacturing process has a bearing on the identity of the finished food," although ordinarily "manufacturing controls intended to ensure safety may exist independent of any standards of identity." Denial Letter at 5, J.A. 463. But the statutory definition at issue here contains no mention of pasteurization nor any other suggestion that undergoing that process prevents a product from qualifying as butter. McAfee may be correct that unpasteurized butter has a distinct taste, texture, and other qualities, but Congress did not speak to those qualities as part of butter's statutory standard of identity. That

statutory provision neither references pasteurization nor requires qualities that pasteurized butter lacks. At least in this case, then, the standard-of-identity statute does not extinguish the agency's authority under the PHSA to ensure food safety.

McAfee argues that the FDA's reading would give the agency sweeping authority to alter standards of identity through public health requirements. But the FDA may act under the Public Health Service Act only where "necessary" to prevent the spread of disease. 42 U.S.C. § 264(a). As the Supreme Court has recently emphasized, actions under that statute must "directly relate to preventing the interstate spread of disease." *Ala. Ass'n of Realtors v. Dep't of Health & Hum. Servs.*, 141 S. Ct. 2485, 2488 (2021). Even then, they must also withstand arbitrary-and-capricious review.

Indeed, it is McAfee's interpretation that would produce odd consequences: It would substantially exempt from public health controls those products whose standards of identity Congress itself set by statute, including most fruits and vegetables, *see* 21 U.S.C. § 341, because on his approach any safety control not in the statutory standard of identity would seem to unlawfully supplement it. The majority of foods, however, would remain subject to FDA safety regulation because the statute authorizes the agency to set their standards of identity, leaving the FDA free to build safety requirements under the PHSA into those definitions. Nothing suggests Congress intended that anomalous bifurcated result.

McAfee raises several other issues for the first time on appeal, including (1) whether the FDA has authority under the PHSA, standing alone, to require that butter marketed interstate be made from pasteurized cream, Appellant Br. at 44; (2) whether the adulteration provisions of the FDCA at 21 U.S.C. § 342 otherwise limit the FDA's Public Health Service Act

authority, Appellant Reply Br. at 6-7, 8-10; and (3) whether the FDA's exercise of rulemaking authority following department reorganization exceeds its authority under the Act, Appellant Br. at 42-43. McAfee forfeited those arguments because he did not raise them before either the FDA or the district court. *See, e.g.*, *McAfee*, 541 F. Supp. 3d at 27 (noting McAfee "do[es] not dispute" that the PHSA "would seem to give the FDA authority to mandate pasteurization"); Petition for Rulemaking at 5-9, J.A. 98-102; Plaintiffs' Br. in Supp. Of. Mot. For Summ. J. at 9-14, No. 19-3161 (D.D.C. Oct. 21, 2020), ECF 15-2, S.A. 15-20; *see also Koretoff v. Vilsack*, 707 F.3d 394, 398 (D.C. Cir. 2013) (per curiam) (holding challenge to statutory authority forfeited). McAfee's counsel also clarified at oral argument that he does not raise a freestanding arbitrary and capricious challenge. Recording of Oral Arg. 10:39-11:33. Amici raise additional challenges, which rest on theories not raised by the parties and thus are not properly before us. *See Metlife, Inc. v. Fin. Stability Oversight Council*, 865 F.3d 661, 666 n.4 (D.C. Cir. 2017).

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For the foregoing reasons, the judgment of the district court is affirmed.

So ordered.