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Got Milk: The Labeling Crisis Taking Over the Nation

By Eric Harmon*

Over the last decade, alternative milks, such as almond, coconut, soy, and oat, have become increasingly popular, growing sales over 60% between 2012 and 2017.¹ These products are widely available and provide those who are lactose intolerant, vegan, or simply desire a different option with a viable substitute. These alternatives, however, have pitted two industries – the plant-based industry and the dairy industry – against one another, and the fight revolves around the definition of and right to the word "milk."

Last summer, the Food and Drug Administration ("FDA"), led by then-Commissioner Dr. Scott Gottlieb, was determined to take steps to advance health through improvements in nutrition and embarked on a multi-year Nutritional Innovation Strategy.² The goal is to modernize the FDA's approach to nutrition and empower consumers with information when they are making decisions about food.³ One of the main focuses of the initiative surrounds labeling and modifying definitions called "standards of identity" for a variety of food products.⁴ This is where the fight for "milk" began.

Since the Food, Drug, and Cosmetic Act was enacted, milk has been defined as "the lacteal secretion obtained by the complete milking of one or more healthy cows."⁵ Prior to his departure from the agency, Commissioner

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¹ Mintel, *US Non-Dairy Milk Sales Grow 61% Over the Last Five Years*, Mintel, January 4, 2018, <https://www.mintel.com/press-centre/food-and-drink/us-non-dairy-milk-sales-grow-61-over-the-last-five-years> (last visited Sept. 25, 2019).

² Dr. Scott Gottlieb, *Statement from FDA Commissioner Scott Gottlieb, M.D., on FDA's new steps to advance health through improvements in nutrition under the agency's Nutrition Innovation Strategy*, Food and Drug Administration, June 26, 2018, <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-fdas-new-steps-advance-health-through-improvements> (last visited Sept. 25, 2019).

³ *Id.*

⁴ *Id.*

⁵ 21 C.F.R. §131.110(a) (2019). See also 21 U.S.C. §341 (2012) (giving the FDA the authority to set food identity standards, regulations that define various foods by specifying their ingredients and composition).

Gottlieb indicated that the FDA would enforce this narrow definition, stating that, “An almond doesn’t lactate” and arguing that labeling alternative “milk” products make consumers think that what they are drinking has the same nutritional value as milk.⁶ This has drawn nationwide attention, and while the FDA has indicated it would be over a year before any decisions are finalized, many are taking action in preparation for what may lie ahead.

In the meantime, members of Congress have proposed legislation that would not allow products to use the term “milk” unless they met the FDA’s definition – the Defending Against Imitations and Replacements of Yogurt, milk, and cheese to Promote Regular Intake of Dairy Everyday (“DAIRY PRIDE”) Act.⁷ Introduced in the Senate by Senators Tammy Baldwin (D-WI) and Jim Risch (R-ID) and in the House by Representatives Peter Welch (D-VT) and Mike Simpson (R-ID), the legislation would require non-dairy products made from nuts, seeds, plants, and algae no longer to be labeled with dairy terms such as “milk.”⁸ Further, the DAIRY PRIDE Act would require the FDA to provide guidance on national enforcement of “mislabeling” by dairy imitation production and to report to Congress two years after its enacted in order to hold the agency accountable regarding the update in enforcement obligations.⁹ In defense of the need for congressional action, Senator Risch has commented that “[t]he nutritional value found in dairy is not replicated by imitation products, and it’s time our labeling requirements reflect that.”¹⁰

⁶ Kimberly Leonard, *FDA will consider whether almond, soy, coconut drinks can call their products ‘milk,’* Washington Examiner, July 17, 2018, <https://www.washingtonexaminer.com/policy/healthcare/fda-will-consider-whether-almond-soy-coconut-drinks-can-call-their-products-milk> (last visited Sept. 25, 2019).

⁷ Senator Tammy Baldwin, *DAIRY PRIDE Act*, United States Senate, March 14, 2019, <https://www.congress.gov/bill/116th-congress/senate-bill/792/text> (last visited Sept. 25, 2019); Representative Peter Welch, *DAIRY PRIDE Act*, United States House of Representatives, March 14, 2019, <https://www.congress.gov/bill/116th-congress/house-bill/1769/all-info> (last visited Sept. 25, 2019).

⁸ *Id.*

⁹ *Id.*

¹⁰ Senator Tammy Baldwin, *U.S. Senators Tammy Baldwin and Jim Risch Stand up for America’s Dairy Farmers*, Tammy Baldwin United States Senator for Wisconsin, March 14, 2019, <https://www.baldwin.senate.gov/press-releases/dairy-pride-2019> (last visited Sept. 25, 2019).

Courts also have been asked to address the issue of plant-based "milk". In *Painter v. Blue Diamond Growers*, a consumer brought a suit purporting several California state law claims and alleging that the defendant's products – non-dairy almond milk – are mislabeled under the Food, Drug, and Cosmetic Act ("FDCA") and California's state law equivalent.¹¹ The Ninth Circuit affirmed the Central District of California's order granting the defendant's motion to dismiss each of the plaintiff's claims, including that the defendant's almond milk products are misbranded under to the FDCA.¹² The court rejected the plaintiff's argument that the defendant must either label its products as "imitation milk" or cease using the term "milk" altogether.¹³ The Ninth Circuit reasoned that, notwithstanding its resemblance to dairy milk, almond milk is not a substitute for dairy milk as contemplated by the statute and agreed with the lower court that a reasonable jury could not conclude that almond milk is nutritionally inferior to dairy milk as two distinct food products necessarily have different nutritional profiles.¹⁴ Further, the court reasoned that it is not plausible that a reasonable consumer would assume that two distinct products have the same nutritional content, thus the product cannot be misbranded as defined by the FDCA.¹⁵ An interesting part of the *Painter* decision is that a private citizen or business may not bring enforcement actions.¹⁶ The court likely factored this into their reasoning but what is interesting is it did not dismiss the enforcement portion of the case on these grounds or even mention it. We may be able to assume the plaintiff brought most of her claims under the color of state law to attempt to get around the preclusion and the court used it as an opportunity to impart on regulators

¹¹ 757 Fed.Appx 517, 518 (9th Cir. 2018); *Painter v. Blue Diamond Growers*, No. 17-CV-02235, 2017 WL 4766510, (C.D. Cal. May 24, 2017); 21 U.S.C. §343(a) (2012) (deeming food misbranded if its label is false or misleading or its advertising is false or misleading in material respect); 21 U.S.C. §343(c) (2012) (deeming food misbranded if it is an imitation of another food and its label does not indicate as much).

¹² *Id.*

¹³ *Id.*

¹⁴ *Id.* See also 21 C.F.R. §101.3(e)(1) (2019) (a food shall be deemed to be an imitation and thus subject to the requirements of section 403(c) of the act if it is a substitute for and resembles another food but is nutritionally inferior to that food); 21 C.F.R. §101.3(e)(4) (2019) (defining what nutritional inferiority includes).

¹⁵ *Id.*

¹⁶ *Painter*, 757 Fed.Appx. at 518; 21 U.S.C. §337 (a) (2012) (except as provided in subsection (b), all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States).

its opinion regarding the milk debate going forward. Other courts also have found similarly that no reasonable consumer could confuse plant-based milks for dairy milk or believe the products come from a cow or have that same qualities as cows' milk.¹⁷

Public interest and industry groups also have joined the conversation. The Institute for Justice, a non-profit libertarian public interest law firm, submitted a comment to the FDA arguing that banning plant-based milks from using the word "milk" would actually confuse consumers and harm small businesses across the country.¹⁸ Further, IJ argues that the government does not have the power to change the dictionary.¹⁹ Supporters of restrictions, however, argue it is less changing the dictionary but rather enforcing a decades-old federal law that ensures consumers are informed by accurate and clear labeling of their food.²⁰ While those opposed to the change argue the debacle is simply a protectionist scheme developed by the dairy industry, leading health organizations, including the Academy of Pediatrics, recently released guidelines stating most children under the age of five should avoid plant-based milk.²¹ While this revelation does not necessarily bolster the argument of confusion or misleading, it likely will not hurt the case made by supporters of the change, Congress, and the FDA if it chooses to move forward.

The future for plant-based milk and the fight for the rights to use the term "milk" remains unclear. The FDA is set to receive its new commissioner in November, which should provide some clarity on how the agency will proceed, but until then the FDA continues to receive comments and the

¹⁷ See *Williams v. Gerber Products Co.*, 552 F.3d 934, 938 (9th Cir. 2008); *Gitson v. Trader Joe's Co.*, No. 13-CV-01333-WHO, 2013 WL 5513711, at *7 (N.D. Cal. Oct. 4, 2013); *Ang v. Whitewave Foods Co.*, No. 13-CV-1953, 2013 WL 6492353, at *3 (N.D. Cal. Dec. 10, 2013).

¹⁸ Andrew Wimer, *IJ to FDA: Milk Doesn't Have to Come from Cows to be Called Milk*, Institute for Justice, January 28, 2019, <https://ij.org/press-release/ij-to-fda-milk-doesnt-have-to-come-from-cows-to-be-called-milk/> (last visited Sept. 25, 2019).

¹⁹ *Id.*

²⁰ Wyatt Bechtel, *DAIRY PRIDE Act Aims to Tackle Mislabeling of Non-Dairy Products*, Dairy Herd, March 14, 2019 <https://www.dairyherd.com/article/dairy-pride-act-aims-tackle-mislabeling-non-dairy-products> (last visited Sept. 25, 2019).

²¹ Jen Christensen, *Most Young Children Shouldn't Drink Plant-Based Milk*, *New Health Guidelines Say*, CNN, September 18, 2019, <https://www.cnn.com/2019/09/18/health/kids-drink-guidelines-milk-trnd/index.html> (last visited Sept. 25, 2019).

DAIRY PRIDE Act remains alive in the House and Senate. The fight is far from over, however, and the ultimate decision could have deep implications, including on lesser discussed areas such as non-cow mammals' milk that is also sold and consumed.

Edited by Jessica Gottsacker