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10	UNITED STATES DISTRICT COURT	
11	NORTHERN DISTRICT OF CALIFORNIA	
12	SAN JOSE DIVISION	
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14	KATIE KANE, individually and on behalf of all others similarly situated,	Case No. CV 12-02425-LHK
15 16 17 18	Plaintiffs, v. CHOBANI, INC., also known as AGRO-FARMA, INC., Defendant.	DECLARATION OF DAVID KATZ IN SUPPORT OF DEFENDANT CHOBANI, INC.'S OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION Second Amended Complaint filed: October 10, 2012
20		Date: July 11, 2013 Time: 1:30 p.m. Judge: Hon. Lucy H. Koh
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I. <u>BACKGROUND AND QUALIFICATIONS</u>

- 1. I, Dr. David L. Katz, am the founding (1998) director of Yale University's Prevention Research Center. I received a Bachelor of Arts degree from Dartmouth College (1984; magna cum laude), a Doctor of Medicine degree from the Albert Einstein College of Medicine (1988), and an Masters in Public Health degree from the Yale University School of Public Health (1993). I am a two-time diplomat of the American Board of Internal Medicine, a board-certified specialist in preventive medicine/public health, and a clinical instructor in medicine at the Yale School of Medicine.
- 2. I am known internationally for my expertise in nutrition, weight management, and chronic disease prevention. I have published roughly 150 scientific articles and textbook chapters, innumerable blogs and columns, nearly 1,000 newspaper articles, and twelve books to date, including two editions of a nutrition textbook and four editions of a preventive medicine textbook. The third edition of my nutrition textbook for health professionals, Nutrition in Clinical Practice, which has been widely used in medical education including, for example, at the Harvard Medical School is now in development and under contract to Wolters Kluwer/Lippincott Williams & Wilkins.
- 3. I am the Editor-in-Chief of the journal *Childhood Obesity*, President-Elect of the American College of Lifestyle Medicine, founder and President of the non-profit Turn the Tide Foundation, and medical director for the Integrative Medicine Center at Griffin Hospital in Derby, Connecticut.
- 4. I also have a significant media portfolio, including working for ABC News/Good Morning America as an on-air contributor, as a writer for the New York Times syndicate, and as a columnist to O Magazine (Oprah's magazine).
- 5. I am the principal inventor of the NuVal nutritional guidance system, currently in roughly 1,700 United States supermarkets in more than 30 states. The NuVal® system is based on the Overall Nutritional Quality Index (ONQITM) algorithm (patents pending) developed by a team under my direction. The ONQI is the first, and to date only, nutritional guidance system ever shown to correlate significantly with health outcomes, including all-cause mortality.¹

¹ Chiuve SE, Sampson L, Willett WC. The association between a nutritional quality index and risk of chronic disease. Am J Prev Med. 2011 May;40(5):505-13.

and their parents, currently in use in thousands to tens of thousands of public schools around the world.³ I am a former Director of a Preventive Medicine Residency program, charged with training physicians in disease prevention, health promotion, and lifestyle counseling among other Along with colleagues, I have studied, and published work, related to the application of behavioral and dietary counseling in the clinical setting for roughly 15 years, ⁴ culminating in the development of an on-line program that teaches dietary/lifestyle counseling to clinicians, and that offers I have been identified by Children's Health Magazine (2009) as one of the 25 most influential people on the health of children in the United States; and by Greatist.com (2012) as one of the top 100 influencers (#19) in the United States in the area of health and fitness (First Lady Michelle In 2009, I was nominated to the Obama Administration for the position of U.S. Surgeon General by the American College of Physicians; the American College of Preventive Medicine; the ² Reynolds JS, Treu JA, Njike V, Walker J, Smith E, Katz CS, Katz DL. The validation of a food label literacy questionnaire for elementary school children. J Nutr Educ Behav. 2012 May-Jun;44(3):262-6; Katz DL, Doughty K, Njike V, Treu JA, Reynolds J, Walker J, Smith E, Katz C. A

⁴ Katz DL, Shuval K, Comerford BP, Faridi Z, Njike VY. Impact of an educational intervention on internal medicine residents' physical activity counselling: the Pressure System Model. J Eval Clin Pract. 2008 Apr;14(2):294-9; Lederman J, Ballard J, Njike VY, Margolies L, Katz DL. Information given to postmenopausal women on coronary computed tomography may influence cardiac risk reduction efforts. J Clin Epidemiol. 2007 Apr;60(4):389-96; Katz DL. Behavior modification in primary care: the pressure system model. Prev Med. 2001 Jan;32(1):66-72; O'Connell M, Comerford BP, Wall HK, Yanchou-Njike V, Faridi Z, Katz DL. Impediment profiling for smoking cessation: application in the worksite. Am J Health Promot. 2006 Nov-Dec;21(2):97-100; Katz DL, Boukhalil J, Lucan SC, Shah D, Chan W, Yeh MC. Impediment profiling for smoking cessation. Preliminary experience. Behav Modif. 2003 Sep;27(4):524-37; O'Connell M, Lucan SC, Yeh MC, Rodriguez E, Shah D, Chan W, Katz DL. Impediment profiling for smoking cessation: results of a pilot study. Am J Health Promot. 2003 May-Jun;17(5):300-3.

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⁵ See http://www.turnthetidefoundation.org/OWCH/about.htm

Center for Science in the Public Interest; and the Association of Yale Alumni in Public Health, among others.

- 11. I have taught dietary counseling to medical students, physician assistant students, nursing students, medical residents, and senior physicians. I have directed nutrition courses at the Yale School of Medicine, and the Yale School of Nursing.
- 12. I have been providing clinical care (Internal Medicine) since 1991, with a particular (although not exclusive) emphasis on dietary counseling, weight management, nutrition, and lifestyle medicine since 1996.
- 13. I have delivered talks at medical and health conferences all over the world, and have delivered keynote addresses in not fewer than seven countries on not fewer than three continents, as well as in national conferences in dozens of states throughout the U.S.
- 14. I have authored or co-authored textbooks on evidence-based medicine; preventive medicine; and nutrition.⁶
- 15. As a biomedical researcher, I have secured as principal investigator or co-principal investigator roughly \$40 million in research funding over the past 17 years from the National Institutes of Health; the Center for Disease Control; Department of Health and Human Services; U.S. Department of Agriculture; health foundations; and industry.
- 16. I was requested by Nature, one of the preeminent scientific journals in the world, to serve as expert reviewer of Dr. Lustig's recently published book, "Fat Chance."
- 17. I have offered expert trial testimony, in the last four years, in a medical malpractice case related in particular to novel nutritional therapies. I have also served as an expert consultant in numerous matters.
 - 18. A true and correct copy of my C.V. is attached hereto as Exhibit 1.
- 19. I am being compensated by Chobani, Inc. based on the number of hours worked on this matter at my standard billing rate for expert testimony and services of \$3,500 per hour. My

⁶ See http://www.davidkatzmd.com/books.asp

⁷ See http://usrexp-sandbox.nature.com/nature/journal/v492/n7429/full/492355a.html

compensation is not contingent in any way on my opinion or the substance of any testimony in this matter or the outcome of this litigation.

II. INFORMATION CONSIDERED AND SUMMARY OF "SUGARS"

- 20. The opinions offered in this report are based on my training, expertise, and background, as well as my review of documents and other materials cited in this report, including plaintiffs' motion for preliminary injunction and the declaration of Dr. Robert H. Lustig. I also have reviewed the Nutrition Facts Panel and ingredient list of a Chobani Greek Yogurt product, as shown at ¶ 13 of plaintiffs' second amended complaint.
- 21. In the medical community, the term "sugar" or "sugars" refers to specific carbohydrates, such as fructose, sucrose, lactose, and glucose. These sugars may be found in sweeteners (*e.g.*, white refined sugar), or in food and beverages (*e.g.*, fruit contains fructose and milk contains lactose). In considering a proper amount of sugars in a healthy diet (or cautioning patients against the overconsumption of sugars), the various sugars (*e.g.*, fructose, sucrose, lactose, glucose) are considered as a group. In other words, I do not advise patients regarding, and the medical community generally does not differentiate between, the amount of any particular type of sugar. Grouping all sugars together is appropriate because there are no material nutritional or health differences between the different sugars. This is consistent with the Food and Drug Administration's ("FDA") decision not to require food and beverage manufacturers to separately list different sugars in the Nutrition Facts Panel on the label of products, but rather requires companies to group all of the sugars together in declaring the total amount of "Sugars."

III. Opinion #1: Dr. Lustig Inaccurately Vilifies Sugars And Specifically Chobani Greek Yogurt Products

22. Dr. Lustig, in his declaration and publications, has taken a common sense notion – that consumers should avoid consuming excessive amounts of sugars – and gone beyond any medically competent opinion, suggesting that all sugars are "poison." Extreme positions about single nutrients have consistently resulted in public health harm, and Dr. Lustig's position would do the same, if unchecked. For example, fruit and dairy contain sugars, but it would be detrimental to eliminate or significantly

restrict their consumption. Moreover, his focus on sugars diverts attention from other important dietary considerations (*e.g.*, exercise, fat, and protein).

- 23. The fundamental flaws in Dr. Lustig's sugar overconsumption opinion are that (1) the overconsumption argument could be made with respect to every single product that contains any amount of sugars, and yet many such products are perfectly safe and healthy, and (2) Chobani's products declare the amount of sugars so that consumers are provided an appropriate level of information to properly monitor their sugar intake. Accordingly, even at 20 grams of sugars per 6 oz. serving, for example, there is no basis to ban Chobani Greek Yogurt Products, just as there is no basis to ban every product in the marketplace containing sugars. Indeed, I eat Chobani Greek Yogurt, as do my children, as part of a healthy balanced diet.
- 24. Dr. Lustig insinuates that the harm from excess sugars in the overall diet comes from evaporated cane juice in Chobani Greek Yogurt products. This is specious at best, and appears to be willfully so. Dr. Lustig refers to "excess" (*e.g.*, Lustig Dec. ¶¶ 11-12) sugar, but he does not indicate what that term means. He continues that "excess" sugar can lead to "overconsumption, obesity, and chronic metabolic disease." (*Id.* ¶ 11.) But this refers to the ill effects of excessive sugar intake overall not the effects of any given product. This assertion attributes to one version of one food ills that are only meaningfully associated with an overall dietary pattern substantially at odds with prevailing recommendations.
- 25. Dr. Lustig cites no evidence that Chobani Greek Yogurt products are an important source of excess calories or sugars in the typical American diet and indeed, we know that much of that excess relates to beverage intake, not food. While, certain consumers in the U.S. may consume too much sugar, to penalize any one source of sugars on this basis makes no more sense than penalizing any given source of calories because calories, too, are over-consumed. Dr. Lustig cites no data on the contribution of sugar by Chobani products to the diet or to any health problem. This is like blaming a t-shirt and shorts for hyperthermia risk on a 100 degree day, because clothes help the body retain warmth, missing the point

⁸ Dr. Lustig (Lustig Dec. ¶ 23) refers to yogurts as an important source of sugar. But this trend predates Chobani's entry into the market, and thus very strongly indicates this problem has nothing whatever to do with what the sweeteners in yogurt are called.

that the particular clothes in question were far more likely part of a partial solution than part of the problem.

26. Here, the inclusion of yogurt and other dairy products in the diet, inclusive of sweetened varieties, is consistently associated with better health outcomes and weight. Chobani Greek Yogurt products, inclusive of sweetened varieties, can be (and most assuredly are) part of a nutritionally balanced and healthy diet, and Dr. Lustig's insinuation otherwise is without foundation.

IV. Opinion #2: Chobani's Label Is Not Misleading

- 27. There are innumerable products in the food supply with added sweeteners under a variety of names. This is one of the reasons why the FDA requires a standard Nutritional Facts Panel on all packaged food products that list the amount of sugars (as defined by the FDA) in a product in a simple and conspicuous manner. Consumers may look to the Nutrition Facts Panel including the Nutrition Facts Panel on Chobani Greek Yogurt products to obtain the information needed to make informed purchasing decisions, including with respect to consumption of sugars.
- 28. Dr. Lustig's opinion does not provide enough weight (any) to the straightforward and accurate information provided by the sugars declaration in the Nutrition Facts Panel. The total amount of sugars, to the gram, is disclosed on Chobani's product labels, providing consumers the information needed to make informed purchasing decisions regarding sugar consumption. That the Nutrition Facts Panel does not break precisely the grams of sugars by their particular type (*e.g.*, fructose, sucrose, lactose, glucose) in not material from a nutrition, medical or public health perspective. From a nutrition, medical and public health perspective and in the judgment of the FDA⁹ any distinction as to the source of sugars (that is whether it is fructose from fruit, sucrose from cane, lactose from milk or glucose from plants) is immaterial because the effect on the body of each type is, in all material respects, the same.

⁹ In requiring food manufacturers to list the amount of "sugars" of food products in the Nutrition Facts Panel (*see* 21 C.F.R. § 101.9(c)(6)(ii)), the FDA requires manufacturers to provide a single number on the Nutrition Facts Panel representing the "sum of all free mono and disaccharides (such as glucose, fructose, lactose, and sucrose)," and does not allow food companies to break down the sugars into more detailed categories. In other words, the FDA determined, correctly in my opinion, that consumers are provided the appropriate level of information on sugar content of food products by the total "sugars" disclosure on the Nutrition Facts Panel to make informed purchasing decisions.

http://health.usnews.com/health-news/blogs/eat-run/2012/11/30/is-dairy-healthy-or-not

That is why in my counseling of patients on sugar consumption, I do not ask patients to try to calculate how much sugar they are consuming from any specific source.

- 29. In my counseling, in my books, and in my programs developed to support food label literacy, I emphasize the importance of looking at the Nutrition Facts Panel. If Dr. Lustig does not include such attention to the Nutrition Facts Panel in his nutrition counseling, his counseling would not meet the standards of good practice. If he does include the same attention in his counseling, then the opinion he has offered in this case that, in essence, variations in the terminology of ingredient lists are the sole determinant of whether or not sugar content is being disclosed on a product package is undermined by his own counseling practice.
- 30. Additionally, in my experience of discussing food choices with thousands of patients and countless other people over the last two decades, consumers could not reasonably and do not suspect that sweet yogurt products contain no added sweeteners; doing so is not consistent with the reasonable consumer and would go beyond "unsuspecting" to oblivious. With regard to evaporated cane juice, and in addition to the complete and accurate disclosure on the Nutrition Facts Panel of "Sugars," it is significant that the word "cane" is used because in the context of food "cane" means sugar cane. Moreover, I am, and for years have been, aware of the use of the phrase "evaporated cane juice" to identify a sweetener ingredient and understand it is included as an ingredient in many products.
- 31. Finally, and perhaps most importantly: while there are important areas of contention and debate among both legitimate experts and the lay public regarding the optimal role of dairy (inclusive of yogurt) in the diet, ¹⁰ the overwhelming weight of evidence in the peer-reviewed literature (of which the citations provided are only a small and illustrative sub-set) indicates protective effects of dairy, and perhaps yogurt and other fermented dairy products in particular, against obesity, diabetes, and cardiovascular risk factors:
 - Chen M, Pan A, Malik VS, Hu FB. Effects of dairy intake on body weight and fat: a metaanalysis of randomized controlled trials. Am J Clin Nutr. 2012 Oct;96(4):735-47

- Spence LA, Cifelli CJ, Miller GD. The Role of Dairy Products in Healthy Weight and Body Composition in Children and Adolescents. Curr Nutr Food Sci. 2011 Feb;7(1):40-49
- Abargouei AS, Janghorbani M, Salehi-Marzijarani M, Esmaillzadeh A. Effect of dairy consumption on weight and body composition in adults: a systematic review and meta-analysis of randomized controlled clinical trials. Int J Obes (Lond). 2012 Dec;36(12):1485-93
- Josse AR, Atkinson SA, Tarnopolsky MA, Phillips SM. Increased consumption of dairy foods and protein during diet- and exercise-induced weight loss promotes fat mass loss and lean mass gain in overweight and obese premenopausal women. J Nutr. 2011 Sep;141(9):1626-34
- Dougkas A, Reynolds CK, Givens ID, Elwood PC, Minihane AM. Associations between dairy consumption and body weight: a review of the evidence and underlying mechanisms. Nutr Res Rev. 2011 Feb 15:1-24
- Zemel MB, Richards J, Mathis S, Milstead A, Gebhardt L, Silva E. Dairy augmentation of total and central fat loss in obese subjects. Int J Obes (Lond). 2005 Apr;29(4):391-7
- Azadbakht L, Haghighatdoost F, Karimi G, Esmaillzadeh A. Effect of consuming salad and yogurt as preload on body weight management and cardiovascular risk factors: a randomized clinical trial. Int J Food Sci Nutr. 2012 Dec 19. [Epub ahead of print] PubMed PMID: 23249429
- Asemi Z, Samimi M, Tabassi Z, Naghibi Rad M, Rahimi Foroushani A, Khorammian H,
 Esmaillzadeh A. Effect of daily consumption of probiotic yoghurt on insulin resistance in
 pregnant women: a randomized controlled trial. Eur J Clin Nutr. 2013 Jan;67(1):71-4
- Abreu S, Santos R, Moreira C, Santos PC, Vale S, Soares-Miranda L, Mota J, Moreira P. Milk intake is inversely related to body mass index and body fat in girls. Eur J Pediatr. 2012 Oct;171(10):1467-74
- Ramchandran L, Shah NP. Yogurt can beneficially affect blood contributors of cardiovascular health status in hypertensive rats. J Food Sci. 2011 May;76(4):H131-6
- Dougkas A, Minihane AM, Givens DI, Reynolds CK, Yaqoob P. Differential effects of dairy snacks on appetite, but not overall energy intake. Br J Nutr. 2012 Dec 28;108(12):2274-85

•	Kim J. Dairy food consumption is inversely associated with the risk of the metabolic syndrome in
	Korean adults. J Hum Nutr Diet. 2013 Apr 8. doi: 10.1111/jhn.12098. [Epub ahead of print]
	PubMed PMID: 23560887

- Sluijs I, Forouhi NG, Beulens JW, van der Schouw YT, Agnoli C, Arriola L, Balkau B, Barricarte A, Boeing H, Bueno-de-Mesquita HB, Clavel-Chapelon F, Crowe FL, de Lauzon-Guillain B, Drogan D, Franks PW, Gavrila D, Gonzalez C, Halkjaer J, Kaaks R, Moskal A, Nilsson P, Overvad K, Palli D, Panico S, Quirós JR, Ricceri F, Rinaldi S, Rolandsson O, Sacerdote C, Sánchez MJ, Slimani N, Spijkerman AM, Teucher B, Tjonneland A, Tormo MJ, Tumino R, van der A DL, Sharp SJ, Langenberg C, Feskens EJ, Riboli E, Wareham NJ; InterAct Consortium. The amount and type of dairy product intake and incident type 2 diabetes: results from the EPIC-InterAct Study. Am J Clin Nutr. 2012 Aug;96(2):382-90
- Rice BH, Quann EE, Miller GD. Meeting and exceeding dairy recommendations: effects of dairy consumption on nutrient intakes and risk of chronic disease. Nutr Rev. 2013 Apr;71(4):209-23
- Asemi Z, Samimi M, Tabassi Z, Sabihi SS, Esmaillzadeh A. A randomized controlled clinical trial investigating the effect of DASH diet on insulin resistance, inflammation, and oxidative stress in gestational diabetes. Nutrition. 2013 Apr;29(4):619-24
- Aggarwal J, Swami G, Kumar M. Probiotics and their Effects on Metabolic Diseases: An Update.
 J Clin Diagn Res. 2013 Jan;7(1):173-7
- Struijk EA, Heraclides A, Witte DR, Soedamah-Muthu SS, Geleijnse JM, Toft U, Lau CJ. Dairy product intake in relation to glucose regulation indices and risk of type 2 diabetes. Nutr Metab Cardiovasc Dis. 2012 Jul 23. [Epub ahead of print] PubMed PMID: 22831954

¹¹ Feijó Fde M, Ballard CR, Foletto KC, Batista BA, Neves AM, Ribeiro MF, Bertoluci MC. Saccharin and aspartame, compared with sucrose, induce greater weight gain in adult Wistar rats, at similar total caloric intake levels. Appetite. 2013 Jan;60(1):203-7.

33. This large body of evidence suggests that any effort directed at restricting consumer access to an array of dairy products, and in particular barring the sale of a brand of yogurt that is the preferred choice of many consumers, could – by resulting in reduced dairy intake – lead to net public health harm. This is diametrically opposed to the argument for injunctive relief, and is, on the basis of available evidence in the peer-reviewed literature, the more plausible net effect of the action proposed by the plaintiff than the avoidance of harm.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed this 15th day of April, 2013 at New Haven, Connecticut.

Dr. David Katz