NOT PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

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No. 12-2475

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THOMAS YOUNG, on behalf of himself and all others similarly situated,
Appellant

v.

JOHNSON & JOHNSON, a New Jersey Corporation

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On Appeal from the United States District Court
for the District of New Jersey
(D.C. No. 3-11-cv-04580)
District Judge: Hon. Joel A. Pisano

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Argued
April 23, 2013

Before: SLOVITER, JORDAN and NYGAARD, *Circuit Judges*.

(Filed: May 9, 2013)

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OPINION OF THE COURT

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JORDAN, *Circuit Judge*.

Thomas Young appeals the dismissal of his class action complaint against Johnson & Johnson ("J&J") asserting various state law causes of action based on allegedly deceptive labeling of certain J&J products. For the following reasons, we will affirm.

## I. Background

J&J manufactures Benecol® Regular Spread and Benecol® Light Spread butter/margarine substitutes (collectively "Benecol"). In two locations on the outside of the Benecol label[1] and one on the inside of the label, it states that Benecol contains "NO

[1] The Benecol label wraps around and is separate from the container holding the actual spread. Representations and disclaimers located on the inside of the Benecol label are not visible until the label is removed from the product.

TRANS FAT." (App. at 47-48.) The "Nutrition Facts" box, which is also on the outside of the label, notes the "Amount/Serving" of "Trans Fat" as "0g." (*Id.* at 47.) Directly above the Nutrition Facts box on the outside of the label is the statement "No Trans Fatty Acids." (*Id.*)

The label also states in large letters immediately below the Benecol name in two locations on the outside and once on the inside that the product is "Proven to Reduce Cholesterol." (App. at 47-48.) The outside of the label provides the basis for that claim, stating, in relevant part, that "[p]roducts containing 0.7 g or more of plant stanol esters per serving eaten twice a day with meals for a daily intake of at least 1.4 g may reduce the risk of heart disease as part of a diet low in saturated fat and cholesterol." (App. at 47-48.) The outside of the label also states that "[e]ach serving contains 0.85 g of Plant Stanol Esters (0.5 g plant stanols)" and that "Plant Stanol Esters[']proven ability to lower cholesterol is supported by ***over 25 studies***, including one in the New England Journal of Medicine." (App. at 47-48 (emphasis in original).) The inside of the label further claims that Benecol "offers you a great way to reduce your cholesterol" because it "[r]educes 'bad' (LDL) cholesterol," "[r]educes total cholesterol," and "[b]locks cholesterol from being absorbed into your body." (App. at 47, 49.)

Young asserts that Benecol's representations concerning its trans fat content and cholesterol-lowering capability are false and misleading because Benecol contains small amounts of trans fats (also referred to as "partially hydrogenated oil") that may be detrimental to heart health. He further alleges that he paid a premium price for Benecol, in reliance on its false and misleading nutrient content and health claims.

Young filed a five-count complaint in the United States District Court for the District of New Jersey asserting claims for violations of the New Jersey Consumer Fraud Act, N.J. Stat. Ann. § 56:8-1, *et seq.*, and the New York General Business Law § 349 (on behalf of a putative New York subclass), breach of express warranties and of the implied covenant of merchantability, and unjust enrichment. The District Court granted J&J's motion to dismiss, concluding that Young had not adequately pled an injury-in-fact and therefore lacked standing, and that his claims were expressly preempted by the Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, as amended by the Nutrition Labeling and Education Act ("NLEA"), 21 U.S.C. § 343-1.

This timely appeal followed.

## II. Discussion[2]

The NLEA expressly preempts any state-imposed requirement for nutrition labeling of food, or with respect to nutritional or health-related claims, "that is not identical to the requirement" set forth in the relevant provisions of the Act. 21 U.S.C. § 343-1(a)(4), (a)(5). Young asserts that his state law causes of action based on J&J's alleged misrepresentations about Benecol are not preempted because they seek to impose

[2] The District Court had jurisdiction pursuant to the Class Action Fairness Act, 28 U.S.C. § 1332(d). We have jurisdiction under 28 U.S.C. § 1291. "To survive a motion to dismiss [under Rule 12(b)(6)], a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Sheridan v. NGK Metals Corp.*, 609 F.3d 239, 263 n.27 (3d Cir. 2010) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)) (internal quotation marks omitted). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (quoting *Iqbal*, 556 U.S. at 678) (internal quotation marks omitted).

requirements that are identical to those set forth in the NLEA.[3] His arguments correspond to the two groups of claims made on the Benecol package: (1) that the product does not contain trans fats (the "Trans Fat Claims"); and (2) that it is proven to reduce cholesterol because it contains beneficial plant stanol esters (the "Cholesterol Claims"). We discuss preemption as it pertains to each of those sets of claims separately.[4]

A. *Trans Fat Claims*

The essence of Young's argument regarding the Trans Fat Claims is that, although the regulations authorize Benecol to claim that it contains "0g of Trans Fat Per Serving," they do not expressly permit a claim of "NO TRANS FAT" for the product as a whole. Thus, Young contends that he "seeks to prohibit false and misleading nutrient content

[3] The District Court did not reach Young's alternative theories of liability based on breach of express and implied warranties and unjust enrichment. He does not press those theories on appeal, and we do not address them.

[4] The District Court also concluded that Young lacked standing because he had not pled a sufficient injury-in-fact. We note that cases from the District of New Jersey have found that plaintiffs have standing to sue under New Jersey's Consumer Fraud Act ("CFA") when they have alleged financial injuries based on their purchase of a product that did not have the attributes it claimed. *See, e.g., Lieberson v. Johnson & Johnson Consumer Cos., Inc.*, 865 F. Supp. 2d 529, 537 (D.N.J. 2011) (finding standing under the CFA based on consumer's assertion that she would not have purchased the product but for its claim that it would help her baby to sleep better); *Green v. Green Mountain Coffee Roasters, Inc.*, 279 F.R.D. 275, 280 (D.N.J. 2011) (finding standing under the CFA based on consumer's allegation that he purchased a coffee maker based on allegedly false representation that it would brew a programmed quantity of coffee); *Zebersky v. Bed Bath & Beyond, Inc.*, No. 06-1735, 2006 WL 3454993, at *2 (D.N.J. Nov. 29, 2006) (concluding that a consumer "alleged an injury in fact sufficient to withstand [a] motion [to dismiss]" under the CFA because she alleged "that the goods purchased were of inferior quality to what was represented by defendants"). Though tenuous, Young's standing under the specific facts of this case is sufficient for us to consider the merits.

claims regarding *trans* fat content ***per product***. Prohibition of such statements is not inconsistent with the FDA's regulation allowing nutrient content claims about *trans* fat ***per serving***." (Appellant's Opening Br. at 25 (emphasis in original).)

The FDA nutrition information regulation that covers trans fat content generally requires "[a] statement of the number of grams of trans fat in a serving," but further provides that "[i]f the serving contains less than 0.5 gram [of trans fat], the content, when declared, shall be expressed as zero." 21 C.F.R. § 101.9(c)(2)(ii). The regulation also says that such amounts are deemed to be "insignificant amounts" for purposes of the "declaration of nutrition information." *Id.* § 101.9(f)(1). Benecol contains less than 0.5 grams of trans fat per serving, and therefore properly discloses that it contains "0g of trans fat" per serving in the Nutrition Facts box.

While FDA regulations do not specifically say a product can advertise itself as containing "NO TRANS FAT" when it has an insignificant amount, they do allow "nutrient content claim[s]," *id.* § 101.13(b), such as claims that a product contains "no fat" or "no saturated fat," without reference to a per-serving limitation, provided that the product indeed contains less than 0.5 grams per serving, *id.* § 101.62(b)(1), (c)(1). And more broadly, FDA regulations permit the label to contain a "statement about the amount or percentage of a nutrient" if it is "not false or misleading." *Id.* § 101.13(i)(3).

The FDA has long recognized the potential for a discrepancy between required disclosure of "zero grams per serving" and an accurate nutrient content claim that the product is not, in fact "free" of the nutrient in question. Because "[s]uch declarations could be confusing to consumers, and this consequence is unintended[,] ... the

determination of whether a product is free of a nutrient [is] based on the value of the nutrient ... per labeled serving." 58 Fed. Reg. 44025 (Aug. 18, 1993). In the interest of clarity and consistency with the nutritional information, FDA regulations therefore authorize nutrient content claims based on per serving amounts, even if those claims are not entirely accurate on a per product basis. For example, the regulations authorize nutrient content claims that a food is "calorie free" if it contains less than 5 calories per serving, 21 C.F.R. § 101.60(b)(1); that a food is "sodium free" if it contains less than 5 milligrams of sodium per serving, *id.* § 101.61(b)(1); and that a food contains "no fat" or "no saturated fat" if it contains less than 0.5 grams per serving, *id.* § 101.62(b)(1), (c)(1). Consequently, the "NO TRANS FAT" claim on the Benecol label is not "misleading" as that term is used in 21 C.F.R. § 1.13(i)(3), and is authorized under that provision, even if a "no trans fat" claim is not expressly contemplated by the regulations.[5]

Nutrient content claim regulations promulgated under the NLEA thus authorize the Trans Fat Claims, based on the per serving amount of trans fats that the product contains. Because Young seeks to bar that disclosure under state law, in effect enforcing

[5] Three other courts that have recently reached the same conclusion. *See Carrea v. Dreyer's Grand Ice Cream, Inc.*, 475 F. App'x 113, 115 (9th Cir. 2010) (concluding that "0g Trans Fat … is an express nutrient content claim that the [FDA] not only permits, but further instructs should mirror the Nutrition Facts panel" (citations omitted)); *Chacanaca v. Quaker Oats Co.*, 752 F. Supp. 2d 1111, 1121 (N.D. Cal. 2010) (concluding that "'nutritionally insignificant amounts' of less than 0.5 grams trans fats means the same thing, according to [FDA] regulations, as '0 grams,'" and that "the use of the latter language in a[] ... nutrient content claim would *not* be misleading within the meaning of [the FDCA] or any of its regulations"); *Reid v. Johnson & Johnson*, No. 11-cv-01310-L-BLM, 2012 WL 4108114, at *10 (S.D. Cal. Sept. 18, 2012) (concluding that FDA regulations authorize the "no Trans Fat" and "No Trans Fatty Acids" claims on the Benecol label because "[m]aking a distinction between 'No Trans Fat' and '0 grams trans fat' is unreasonable").

state law requirements that are not identical to the NLEA, his action is expressly preempted as it relates to those claims.

B. *Cholesterol Claims*

Young contends that the FDCA does not preempt his action with respect to the Cholesterol Claims because he seeks to enforce state law requirements that are identical to regulations prohibiting false and misleading health claims. Young argues that the District Court failed to distinguish between "Defendant's false claim that Benecol as a whole is 'Proven to Reduce Cholesterol' [and] the FDA-approved claim that plant sterol/stanol esters are 'Proven to Reduce Cholesterol.'" (Appellant's Opening Br. at 26.)

Two interrelated FDA regulations, 21 C.F.R. §§ 101.14 and 101.83, govern the Benecol Cholesterol Claims. J&J's claim that the product is "Proven to Reduce Cholesterol" is a "health claim" subject to 21 C.F.R. § 101.14 because it is based on the fact that the product includes particular amounts of plant stanol esters, and therefore "characterizes the relationship of a[] substance to a disease or health-related condition." *Id.* § 101.14(a). Food labeling may not include a health claim, whether express or implied, unless the claim is "specifically provided for" in 21 C.F.R. §§ 101.70-83, and the claim "conforms to all general provisions of [§ 101.14]." *Id.* § 101.14(e)(1), (e)(2). The general provisions of § 101.14 require, *inter alia*, that health claims must be "complete, truthful, and not misleading." *Id.* § 101.14(d)(2)(iii). The Benecol Cholesterol Claims also come under 21 C.F.R. § 101.83, which specifically provides for health claims "which summarize the relationship between diets that include plant

sterol/stanol esters and the risk of [heart disease] and the significance of the relationship." *Id.* § 101.83(d)(3).

Young argues that J&J's claim that its product (rather than the plant stanol esters the product contains) is "Proven to Reduce Cholesterol" is not "specifically provided for" in §§ 101.70-101.83 (as required by § 101.14(e)), and that it violates § 101.14(d) because it is false and misleading. The first argument is directly contradicted by § 101.83, which permits a food product to make a health claim based on plant stanol esters if "the food product ... contain[s] ... [a]t least 1.7 g of plant stanol esters ... *per reference amount customarily consumed* of the food products eligible to bear the health claims, specifically spreads ... ." 21 C.F.R. § 101.83(c)(2)(iii)(A)(2) (emphasis added).[6] Thus, "[t]he regulations state the minimum amount of plant stanol esters that a product must contain before it can bear health claims, but[] ... do not require that products show that they effectively reduce cholesterol as formulated." *Reid v. Johnson & Johnson*, No. 11-cv-01310-L-BLM, 2012 WL 4108114, at *9 (S.D. Cal. Sept. 18, 2012) (internal quotation marks omitted).

Young's second argument, that the "Proven to Reduce Cholesterol" claim is false and misleading, rests on the assertion that the claim is expressed with reference to the product itself rather than to the plant stanol esters it contains, and that the product

[6] In 2003, the FDA reduced the amount of plant stanol esters required for a food to make the health claims listed in 21 C.F.R. § 101.83 to 0.4 grams per serving, and a total daily intake of 0.8 grams, but the regulation was not revised to reflect that change. Benecol contains more than those required amounts, and Young does not appear to challenge Benecol's ability to make cholesterol-lowering claims based on the amount of plant stanol esters it contains.

contains harmful trans fats. Both of those facts are irrelevant. It is of no consequence that the claim may be read as referring to the product rather than to the plant stanol esters it contains because the regulations expressly authorize the product to make the health claim. *See* 21 C.F.R. § 101.83(c)(2)(iii)(A) (describing the "[n]ature of the food eligible to bear the claim" in terms of the amount of plant stanol esters that the "food product shall contain"). Also, the regulations set forth a "model health claim" that speaks in terms of "[f]oods containing" and "servings of foods containing" the specified amounts of plant stanol esters. *Id.* § 101.83(e)(2)(i), (e)(2)(ii). Likewise, the fact that Benecol contains small amounts of trans fats does not render its Cholesterol Claims false and misleading because the Cholesterol Claims are authorized by the regulations based solely on the product's plant stanol ester content, without reference to other nutrients such as trans fats. *Id.* § 101.83(c)(2)(iii)(A)(2).

In summary, J&J is permitted to make heart health claims that relate to Benecol based on the product's plant stanol esters content. The Cholesterol Claims are authorized by FDA regulations and are not false or misleading. Because Young's state law action seeks to impose standards that are not identical to those set forth in the regulations, it is expressly preempted by the NLEA as it relates to those claims.

## III. Conclusion

The District Court therefore properly dismissed Young's complaint because all of his theories of liability are expressly preempted.[7] We will therefore affirm the District Court's ruling.

[7] Young also argues that the District Court abused its discretion when it dismissed his complaint with prejudice, effectively denying him leave to amend. "Under [Federal Rule of Civil Procedure] 15(a), futility of amendment is a sufficient basis to deny leave to amend." *Great W. Mining & Mineral Co. v. Fox Rothschild LLP*, 615 F.3d 159, 175 (3d Cir. 2010). "Futility means that the complaint, as amended, would fail to state a claim upon which relief could be granted." *In re Merck & Co. Sec., Inc., Derivative & ERISA Litig.*, 493 F.3d 393, 400 (3d Cir. 2007) (internal quotation marks omitted). Therefore, a court need not grant leave to amend if "the amendment would not cure the deficiency." *Shane v. Fauver*, 213 F.3d 113, 115 (3d Cir. 2000). In this case, the District Court dismissed Young's complaint because his claims are expressly preempted. That is a determination of law, not fact. *See Roth v. Norfalco LLC*, 651 F.3d 367, 374 (3d Cir. 2011) (noting that a district court's "preemption ... determinations were based on questions of law"). Any attempt by Young to amend the factual allegations in his complaint would not have saved it as a matter of law, and the District Court did not abuse its discretion when it dismissed the complaint with prejudice.