BURSOR & FISHER, P.A.
L. Timothy Fisher (State Bar No. 191626)
Julia A. Luster (State Bar No. 295031)
1990 North California Blvd., Suite 940
Walnut Creek, CA 94596
Telephone: (925) 300-4455
Facsimile: (925) 407-2700
E-Mail: ltfisher@bursor.com
jluster@bursor.com

BURSOR & FISHER, P.A.
Scott A. Bursor (State Bar No. 276006)
888 Seventh Avenue
New York, NY 10019
Telephone: (212) 989-9113
Facsimile: (212) 989-9163
E-Mail: scott@bursor.com

Counsel for Plaintiffs

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

STEVEN BAILEY and LOREE MORAN, on behalf of themselves and all others similarly situated,

Plaintiffs,

v.

KIND, LLC,

Defendant.

Case No. 8:16-CV-00168

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

Plaintiffs Steven Bailey and Loree Moran ("Plaintiffs"), by and through their attorneys, make the following allegations pursuant to the investigation of their counsel and based upon information and belief, except as to allegations specifically pertaining to themselves and their counsel, which are based on personal knowledge, against Defendant KIND, LLC ("KIND" or "Defendant").

NATURE OF THE ACTION

1. This is a class action lawsuit on behalf of purchasers of KIND nut-based candy bars in the United States.

2. From October 2012 until May 2014, KIND bars uniformly represented that "[a] study from the Yale-Griffin Prevention Research Center indicates that eating two KIND bars a day helps prevent weight gain" (the "Misrepresentation"). That representation is false and misleading.[1]

3. In fact, the above-referenced study (the "First Yale-Griffin Study") found **no difference** in weight gain between participants who ate two KIND bars a day and those who did not. There was nothing in the study's results that indicated "that eating two KIND bars a day helps prevent weight gain."[2]

4. The First Yale-Griffin Study, which was financed in 2008 by KIND's former affiliate, PeaceWorks Holdings LLC, tracked two groups of overweight adults for 8 weeks. While participants in the "control" group were given no instructions at all, participants in the "intervention" group were instructed to consume KIND bars twice a day. At the end of 8 weeks, the study found that

> "Anthropometric measures (i.e. body mass index, weight and waist circumference) **did not improve** from baseline

[1] KIND bars come in several varieties and flavors. All contained the same false and misleading representation about the same study.

[2] A true and correct copy of the First Yale-Griffin Study is attached hereto as **Exhibit A**.

> after consumption of fruit and nut snack bar compared to controls."

Far from indicating that the KIND Bars helped prevent weight gain, the study's authors concluded that "[t]he addition of two daily fruit and nut snack bars to habitual baseline diet **had no effect on body weight** …."[3]

5. The data from the First Yale-Griffin Study at best showed that consumption of KIND Bars "did not cause weight gain," as its authors concluded. But the fact that a product does not *cause* weight gain is distinguishable from whether it *prevents* weight gain, as KIND represents.

6. After reviewing the First Yale Griffin Study in the course of a similar litigation, Judge Alvin K. Hellerstein found that "KIND makes a leap in logic by reading the Study to say that KIND bars affirmatively *prevent* weight gain." *Cohn v. KIND, LLC*, 2015 WL 9703527, at *2 (S.D.N.Y. Jan. 14, 2015) (emphasis in original).

7. The First Yale-Griffin Study is written in plain English. No scientific or medical expertise is required to understand its data and conclusions. There is no reasonable way to interpret the study as supporting the above-referenced representation that KIND bars help prevent weight gain.

8. Moreover, the First Yale-Griffin Study was fraught with design problems. It only examined a decidedly small sample size of 94 people, of whom only 89 completed the study. The study also involved only "overweight adults," and could not have indicated anything about individuals in the general public who are not overweight. Yet, no such qualification appeared on the KIND Bars' labeling.

9. More importantly, because the study did not keep track of its participants' caloric intake, its data are irrelevant to the determination of whether or not KIND Bars help prevent weight gain. The only way one could conclude that

[3] Emphasis added.

KIND Bars help prevent weight gain from the study's data would be if the experimental group (which ate KIND Bars) had consumed more calories than the control group (which was unmonitored), but still did not show signs of weight gain. That was not done.

10. It gets worse. After the First Yale Griffin Study failed to show any difference in weight gain between subjects who ate KIND bars and those who did not, KIND attempted to engineer a second study in search of a more favorable result. Thus, in late 2013, KIND funded the a second study (the "Second Yale Griffin Study" and together with the First Yale Griffin Study, the "Yale Griffin Studies") which compared a group of people who consumed KIND bars daily with a group of people who consumed "conventional snack foods" daily, including "Nabisco Snackwell Creme Sandwich 1.7 oz pack, Nabisco Newtons Fig 2 oz pack, Nabisco Cips Ahoy! Chocolate Chip 1.4 oz pack, and Nabisco Oreo Double Stuff Chocolate 1.3 oz pack."[4] In order to control for subjects' diets outside the study, the Yale Griffin Prevention Research Center ("YGPRC") gave subjects "clear guidance about the calorie content of snack items, and how to make room for those calories in their diets."[5] Before conducting the study, YGPRC stated "[w]e expect to find that snacking on conventional snack foods will contribute to weight gain, whereas snacking on [KIND bars] will contribute to … weight loss …." YGPRC Newsflash, July 2012, attached hereto as **Exhibit B** at 4.

11. But that hypothesis turned out to be incorrect. Instead, the Second Yale Griffin Study found "[t]here were no significant differences between the two snack groups with regard to changes in weight." YGPRC Newsflash, May 2014, attached hereto as **Exhibit C** at 4. **The Second Study thus found that the weight-gain**

[4] *See* Study Record Detail from clinicaltrials.gov, https://clinicaltrials.gov/ct2/show/NCT02050165.

[5] *Id.*

prevention qualities of KIND bars were roughly equal to those of Double Stuff Oreos. These results confirmed that KIND's interpretation of the First Yale Griffin Study's findings was decidedly incorrect.

12. KIND knew about the findings of the Second Yale Griffin Study by January 2014, but continued selling KIND bars with the Misrepresentation on them for several months thereafter. KIND finally removed the Misrepresentation from the label in or about May 2014.

13. The Misrepresentation was central to KIND's marketing of KIND bars during the relevant period, and was a primary basis upon which consumers relied in purchasing KIND bars. The packaging for KIND bars prominently bears the slogan "Fill up without filling out!" And in a similar marketing effort, KIND sent out 2,000 New Year's greeting cards with KIND bars, stating, "eat 2 KIND bars a day, and lose weight."[6]

14. The Misrepresentation appeared on the back of the KIND Bar wrapper, in a more prominent location than the nutrition information, which appears underneath the fold of the wrapper. KIND knew that consumers would rely on it in deciding to purchase KIND Bars over other similar bars made by competitors. That is the sole reason KIND funded the Yale Griffin Studies and printed a (false and misleading) reference thereto on the label.

15. By virtue of the Misrepresentation, Defendant was able to sell KIND bars at a substantial premium over similar nut-based candy bars that did not contain the Misrepresentation:

[6] *See* http://blog.peaceworks.net/2009/01/yale-study-eating-kind-bars-helps-lose-weight/.

Store	Product	Units Per Box	Price Per Box	Price Per Unit
Drugstore.com	KIND Bars[7]	12	$19.99	$1.66
Drugstore.com	Nature Valley Trail	6	$2.99	$.50

16. Plaintiffs are purchasers of KIND Bars who assert claims on behalf of themselves and similarly situated purchasers of KIND bars for breach of warranty, violations of the consumer protection laws of California and New York, and negligent misrepresentation, fraud, and unjust enrichment.

PARTIES

17. Plaintiff Steven Bailey is a citizen of California who resides in Orange County. Mr. Bailey purchased KIND bars at Sam's Club and Walmart on many occasions since early 2013. Prior to purchase, Mr. Bailey carefully read the KIND bars' labeling, including the statement that "[a] study from the Yale-Griffin Prevention Research Center indicates that eating two KIND bars a day helps prevent weight gain." Mr. Bailey believed this statement to be true, and relied on it in that he would not have purchased KIND bars at all, or would have only been willing to pay a substantially reduced price for KIND bars had he known that this representation was false and misleading.

18. Plaintiff Loree Moran is a citizen of New York who resides in Nassau County. Ms. Moran purchased KIND bars at Stop & Shop, King Cullen, and Trader Joe's in Nassau County on many occasions since 2013. Prior to purchase, Ms. Moran carefully read the KIND bars' labeling, including the statement that "[a] study from the Yale-Griffin Prevention Research Center indicates that eating two KIND bars a day helps prevent weight gain." Ms. Moran believed this statement to be true,

[7] The price for KIND bars listed in this table was the same for all varieties of KIND bars containing the Misrepresentation sold at Drugstore.com.

and relied on it in that she would not have purchased KIND bars at all, or would have only been willing to pay a substantially reduced price for KIND bars had she known that this representation was false and misleading.

19. Defendant KIND is a Delaware corporation with a principal place of business at 1372 Broadway, New York, NY 10018. KIND is responsible for the manufacture, distribution, sales, and marketing of KIND bars in the United States.

Jurisdiction And Venue

20. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because there are more than 100 class members and the aggregate amount in controversy exceeds $5,000,000.00, exclusive of interest, fees, and costs, and at least one Class member is a citizen of a state different from Defendant.

21. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391 because Defendant does business throughout this District.

22. All conditions precedent necessary for filing this Complaint have been satisfied and/or such conditions have been waived by the conduct of the Defendant.

CLASS REPRESENTATION ALLEGATIONS

23. Plaintiffs seek to represent a class defined as all persons in the United States who purchased KIND bars which were packaged from October 2012 to May 2014 (the "Class"). Excluded from the Class are persons who made such purchase for purpose of resale.

24. Mr. Bailey also seeks to represent a subclass defined as all Class members who purchased KIND bars in California (the "California Subclass"). Ms. Moran also seeks to represent a subclass defined as all Class members who purchased KIND bars in New York (the "New York Subclass").

25. Members of the Class and Subclasses are so numerous that their individual joinder herein is impracticable. On information and belief, members of the Class and Subclasses number in the millions. The precise number of Class

members and their identities are unknown to Plaintiffs at this time but may be determined through discovery. Class members may be notified of the pendency of this action by mail and/or publication through the distribution records of Defendant and third party retailers and vendors.

26. Common questions of law and fact exist as to all Class members and predominate over questions affecting only individual Class members. Common legal and factual questions include, but are not limited to whether Defendant's labeling, marketing and promotion of the KIND bars is false and misleading.

27. The claims of the named Plaintiffs are typical of the claims of the Class in that the named Plaintiffs were exposed to Defendant's false and misleading marketing and promotional materials and representations, purchased KIND bars, and suffered a loss as a result of that purchase.

28. Plaintiffs are adequate representatives of the Class and Subclasses because their interests do not conflict with the interests of the Class members they seek to represent, they have retained competent counsel experienced in prosecuting class actions, and they intend to prosecute this action vigorously. The interests of Class members will be fairly and adequately protected by Plaintiffs and his counsel.

29. The class mechanism is superior to other available means for the fair and efficient adjudication of the claims of Class members. Each individual Class member may lack the resources to undergo the burden and expense of individual prosecution of the complex and extensive litigation necessary to establish Defendant's liability. Individualized litigation increases the delay and expense to all parties and multiplies the burden on the judicial system presented by the complex legal and factual issues of this case. Individualized litigation also presents a potential for inconsistent or contradictory judgments. In contrast, the class action device presents far fewer management difficulties and provides the benefits of single adjudication, economy of scale, and comprehensive supervision by a single court on

the issue of Defendant's liability. Class treatment of the liability issues will ensure that all claims and claimants are before this Court for consistent adjudication of the liability issues.

COUNT I

(Breach Of Express Warranty)

30. Plaintiffs incorporate by reference and re-allege each and every allegation set forth above as though fully set forth herein.

31. Plaintiffs bring this claim individually and on behalf of members of the Class and Subclasses against Defendant.

32. In connection with the sale of KIND Bars, Defendant, as the designer, manufacturer, marketer, distributor, and/or seller issued written warranties by representing that "[a] study from the Yale-Griffin Prevention Research Center indicates that eating two KIND bars a day helps prevent weight gain."

33. In fact, KIND bars do not conform to the above-referenced representation because the Yale-Griffin Studies found the consumption of KIND bars "had no effect on body weight."

34. Plaintiffs and Class members were injured as a direct and proximate result of Defendant's breach because (a) they would not have purchased KIND Bars if they had known that the Yale-Griffin Studies found the consumption of KIND bars "had no effect on body weight," and (b) they overpaid for KIND Bars because they were sold at a price premium on account of this misrepresentation.

COUNT II

(Violation Of California's Consumers Legal Remedies Act, California Civil Code §§ 1750, *et seq.*)

35. Plaintiffs incorporate by reference and re-allege each and every allegation set forth above as though fully set forth herein.

36. Plaintiff Bailey brings this claim individually and on behalf of the

members of the California Subclass against Defendant.

37. California's Consumers Legal Remedies Act, Cal. Civ. Code § 1770(a)(5), prohibits "[r]epresenting that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities which they do not have or that a person has a sponsorship, approval, status, affiliation, or connection which he or she does not have."

38. California's Consumers Legal Remedies Act, Cal. Civ. Code § 1770(a)(7), prohibits "[r]epresenting that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another."

39. California's Consumers Legal Remedies Act, Cal. Civ. Code § 1770(a)(9), prohibits "[a]dvertising goods or services with intent not to sell them as advertised."

40. Defendant violated these provisions by misrepresenting that "[a] study from the Yale-Griffin Prevention Research Center indicates that eating two KIND bars a day helps prevent weight gain."

41. Plaintiff Bailey and members of the California Subclass have been injured and harmed because: (a) they would not have purchased KIND Bars if they had known that the Yale-Griffin Studies found the consumption of KIND bars "had no effect on body weight," and (b) they overpaid for KIND Bars because they were sold at a price premium on account of this misrepresentation.

42. On or about December 18, 2015, prior to filing this action, a CLRA notice letter was served on Defendant which complies in all respects with California Civil Code § 1782(a). Mr. Bailey sent Defendant a letter via certified mail, return receipt requested, advising Defendant that it violated the CLRA and demanding that it make full restitution by refunding the monies received therefrom. A true and

correct copy of the letter is attached hereto as **Exhibit D**.[8]

43. Wherefore, Plaintiff Bailey seeks damages and restitution for this violation of the CLRA.

COUNT III

(Violation Of California's Unfair Competition Law, California Business & Professions Code §§ 17200, *et seq.*)

44. Plaintiffs incorporate by reference and re-allege each and every allegation set forth above as though fully set forth herein.

45. Plaintiff Bailey brings this claim individually and on behalf of the members of the California Subclass against Defendant.

46. Defendant is subject to California's Unfair Competition Law, Cal. Bus. & Prof. Code §§ 17200, et seq. The UCL provides, in pertinent part: "Unfair competition shall mean and include unlawful, unfair or fraudulent business practices and unfair, deceptive, untrue or misleading advertising …."

47. Defendant's Misrepresentation, described herein, violated the "unlawful" prong of the UCL by violating the CLRA as described herein; the FAL as described herein; and Cal. Com. Code § 2607.

48. Defendant's Misrepresentation, described herein, violated the "unfair" prong of the UCL in that its conduct is substantially injurious to consumers, offends public policy, and is immoral, unethical, oppressive, and unscrupulous, as the gravity of the conduct outweighs any alleged benefits.

49. Defendant violated the "fraudulent" prong of the UCL by making the Misrepresentation, as described herein.

50. Plaintiff Bailey and the California Subclass lost money or property as a result of Defendant's UCL violations because: (a) they would not have purchased

[8] Duplicate copies of Exhibit D were delivered to KIND by hand delivery and by certified mail, return receipt requested.

KIND Bars if they had known that the Yale-Griffin Studies found the consumption of KIND bars "had no effect on body weight," and (b) they overpaid for KIND Bars because they were sold at a price premium on account of this misrepresentation.

COUNT IV

(Violation Of California's False Advertising Law, California Business & Professions Code §§ 17500, *et seq.*)

51. Plaintiffs hereby incorporate by reference the allegations contained in all preceding paragraphs of this complaint.

52. Plaintiff Bailey brings this claim individually and on behalf of the members of the California Subclass against Defendant.

53. California's False Advertising Law, Cal. Bus. & Prof. Code §§ 17500, et seq., makes it "unlawful for any person to make or disseminate or cause to be made or disseminated before the public in this state, ... in any advertising device ... or in any other manner or means whatever, including over the Internet, any statement, concerning ... personal property or services, professional or otherwise, or performance or disposition thereof, which is untrue or misleading and which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading."

54. Defendant committed acts of false advertising, as defined by § 17500, by making the Misrepresentation on the labels of KIND bars.

55. Defendant knew or should have known, through the exercise of reasonable care that the Misrepresentation was untrue and misleading.

56. Defendant's actions in violation of § 17500 were false and misleading such that the general public was likely to be deceived.

57. Plaintiff Bailey and members of the California Subclass lost money or property as a result of Defendant's FAL violations because: (a) they would not have purchased KIND Bars if they had known that the Yale-Griffin Studies found the

consumption of KIND bars "had no effect on body weight," and (b) they overpaid for KIND Bars because they were sold at a price premium on account of this misrepresentation.

COUNT V

(Negligent Misrepresentation)

58. Plaintiffs hereby incorporate by reference the allegations contained in all preceding paragraphs of this complaint.

59. Plaintiffs bring this claim individually and on behalf of the members of the Class and Subclasses against Defendant.

60. As discussed above, Defendant placed the Misrepresentation on the labels of KIND bars.

61. At the time Defendant made the Misrepresentation, Defendant knew or should have known that the Misrepresentation was false or made it without knowledge of its truth or veracity.

62. At an absolute minimum, Defendant negligently misrepresented and/or negligently omitted material facts about the Yale Griffin Studies.

63. The negligent misrepresentations and omissions made by Defendant, upon which Plaintiffs and Class and California and New York Subclass members reasonably and justifiably relied, were intended to induce and actually induced Plaintiffs and Class and California and New York Subclass members to purchase KIND bars.

64. Plaintiffs and Class and Subclass members would not have purchased KIND bars if the true facts had been known.

65. The negligent actions of Defendant caused damage to Plaintiffs and Class and Subclass members, who are entitled to damages and other legal and equitable relief as a result.

COUNT VI

(Fraud)

66. Plaintiffs hereby incorporate by reference the allegations contained in all preceding paragraphs of this complaint.

67. Plaintiffs bring this claim individually and on behalf of the members of the Class and California and New York Subclasses against Defendant.

68. As discussed above, Defendant misrepresented that "[a] study from the Yale-Griffin Prevention Research Center indicates that eating two KIND bars a day helps prevent weight gain" on the labels for KIND bars.

69. The false and misleading representations and omissions were made with knowledge of their falsehood.

70. The false and misleading representations and omissions were made by Defendant, upon which Plaintiffs and members of the Class and California and New York Subclasses reasonably and justifiably relied, and were intended to induce and actually induced Plaintiffs and Class members to purchase KIND bars.

71. The fraudulent actions of defendant caused damage to Plaintiffs and members of the Class, who are entitled to damages and other legal and equitable relief as a result.

COUNT VII

(Deceptive Acts Or Practices, New York Gen. Bus. Law § 349)

72. Plaintiffs incorporate by reference and re-allege each and every allegation set forth above as though fully set forth herein.

73. Plaintiff Moran brings this claim individually and on behalf of members of the New York Subclass against Defendant.

74. By the acts and conduct alleged herein, Defendant committed unfair or deceptive acts and practices by making false representations on the labels of KIND bars.

75. The foregoing deceptive acts and practices were directed at consumers.

76. The foregoing deceptive acts and practices are misleading in a material way because they fundamentally misrepresent the results of the First Yale-Griffin Study regarding KIND bars.

77. Plaintiff Moran and members of the New York Subclass were injured as a result because (a) they would not have purchased KIND Bars if they had known that the Yale-Griffin Studies found the consumption of KIND bars "had no effect on body weight," and (b) they overpaid for KIND Bars because they were sold at a price premium on account of this misrepresentation.

78. On behalf of herself and other members of the New York Subclass, Plaintiff Moran seeks to recover actual damages or fifty dollars, whichever is greater, three times actual damages, and reasonable attorneys' fees.

COUNT VIII

(False Advertising, New York Gen. Bus. Law § 350)

79. Plaintiffs incorporate by reference and re-allege each and every allegation set forth above as though fully set forth herein.

80. Plaintiff Moran brings this claim individually and on behalf of members of the New York Subclass against Defendant.

81. Based on the foregoing, Defendant has engaged in consumer-oriented conduct that is deceptive or misleading in a material way which constitutes false advertising in violation of Section 350 of the New York General Business Law by misrepresenting the results of the Yale-Griffin Study on the labeling of KIND bars.

82. The foregoing advertising was directed at consumers and was likely to mislead a reasonable consumer acting reasonably under the circumstances.

83. This misrepresentation has resulted in consumer injury or harm to the public interest.

84. As a result of this misrepresentation, Plaintiff Moran and members of the New York Subclass have suffered economic injury because (a) they would not have purchased KIND Bars if they had known that the Yale-Griffin Studies found the consumption of KIND bars "had no effect on body weight," and (b) they overpaid for KIND Bars because they were sold at a price premium on account of this misrepresentation.

85. On behalf of herself and other members of the New York Subclass, Plaintiff Moran seeks to recover actual damages or five hundred dollars, whichever is greater, three times actual damages, and reasonable attorneys' fees.

COUNT IX

(Unjust Enrichment)

86. Plaintiffs incorporate by reference and re-allege each and every allegation set forth above as though fully set forth herein.

87. Plaintiffs bring this claim individually and on behalf of members of the Class and Subclasses against Defendant.

88. Plaintiffs and Class members conferred benefits on Defendant by purchasing KIND bars.

89. Defendant has knowledge of such benefits.

90. Defendant has been unjustly enriched in retaining the revenues derived from Plaintiffs' and Class members' purchases of KIND bars. Retention of those moneys under these circumstances is unjust and inequitable because Defendant misrepresented that the First Yale-Griffin Study indicated that "eating two KIND bars a day helps prevent weight gain."

91. Because Defendant's retention of the non-gratuitous benefits conferred on it by Plaintiff and Class members is unjust and inequitable, Defendant must pay restitution to Plaintiffs and the Class members for their unjust enrichment, as ordered by the Court.

COUNT X

(Breach Of The Implied Warranty Of Merchantability)

92. Plaintiffs incorporate by reference and re-allege each and every allegation set forth above as though fully set forth herein.

93. Plaintiff Bailey brings this claim individually and on behalf of the members of the proposed California Subclass against Defendant.

94. Defendant, as the designer, manufacturer, marketer, distributor, and/or seller, impliedly warranted that "[a] study from the Yale-Griffin Prevention Research Center indicates that eating two KIND bars a day helps prevent weight gain."

95. Defendant breached the warranty implied in the contract for the sale of KIND bars because they could not "pass without objection in the trade under the contract description," the goods were not "of fair average quality within the description," the goods were not "adequately contained, packaged, and labeled as the agreement may require," and the goods did not "conform to the promise or affirmations of fact made on the container or label." See U.C.C. § 2-314(2) (listing requirements for merchantability). As a result, Plaintiff Bailey and California Subclass members did not receive the goods as impliedly warranted by Defendant to be merchantable.

96. Plaintiff Bailey and California Subclass members purchased KIND bars in reliance upon Defendant's skill and judgment in properly packaging and labeling the KIND bars.

97. The KIND Bars were not altered by Plaintiff Bailey or California Subclass members.

98. The KIND bars were defective when they left the exclusive control of Defendant.

99. Defendant knew that the KIND bars would be purchased and used without additional testing by Plaintiff Bailey and California Subclass members.

100. The KIND bars were defectively designed and unfit for their intended purpose and Plaintiff Bailey and California Subclass members did not receive the goods as warranted.

101. As a direct and proximate cause of Defendant's breach of the implied warranty, Plaintiff Bailey and California Subclass members have been injured and harmed because they would not have purchased the KIND bars if they knew the truth about the product and the KIND bars they received were worth substantially less than the KIND bars they were promised and expected.

RELIEF DEMANDED

102. WHEREFORE, Plaintiffs, individually and on behalf of all others similarly situated, seek judgment against Defendant, as follows:

A. For an order certifying the nationwide Class and the Subclasses under Rule 23 of the Federal Rules of Civil Procedure and naming Plaintiffs as representatives of the Class and Subclasses and Plaintiffs' attorneys as Class Counsel to represent the Class and Subclass members;

B. For an order declaring that Defendant's conduct violates the statutes referenced herein;

C. For an order finding in favor of Plaintiffs, the nationwide Class, and the Subclasses on all counts asserted herein;

D. For compensatory and punitive damages in amounts to be determined by the Court and/or jury;

E. For prejudgment interest on all amounts awarded;

F. For an order of restitution and all other forms of equitable monetary relief;

G. For injunctive relief as pleaded or as the Court may deem proper; and

H. For an order awarding Plaintiffs and the Class and Subclasses their reasonable attorneys' fees and expenses and costs of suit.

JURY TRIAL DEMANDED

Plaintiffs demand a trial by jury on all claims so triable.

Dated: February 1, 2016

Respectfully submitted,

BURSOR & FISHER, P.A.

By: */s/ L. Timothy Fisher*
L. Timothy Fisher

L. Timothy Fisher (State Bar No. 191626)
Julia A. Luster (State Bar No. 295031)
1990 North California Blvd., Suite 940
Walnut Creek, CA 94596
Telephone: (925) 300-4455
Facsimile: (925) 407-2700
Email: ltfisher@bursor.com
jluster@bursor.com

BURSOR & FISHER, P.A.
Scott A. Bursor (State Bar No. 276006)
888 Seventh Avenue
New York, NY 10019
Telephone: (212) 989-9113
Facsimile: (212) 989-9163
E-Mail: scott@bursor.com

Counsel for Plaintiffs

I, Steven Bailey, declare as follows:

1. I am a plaintiff in this action and a citizen of the State of California. I have personal knowledge of the facts stated herein and, if called as a witness, I could and would testify competently thereto.

2. The complaint filed in this action is filed in the proper place for trial under California Civil Code Section 1780(d) in that Defendant conducts a substantial amount of business in this District.

3. While living in California, I purchased KIND bars for my personal use after I read the packaging that said "[a] study from the Yale-Griffin Prevention Research Center indicates that eating two KIND bars a day helps prevent weight gain." This representation on the label was a substantial factor influencing my decision to purchase KIND bars. I would not have purchased KIND bars had I known that this representation was false and misleading.

I declare under the penalty of perjury under the laws of the State of California that the foregoing is true and correct, executed on January ___, 2016 at Fullerton, California.

DocuSigned by:
Steve Bailey
768430A82C68444...
1/21/2016

STEVEN BAILEY

EXHIBIT A

Journal of Human Nutrition and Dietetics

RESEARCH PAPER

The effect of the addition of daily fruit and nut bars to diet on weight, and cardiac risk profile, in overweight adults

A. Davidi,* J. Reynolds,* V. Y. Njike,* Y. Ma,* K. Doughty* & D. L. Katz*†

*Yale-Griffin Prevention Research Center, Derby, CT, USA
†Yale University School of Medicine, New Haven, CT, USA

Keywords
cardiac risk, fruit, nut, overweight, snack.

Correspondence
D. L. Katz, Yale-Griffin Prevention Research Center, 130 Division Street, Derby, CT 06418, USA.
Tel.: +1 203 732 1265
Fax: +1 203 732 1264
E-mail: katzdl@pol.net

doi:10.1111/j.1365-277X.2011.01201.x

Abstract

Background: The frequency of unhealthful snacking has increased dramatically over the last three decades. Fruits and nuts have been shown to have positive health effects. No study has investigated the aggregate effects of various fruits combined with nuts in the form of snack bars on cardiovascular risk factors. The aim of this randomised trial was to investigate the effects of a fruit and nut snack bar on anthropomorphic measures, lipid panel and blood pressure in overweight adults.

Methods: Ninety-four overweight adults (body mass index > 25 kg m^{-2}) were randomly assigned to add two fruit and nut bars totalling 1421.9 kJ (340 kcal) to their *ad libitum* diet (intervention group) or to continue with their *ad libitum* diet (control group). Subjects underwent assessment for weight (primary outcome measure), as well as waist circumference, lipid panel and blood pressure (secondary outcome measures), before and at the end of the 8-week treatment.

Results: Weight did not change from baseline after snack bar addition compared to controls ($P = 0.44$). Waist circumference ($P = 0.69$), blood pressure (systolic, $P = 0.83$; diastolic, $P = 0.79$) and blood lipid panel (total cholesterol, $P = 0.72$; high-density lipoprotein, $P = 0.11$; total cholesterol/high-density lipoprotein, $P = 0.37$; triglycerides, $P = 0.89$; low-density lipoprotein, $P = 0.81$) also did not change from baseline compared to controls.

Conclusions: Two daily fruit and nut bars, totalling 1421.9 kJ (340 kcal), did not cause weight gain. The role of habitual snacking on nutrient dense and satiating foods on both weight over time, and diet quality, warrants further study. Satiating snacks rich in fibre may provide a means to weight stabilisation.

Introduction

The global epidemic of adult and childhood obesity, along with its accompanying constellation of co-morbidities, is one of the most complex public health issues (Pi-Sunyer, 2009; Dixon, 2010). At present, the World Health Organization (WHO) estimates that more than one billion adults are overweight globally (World Health Organization, 2007). Thirty-four percent of American adults, on the other hand, meet the criteria for metabolic syndrome as defined by National Cholesterol Education Program (NCEP/ATP III) (Centers for Disease Control, & National Center for Health Statistics, 2009). Visceral obesity, one of the hallmarks of metabolic syndrome, is accompanied by a plethora of metabolic perturbations that have an effect on cardiovascular disease (CVD) incidence independent of that of general obesity (Despres *et al.*, 2008; Dhaliwal & Welborn, 2009; Pataky *et al.*, 2009; Mathieu *et al.*, 2010). The root cause of obesity is energy imbalance: calories in outweigh calories out (Katz, 2011).

Studies have shown that, in the last three decades, adults and children have experienced a substantial increase in snacking frequency (Piernas & Popkin, 2010a,b; Popkin & Duffey, 2010). Even though scientific evidence to date has yet to reach a conclusion regarding the contribution of this frequency on obesity, weight management and other health outcomes at large (Palmer *et al.*, 2009; Cameron *et al.*, 2010; Koletzko & Toschke, 2010), there is no doubt that the snacks consumed are primarily dense in calories and poor in nutrient quality (Van Horn, 2011).

Evidence from both epidemiological and randomised control trials, on the other hand, continues to highlight the positive health effects that are associated with nut consumption, as well as fruit and vegetable consumption. The Nurses Health Study (Hu *et al.*, 1998), the Physician's Health Study (Albert *et al.*, 2002), the Adventist Health Study (Fraser *et al.*, 1992) and the Iowa Women's Health Study (Ellsworth *et al.*, 2001) have all shown an association between nut consumption and reduced coronary heart disease risk, partly owing to the hypocholesterolemic properties of nuts. Long-term nut consumption is also associated with a lower risk of weight gain and obesity (Mattes *et al.*, 2008). Likewise, fruits and vegetables are rich in antioxidants, vitamins, and fibre, all of which have been shown to reduce CVD risk factors such as inflammation and oxidative stress (Liu *et al.*, 2000; Joshipura *et al.*, 2001; Dauchet *et al.*, 2004; He *et al.*, 2007; Watzl, 2008; Holt *et al.*, 2009; Polidori *et al.*, 2009). Furthermore, both nut and fruit and vegetable ingestion have also been associated with lower blood pressure (Dauchet *et al.*, 2007; Mirmiran *et al.*, 2009; Ros, 2009). Moreover, the fibre present in all these food categories has been shown to increase diet quality (Slavin, 2008) and reduce food intake (Kristensen & Jensen, 2011).

No study to date has investigated the aggregate effects of different kinds of fruits combined with nuts in the form of wholesome snack bars on cardiovascular risk factors. Given the current prevalence of metabolic syndrome in the USA, the increased levels of unhealthful snacking, and the fact that accumulating evidence is showing that a daily energy gap of as little as 418 kJ (100 kcal) can help prevent weight gain (Hill *et al.*, 2009), examination of healthful dietary strategies that succeed to increase satiety at lower energy levels would potentially be useful for preventing further obesity expansion. In response to the growing concern around the aforementioned conditions, the present randomised clinical trial was performed to investigate the effects of a fruit and nut snack bar on anthropomorphic measures, lipid panel and blood pressure in adults with increased weight circumference.

Materials and methods

Participants

Ninety-four overweight, but otherwise healthy men and women were recruited from the Lower Naugatuck Valley in Connecticut through flyers and newspaper advertisements. Those responding ($n = 159$) were prescreened using a semi-structured telephone interview. Inclusion criteria were: (i) men and women ages 18 years and greater; (ii) able to have blood pressure taken bilaterally; (iii) overweight with a body mass index (BMI) >25.0 kg m^{-2}; and (iv) one or more additional risk factors for insulin resistance: Abdominal obesity determined by waist circumference >102 cm (>40 inches) in men, >88 cm (>35 inches) in women; triglyceride level ≥150 mg dL^{-1}; high-density lipoprotein (HDL)-cholesterol < 40 mg dL^{-1} in men,<50 mg dL^{-1} in women, or blood pressure ≥130/≥85 mmHg; and fasting glucose ≥100 mg dL^{-1}.

Exclusion criteria included current eating disorder; known atherosclerotic vascular disease; restricted diet; allergy to any kind of nuts, including walnuts and peanuts; use of lipid-lowering or antihypertensive medications, unless stable on medication for at least 3 months; and age, gender and ethnically-adjusted HDL and low-density lipoprotein (LDL) levels, respectively, below the 10th percentile and above the 90th percentile. Those passing telephone screening ($n = 94$) underwent a clinical screening examination consisting of height, weight, BMI, blood pressure measurements and laboratory testing for fasting serum glucose and fasting lipid panel. The study protocol and consent form were approved by the Griffin Hospital (Derby, CT, USA) Institutional Review Board. Signed informed consent was obtained from all study participants, and all participants received monetary compensation for their participation. Subject participation and flow are shown in Fig. 1.

Study design

The present study comprised a randomised, controlled trial designed to assess the effects of 8 weeks of daily consumption of two bars (80 g) of KIND Fruit and Nut Delight snack bars (KIND LLC, New York, NY, USA) on blood pressure, lipid panel and anthropometric measures (BMI and waist circumference) relative to a control condition in overweight subjects. Participants ($n = 94$) were randomised into either the control or the intervention group. Participants were randomised using a random number generated by SAS, version 9.1 (SAS Institute, Cary, NC, USA). Participants assigned to the intervention consumed two fruit and nut snack bars per day (Table 1). Participants were given an 8-week supply of snack bars

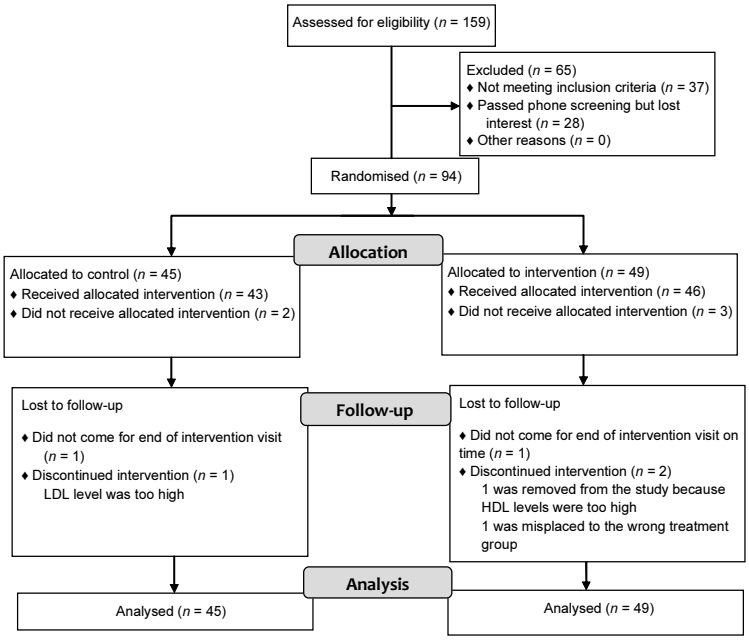

Figure 1 Flow of participants in the snack bar trial. HDL, high-density lipoprotein; LDL, low-density lipoprotein.

Table 1 Nutrient content of study snack bars

Intervention amount	Two bars (80 g)
Calories per two bars	340 kcal (1421.9 kJ)
Amount per intervention serving	% Daily value
Total fat 22 g	34%
Saturated fat 3.0 g	16%
Trans fat 0 g	0%
Cholesterol 0 g	
Sodium 50 mg	
Total carbohydrate 32 g	10%
Dietary fibre 6 g	
Sugars 24 g	
Protein 10 g	
Almonds 22 g	

Ingredients: mixed nuts (peanuts, almonds, Brazil nuts, walnuts), dried fruits [raisins, apricots, (apricot paste, glycerol (vegetable based), pectin, apple fiber, citric acid), dates], honey, glucose, puffed rice, linseed, chicory fibre, soy lecithin.

and were instructed to consume them as a snack or with a meal. Participants were also asked to fill out a log detailing their compliance to the intervention. At the end of the study, participants were asked to bring their empty packages. All subjects were encouraged to maintain their habitual *ad libitum* diet.

Anthropometric measures

To measure weight, participants were asked to remove their heavy outer garments (jacket, coat, etc.) and shoes, and to stand in the centre of a platform with weight distributed evenly on both feet. BMI was calculated using the weight and height measurements. Waist circumference was measured at the umbilicus with a measuring tape surrounding the abdomen horizontal to the floor.

Lipid panel

Serum lipids consisting of total cholesterol (TC), HDL, LDL, triglycerides and TC/HDL ratio were conducted at the Griffin Hospital laboratory using the VITROS Chemistry Analyzer (Abbott Laboratories, Abbott Park, IL, USA) colorimetric method.

Blood pressure

Blood pressure was determined using the Datascope Accutorr Plus automatic digital blood pressure device (Datascope Corp., Mahwah, NJ, USA) with the subject in a supine position after a 5-min period of rest. Both systolic and diastolic blood pressures were calculated as the mean value of two readings, taken 5 min apart.

Statistical analysis

Study data was entered into Excel spreadsheets (Microsoft Corp, Redmond, WA, USA) and analysed using SPSS, version 15 (IBM, Endicott, NY, USA). Exploratory data analysis was carried out to assess descriptive statistics

Table 2 Summary of participant demographics and baseline values

Variable	Control (n = 45)	Intervention (n = 49)	P
Gender (%)			
Female	36 (80)	38 (78)	0.49
Male	9 (20)	11(22)	
Age (years)	54.8 (15.7)	52.6 (13.0)	0.47
Anthropometric measures			
Body mass index (kg m^{-2})	34.7 (5.3)	32.7 (5.3)	0.06
Weight (kg)	94.6 (20.4)	89.2 (17.3)	0.18
Waist circumference (cm)	109 (12.9)	106 (12.4)	0.23
Lipid panel			
Total cholesterol (mmol L^{-1})	5.0 (1.0)	5.3 (0.9)	0.22
High-density lipoprotein (mmol L^{-1})	1.5 (0.3)	1.5 (0.4)	0.59
Total cholesterol/high-density lipoprotein ratio	3.6 (0.8)	3.7 (0.9)	0.51
Triglyceride (mmol L^{-1})	1.5 (1.0)	1.5 (0.6)	0.83
Low-density lipoprotein (mmol L^{-1})	2.9 (0.7)	3.0 (0.8)	0.31
Blood pressure			
Systolic blood pressure (mmHg)	129.2 (12.8)	125.9 (10.8)	0.18
Diastolic blood pressure (mmHg)	74.3 (9.1)	75.6 (7.1)	0.44

Values are the mean (SD), excpet for gender.

(mean, SD, range and normality) for each pertinent variable at baseline. Distributions of variables met criteria for analysis with parametric statistics.

Two samples t-tests were used to assess the between groups change from baseline in anthropometric measures, lipid panel and blood pressure. Paired samples t-tests were used to assess within groups change from baseline in all dependent outcome measures. The combined effects of independent variables and treatment assignment on anthropometric measures, lipid panel measures and blood pressure were measured with multivariable models using analysis of covariance.

All analyses of endpoints were based on the intention-to-treat principle. Using the principle of last observation carried forward, missing follow-up values were filled with the values that were collected closest to the time of drop-out. Secondary analyses included tests to determine whether the interventions are effective for those subjects who completed the study (i.e. per-protocol analysis). In all analyses, $\alpha < 0.05$ (two-tailed) was considered statistically significant.

The sample size was determined to allow for approximately 10% attrition and noncompliance and to provide ≥80% power to detect a minimal weight loss difference of 1 kg between treatments with a maximum allowable type I error of 5%. Analysis was by intention-to-treat.

Results

Subjects

Ninety-four subjects participated in the study; 45 (48%) were enrolled in the control group and 49 (52%) in the intervention group. Of the 94 enrolled, 89 completed the study. Five subjects dropped out of the study; two from the control group and three from the intervention group (Fig. 1). The groups were balanced with respect to gender and age, and were also balanced in terms of baseline anthropometric measures, lipid panel levels and blood pressure (Table 2).

Anthropometric measures (i.e. body mass index, weight and waist circumference) did not improve from baseline after consumption of fruit and nut snack bar compared to controls (P = 0.40, 0.44 and 0.69, respectively) (Table 3).

Lipid panel levels (i.e. TC, HDL protein, TC/HDL ratio, LDL and triglycerides) also did not improve from baseline compared to controls (P = 0.72, 0.11, 0.37, 0.81 and 0.89, respectively (Table 3).

The blood pressure (both systolic and diastolic) of the study participants did not change from baseline after the consumption of fruit and nut snack bar compared to controls (P = 0.83 and 0.79, respectively) (Table 3).

A combined effect of gender and age with treatment assignment on changes from baseline in all outcome measures was also not observed ($P > 0.05$).

Discussion

The addition of two daily fruit and nut snack bars to habitual baseline diet had no effect on body weight, waist circumference, lipid panel and blood pressure in this sample of overweight adults with elevated waist circumference. The addition of 1421.9 kJ (340 kcal) per day from the snack bars produced no weight gain.

The findings pertaining to changes in anthropometric measures and blood pressure are consistent with the

Table 3 Summary of changes in outcome measures from baseline values

Variable	Control (n = 45)	Intervention (n = 49)	P
Anthropometric measures			
Body mass index (kg m^{-2})	−0.1 (0.6)	0.0 (0.6)	0.40
Weight (kg)	−0.1 (1.5)	0.1 (1.8)	0.44
Waist circumference (cm)	−0.7 (2.7)	−0.9 (3.2)	0.69
Lipid panel			
Total cholesterol (mmol L^{-1})	0.0 (0.4)	−0.0 (0.5)	0.72
High-density lipoprotein (mmol L^{-1})	−0.0 (0.2)	−0.1 (0.2)	0.11
Total cholesterol/high-density lipoprotein ratio	0.1 (0.5)	0.1 (0.5)	0.37
Triglyceride (mmol L^{-1})	0.0 (0.4)	0.0 (0.5)	0.89
Low-density lipoprotein (mmol L^{-1})	0.0 (0.4)	0.0 (0.5)	0.81
Blood pressure			
Systolic blood pressure (mmHg)	−1.1 (8.9)	−0.6 (10.0)	0.83
Diastolic blood pressure (mmHg)	0.5 (6.5)	0.8 (6.2)	0.79

Values are the mean ± SD.

results of previous trials (Bes-Rastrollo *et al.*, 2009; Casas-Agustench *et al.*, 2009), which demonstrated that increased fruit and nut consumption leads to little or no change in these measures. However, results pertaining to lipid panel changes are similar to those obtained in trials involving fruits and vegetables (Obarzanek *et al.*, 2001), as well as almonds, walnuts, pistachios and brazil nuts (Jenkins *et al.*, 2003; Sheridan *et al.*, 2007; Strunz *et al.*, 2008; Casas-Agustench *et al.*, 2009). At the same time, this findings of the present study are unlike those of other trials involving mixed nuts consumption (Djousse *et al.*, 2009; Martinez-Lapiscina *et al.*, 2009). Nevertheless, given that the composition of the snack bar used in the present study is unlike any of the ones utilised elsewhere in the literature, we conclude that these findings reflect the overall compositional uniqueness of the bar, and not that of its individual constituents.

The findings of no observed changes in anthropometric measures are in line with that of numerous epidemiological studies (Jiang *et al.*, 2002; Bes-Rastrollo *et al.*, 2007, 2009) and clinical studies (Fraser *et al.*, 2002; Hollis & Mattes, 2007; Sheridan *et al.*, 2007; Zaveri & Drummond, 2009; Ma *et al.*, 2010). One nonrandomised study investigating the effects of almond consumption in normoglycaemic patients found that the latter had slightly elevated body weights at the end of the intervention period (Lovejoy *et al.*, 2002). Apart from this study, the remaining studies conducted have consistently shown that nut consumption (irrespective of the type of nuts, or the amount that is consumed) is not associated with weight gain or with a higher BMI. According to the majority of the present evidence, fruit consumption appears to be inversely related to body weight (Lin & Morrison, 2002; Alinia *et al.*, 2009; Tetens & Alinia, 2009). Because fruit and nut snack bar is primarily made up of nuts (50% nuts and 30% fruits), and the latter are energy dense foods, there is justified concern that weight gain would ensue post consumption. This in turn would exacerbate, rather than ameliorate, the cardiovascular risk burden of the population under investigation. However, the absence of observed weight gain in the present study suggests that energy compensation must have taken place. Possible mechanisms explaining the effects of fruit and nut snack bar consumption on body weight could be a result of the ability of nuts to increase energy expenditures at the same time as providing a high satiety and low metabolisable energy source (Mattes & Dreher, 2010). It is possible, that the satiating effect of nuts is partly attenuated by the dried fruits, given that the latter have a high satiety threshold. Even so, the anthropometric data obtained from the present study suggests that the net satiety impact of snack bars remains favourable.

The present study also revealed that fruit and nut snack bar consumption has no effect on altering systolic or diastolic blood pressure relative to the control group. To date, little consensus exists on the role of nuts on blood pressure because there are relatively few nut consumption studies that have evaluated this. Randomised clinical trials performed in individuals with metabolic syndrome (Jenkins *et al.*, 2003; Sheridan *et al.*, 2007; Casas-Agustench *et al.*, 2009) and epidemiological studies in healthy and overweight individuals (Djousse *et al.*, 2009; Martinez-Lapiscina *et al.*, 2009) support these findings. Nevertheless, two studies have shown that, when individuals at risk of CVD consume nuts as part of a Mediterranean diet or as part of a plant-based dietary portfolio, then significant reductions in blood pressure follow (Estruch *et al.*, 2006; Jenkins *et al.*, 2008). The interpretation of all these results is further compounded by the fact that all these studies employ differing amounts of various types of nuts.

Studies exploring the relationship of fruit intake alone on blood pressure, as opposed to joint fruit and vegetable

intake, are indeed limited. Even so, evidence from epidemiological studies (Dauchet *et al.*, 2007; Tsubota-Utsugi *et al.*, 2010) and clinical trials (Chen *et al.*, 2010) (John *et al.*, 2002) appears to support the hypothesis that fruit and vegetable consumption positively impacts blood pressure regulation. Nevertheless, the absence of an observed positive change in blood pressure change in the present study could be related an absence of observed reductions in anthropometric measures. Equally, the small amounts of anti-hypertensive omega-3 fatty acids might also have contributed to this effect.

Finally, the present study showed that the introduction of fruit and nut snack bar to an *ad libitum* diet did not result in a significant change in serum lipid panel measures. Previous trials investigating the lipid modulating effects of nuts have resulted in mixed results. Some report no change in the lipid profiles (Banel & Hu, 2009; Casas-Agustench *et al.*, 2009; Phung *et al.*, 2009), whereas others report slight improvements for levels of triglycerides, TC, or LDL in normolipidemic or hypercholesterolaemic subjects (Jenkins *et al.*, 2002; Alper & Mattes, 2003; Sabate *et al.*, 2003; Gebauer *et al.*, 2008; Griel *et al.*, 2008). However, methodological nuances and the varying amounts of nuts used in these studies make cross-trial comparisons difficult. For example, one 12-week long feeding trial (Casas-Agustench *et al.*, 2009) used 30 g of raw nuts per day (15 g of walnuts, 7.5 g of almonds and 7.5 g of hazelnuts). Another nonrandomised 30-week cross-over intervention (Alper & Mattes, 2003) used a mean peanut ration of 89 g day^{-1}, and yet Gebauer *et al.* (2008) fed their subjects two differing doses of pistachios (32–63 or 63–126 g day^{-1}) depending on the subjects caloric level assignment in a randomised cross-over 12-week long controlled feeding study. Similalrly, there exists little consensus on the impact of fruits on blood lipid profiles, mainly because this area remains largely unexplored (Williamson & Carughi; Djousse *et al.*, 2004; Rankin *et al.*, 2008; Puglisi *et al.*, 2009).

The cumulative impact of all the ingredients on the blood lipid components could be influenced by the varying levels of saturated fatty acids (SFAs), monounsaturated fatty acids (MUFAs) and polyunsaturated fatty acids (PUFAs) in nuts (Table 4). The impact of SFAs on serum LDL, HDL, TC and cholesterol/HDL ratio has been shown to be antagonistic to that of MUFAs or PUFAs (Ros & Mataix, 2006). Likewise, although omega-3 fatty acids are known to lower blood pressure and triglyceride levels as well as raise HDL and LDL levels (Bays *et al.*, 2008; Drexel, 2009), omega-6 fatty acids on the other hand are known to lower LDL levels (Lecerf, 2009; Preiss & Sattar, 2009; Saremi & Arora, 2009). The minimal amounts of omega-3 fatty acids in all the primary constituent nuts of fruit and nut snack bar, coupled with the high amounts of sugar, could have contributed to the neutral effects observed on the levels of triglyceride and HDL. Likewise, any LDL-lowering effects brought about by the amounts of linoleoc acid present, or the present raisins, could have been counterbalanced by that of SFAs as well as sugars (Francis *et al.*, 2009; Munstedt *et al.*, 2009).

Table 4 Summary of average fatty acid content of nuts found in study snack bars (grams per 100 g)

Nuts	Total fat	SFA	MUFA	PUFA	LA	ALA
Peanuts	51.45	6.889	31.395	10.768	10.535	0.190
Almonds	49.42	3.731	30.889	12.070	12.055	0.006
Brazil nuts	66.43	5.137	24.548	20.577	20.543	0.017
Walnuts	65.21	6.126	8.933	47.174	38.093	9.080

Data for dry roasted unsalted peanuts, raw almonds, dried unblanched Brazil nuts and English walnuts. Source: USDA (www.nal.usda.gov/fnic/foodcomp/search/ accessed 9 April 2010).
ALA, α-linolenic acid; LA, linoleic acid; MUFA, monounsaturated fatty acid; PUFA, polyunsaturated fatty acid; SUFA, saturated fatty acid.

Thus, the net lipid modulating impact of fruit and nut snack bar consumption is nondeleterious. Recipes with more omega-3 and/or MUFAs, and less sugar, might be expected to improve lipid profiles.

There are several limitations to the present study. The study sample size is small. Participants were mostly pooled from the Lower Naugatuck Valley area, which is a predominantly white region, thus limiting the generalisability of these results with respect to race. In addition, the participants were not requested to provide information detailing their dietary patterns. Nevertheless, because both groups adhered to *ad libitum* diets, this should approximate these findings to real world settings.

The consumption of two daily fruit and nut snack bars [totalling 1421.9 kJ (340 kcal)] for 2 months did not cause weight gain. Satiating snacks rich in fibre may provide a means for improving diet quality rather than increase total energy intake. Further studies of the effects of snacking on weight are warranted, with particular attention being paid to nutrient dense and satiating snack foods.

Conflict of interests, source of funding and authorship

The authors declare no conflicts of interest.

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AD wrote the manuscript. JR analysed the data and critically reviewed the manuscript. VYN designed the project, interpreted the data, and critically reviewed the manuscript. YM collected data. KD was responsible for the primary oversight of study. DLK designed and supervised the study and critically reviewed the manuscript.

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EXHIBIT B

The Yale-Griffin Prevention Research Center
Newsflash
July 2012

This electronic ***Newsflash*** is intended to keep you informed about our work and to invite you to participate in our various research, education and outreach activities. The ***Newsflash*** began as a communication tool for our Community Committee, but readership continues to expand to include colleagues in academia, clinical settings and social service agencies around the state. If you see ways that we can work together on shared projects, please let us know.

In this ***Newsflash,*** you will find the following information:

- **PRC News, Activity, and Research Findings**
- **Grant Submissions and Awards**
- **Presentations and Manuscript Publications**
- **In-Service Training Opportunities**

For a complete list of our projects, please visit our website at www.yalegriffinprc.org.

PRC News

Our next Community Committee meeting will be held on Tuesday Sept 25th from 12:00 – 1:45 p.m. in the Childbirth Center meeting room A & B on the ground floor of Griffin Hospital. Lunch will be provided.

PRC Workshop Series on "The Fundamentals of Evaluation" - On May 16th and 23rd, the PRC offered a 2-part evaluation workshop to our community partners. The PRC's Director Dr. David Katz, Assistant Director of Research and Evaluation Dr. Valentine Njike and Data Analyst Jesse Reynolds presented the workshop during 2 half-day sessions at Griffin Hospital. Session 1 focused on basic concepts of evaluation and types of evaluation strategies, and Session 2 focused on addressing constraints and weakness in evaluation design. The sessions included examples sent in advance by attendees as case studies for evaluation design. A total of 13 people attended Session 1, and 10 attended Session 2. Most indicated that the workshop had increased their awareness and understanding of the evaluation process, and all felt they could now recognize the components needed to develop an evaluation plan.

Update on NuVal in the Derby Public Schools - We are proceeding with our pilot test of the NuVal™ Nutritional Scoring System in the Derby Public Schools as part of the VITAHLS initiative (see below). NuVal uses an algorithm, developed by PRC Director Dr. David Katz and a team of nutrition experts, to quantify the overall nutritional value of individual foods by assigning a score to each food on a scale of 1 to 100 (the higher the score, the higher the nutritional value). In June, we met with Derby Public Schools administrators to finalize plans to launch NuVal in the district's middle school and high school by mid-October. The schools are on the same campus and have similar snacks and menus. The scoring system will be applied to foods served in the cafeteria and vending machines. The goal is to inform students about the variation in nutritional quality and the range of scores within each category of foods, to get them thinking about the power of choice, and to make healthier food choices. We will evaluate the project by assessing changes in students' attitudes, knowledge, and self-efficacy, along with changes in food products purchased at school. The project is funded by the Turn the Tide Foundation (www.turnthetidefoundation.org) through a donation from the California Walnut Commission.

PRC Staff Updates

Welcome to new PRC staff member….

- **Sue Acheychek,** who has joined the PRC as a Vascular Research Technician and will be performing ultrasound scans for our endothelial function studies. Sue has 22 years of experience in the medical field, and has spent the last 7 years working as an ultrasound technician in health care facilities in Wallingford and Hamden.

Goodbye and best wishes to.…

- **Jesse Reynolds, MS,** PRC Data Analyst, who has been involved with several of our school-based health promotion projects, and who has served as project manager for the Community Health Profile, has accepted a position with the Yale Center for Analytic Sciences, although he will stay on per diem status with the PRC.
- **Ying Ying Ma, MD, RVT,** Assistant Director of the Vascular Research Lab, who has been actively involved in our endothelial function research, is relocating with her family to California.

Current Activity and Research Findings

PROGRESS REPORT - Valley Initiative to Advance Health & Learning in Schools (VITAHLS) – This initiative, led by Griffin Hospital and the PRC and in collaboration with 5 Valley School Districts, involves developing, implementing, evaluating and sustaining a comprehensive Valley-wide school-based program focusing on nutrition and physical activity. The goal is to reduce the prevalence of obesity, and promote health and academic readiness, in students in grades Pre-K through 12. Our partners include the Ansonia, Derby, Oxford, Seymour, and Shelton School Districts, along with the Emmett O'Brien Regional Technical School. The first phase of this initiative focused on encouraging schools to offer elementary school programming (including our Nutrition Detectives and ABC for Fitness programs) during the second half of the 2011-2012 school year, with the intent of expanding in future years to reach middle and high school students, school staff, and parents/families.

In prior Newsflash issues, we've described the launch, teacher training, and initial planning stages of this initiative. Since our last progress report in January, we've made additional progress with our school district partners, including the following:

- Offering the Nutrition Detectives and ABC for Fitness programs in many of the elementary schools
- Conducting baseline measurements of body mass index (BMI) in elementary schools
- Holding a contest for school districts to create a VITAHLS logo
- Seeking funding from the state of CT to support VITAHLS as a pilot project
- Holding discussions with the Alliance for a Healthier Generation about the possibility of enrolling school districts to receive free online and on-site access to resources and guidance
- Strengthening the infrastructure within each school district to support and coordinate the VITALS implementation and evaluation, and to report progress within each district back to the VITAHLS working group
- Holding regular meetings of subcommittees on physical activity, nutrition, communications, and special events, with the intent of examining the current status of nutrition and physical activity programming and policies and school food service offerings, and developing recommendations and plans for programming, outreach, and policy changes

Some of our plans so far for the next school year include:

- Offering an adapted version of the Nutrition Detectives program to middle school and high school students, and searching for additional low-cost or no-cost nutrition and physical activity programs that require little time or resources
- Holding a Family Fun Day/VITAHLS Kick-off on Sunday, October 21st for students and parents from participating schools, which will be preceded by a "fun run" and will include healthy snacks, games, nutrition booths, physical activity opportunities, health screenings, and a farmer's market

- Holding a professional development day in the fall to provide additional teacher training
- Exploring additional options such as: promoting district-wide walking programs for students, staff, and parents; encouraging school staff to exercise during break times using A-B-E (Activity Bursts Everywhere) for Fitness video clips; and encouraging greater participation in the USDA School Breakfast Program

In addition, the VITAHLS project will benefit from two fund-raising events to be held this fall. The Jones Family Farm has graciously offered to donate some of the proceeds from a wine and cheese festival to be held in September, and the Griffin Hospital Development Fund has announced that the focus of this year's annual fundraising event (called Autumn Elegance) will be to raise money specifically earmarked for the VITAHLS initiative.

The VITAHLS main working group continues to meet on the 2nd Wednesday of each month from 10:00 to 11:30 a.m. If you are interested in attending planning meetings of the working group and/or any of its subcommittees, please contact Beth Comerford by email at beth.comerford@yalegriffnprc.org

PRC to Teach Nutrition to Youth for Yale Community Rowing – This summer, the PRC will return to the Yale boathouse in Derby to offer nutrition classes to Yale Community Rowing participants. The program, called *Eat to Row, Eat for Life*, will be offered to select groups of middle school and high school students from the Lower Naugatuck Valley who have signed up for rowing sessions. We are collaborating with college students Laura Knath and Katrina Parke from Southern CT State University and Kim Szokol from Yale University to develop and deliver the nutrition classes. Participants will learn how to make healthful food choices and will have the chance to practice what they learn. For more information, please contact PRC Research Associate Judy Treu by email at judy.treu@yalegriffinprc.org.

NOW RECRUITING!

- ***Dose and Response to Chocolate (DARC)*** – The PRC and Boston Medical Center have received $787,000 in funding from the Hershey Company for an 18-month study to compare the effects of 2 doses of cocoa consumption (5 vs. 10 grams of cocoa powder provided as a combination of chocolate and cocoa beverages) per day over an 8-week period on risk factors for cardiovascular disease in 120 adults with stage 1 hypertension. Specifically, we will look for any changes in their blood pressure, blood vessel function (their ability to constrict and dilate as the heart pumps blood through them), serum lipids, glucose, insulin, body weight, and waist circumference. Cocoa-containing products are already known to have cardio-protective effects, perhaps due to their flavonoid content. Our own studies have shown that a dose of 10 grams of cocoa powder can lead to improved blood vessel function in overweight adults. We now want to learn whether the cardiovascular benefits of cocoa-containing products vary when compared to a smaller dose, and whether there is a direct impact on blood pressure. Because chocolate is a popular dietary source of cocoa but is high in calories and fat and often high in added sugar, it's important to determine the minimum dose of cocoa that can provide "heart-healthy" benefits without affecting weight and blood sugar, if used in chocolate products. Results of this study will help guide recommendations for consumers' daily lives. **The PRC is now recruiting 60 men and women age 18-75 years who have stage 1 hypertension (high blood pressure, with systolic pressure ranging from 140 to 159 and diastolic pressure ranging from 90 to 99) who are currently taking no more than one blood pressure medication, and who have a body mass index (BMI) of less than 35. If you or someone you know is interested in participating in this study, please contact Ms. Rockiy Ayettey by email at rockiy.ayettey@yalegriffinprc.org or by phone at 203-732-1265 ext. 300.**

- ***Exploring Massage Benefits for Arthritis of the Knee (EMBARK)*** **–** The National Institutes of Health (NIH) awarded a $2.75 million shared grant to Duke Integrative Medicine and its key research partners at the Yale-Griffin PRC and the University of Medicine and Dentistry of New Jersey (UMDNJ) to investigate the impact of massage therapy on people with osteoarthritis (OA) of the knee. The combined research team will conduct a randomized controlled trial over a 4-year period to definitively evaluate the impact of an 8-week course of Swedish massage on pain, stiffness, and

physical function in people with OA of the knee, how long the effects last over a one-year period, and the cost-effectiveness of this treatment. OA, a slowly progressive, degenerative disease of the joints that afflicts up to 40 million Americans, can lead to chronic pain and disability. Conventional treatments are often associated with incomplete pain relief and/or side effects of pharmacological treatments, and surgery requires a long period of recovery. Our initial pilot study in 2004 showed massage to be feasible and effective in treating OA of the knee, leading to improved flexibility, less pain, and improved range of motion lasting for several weeks after the treatment ended. A follow-up study (2009-2011) to determine an optimal "dose" found that a 60-minute massage offered once a week over an 8-week period was most effective and practical, compared to 60 minutes twice a week, or 30 minutes once or twice a week, thus establishing a standard for future trials. The effectiveness of massage for OA may be due to a variety of mechanisms, including stress reduction, increased blood and lymph circulation, decreased muscle strain, and/or improved function of joints or muscles. The new study will recruit more than 200 participants with OA of the knee and will follow each participant for a full year. Participants will be randomly assigned to receive Swedish massage therapy, light touch bodywork, or conventional care. Outcomes of interest include: joint pain, stiffness, and flexibility; physical function; and health care utilization and cost. For those who qualify, treatments will be available at the Integrative Medicine Center at Griffin Hospital in Derby, CT, Barnabas Health Ambulatory Care Center in Livingston, NJ, and Duke University in Durham, NC. **We are currently recruiting adults over 35 years of age with radiographically diagnosed osteoarthritis of the knee, who meet the American College of Rheumatology criteria for OA, are experiencing moderate pain, and are under the care of a board-certified primary care physician. If you or someone you know is interested in participating in this study, please contact Michelle at 203-732-1265, ext. 218 or ext 306. You may also email us at oa.massage@gmail.com.**

RECRUITMENT COMPLETED!

Walnut Ingestion in Adults at Risk for Diabetes: Effects on Body Composition, Diet Quality, and Cardiac Risk Measures – Since this spring, we have been busy recruiting and enrolling 112 adults who are at risk for developing diabetes to participate in this clinical research study. We will keep you posted on the progress of this study, which is funded by the California Walnut Commission.

In the Works
Recent /Upcoming Grant Submissions

RECENTLY SUBMITTED PROPOSALS

Snacking, Satiety, & Weight: A Randomized, Controlled Trial **–** In June, we submitted a proposal to KIND Healthy Snacks for a study to compare the effects of consuming 3 types of snacks on health outcomes, diet quality, and self-reported satiety in overweight adults. Prior studies have found that people often fail to compensate for the calories that they consume from snacks, leading to the conclusion that eating snacks could lead to weight gain. However, when chosen judiciously, snacks have the potential to contribute valuable nutrients to the daily diet. In addition, snacks high in protein and/or fiber can potentially to contribute to satiety, which could actually help control overall calorie intake over the course of the day. Nuts such as almonds are a good source of protein and fiber, and have been shown to improve lipid profiles without leading to weight gain. Therefore, we'd like to compare the effects of eating 2 types of snacks that are high in protein and fiber (raw or toasted almonds vs. KIND snack bars with almonds), to the effects of eating conventional snacks such as crackers, chips, or cookies that are low in nutrients and high in calories. If funded, we will recruit 42 overweight adults, randomly assign each person to eat one of the 3 types of snacks for a 12-week period, and compare their pre/post measures of weight, body mass index, body composition, waist circumference, blood pressure, lipid profile, diet quality, hunger/satiety, and perceived quality of life. We expect to find that snacking on conventional snack foods will contribute to weight gain, whereas snacking on nutrient-dense, highly satiating snack foods will contribute to satiety, weight loss, and health improvements.

Presentations and Publications

PRESENTATIONS

David Katz, MD, MPH, FACPM, FACP, PRC Director, delivered the following presentations:

- *Into the Mouths of Babes: Who's the BAWSS,* keynote presentation on May 11th at the Healthy Flavors, Healthy Kids National Leadership Summit held at Culinary Institute of America in San Antonio TX.
- *Feet, Forks, and Fate,* keynote presentation on May 19th at the Weight Loss Surgery Foundation of America's Mother of all Meet and Greets in Las Vegas, NV.
- *Feet, Forks, and the Fate of Our Families,* keynote presentation on May 23rd at the St. Raphael's Auxiliary Dinner held at the Racebrook Country Club in Orange, CT.
- *The Road to Health* on June 3rd at the Food for Your Whole Life Symposium in New York, NY.
- *Food as Medicine* on June 4th at the Food for Your Whole Life Symposium in New York, NY.
- Guest speaker on June 13th at the Emmett O'Brien Technical High School in Ansonia, CT.
- *Feet, Forks, and the Fate of Our Families,* keynote presentation on June 18th at the Mount Sinai Health Care Foundation in Cleveland, OH.

PUBLICATIONS

- Katz DL. *Food Marketing to Children: Why We Should All Mind Our Own Business!* Resiliency, Inc. News. 2012 May; 1-4.
- Katz DL. *Jumping Through Hoops? Health, Hoopla, and the Infectivity of Fun*. Childhood Obesity 2012 June; 8(3):181-182.
- Katz DL, Vinante V. (2012). *Promotion of Healthful Nutrition in Childhood.* In: Bloom M. and Gullotta T (Eds.), Encyclopedia of Primary Prevention and Health Promotion, 2nd ed. New York, NY: Springer Science and Media, LLC.
- Katz DL, Vinante V. (2012) *Promotion of Healthful Nutrition from Conception to Early Childhood.* In: Bloom M. and Gullotta T (Eds.), Encyclopedia of Primary Prevention and Health Promotion, 2nd ed. New York, NY: Springer Science and Media, LLC.
- 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*. Journal of Nutrition Education and Behavior 2012 May;44(3):262-6. Epub 2012 Mar 9.

In-Service/Training Opportunities

You are invited to join us at our **Journal Club meetings**, usually held every other month. We review and critique publications on topics such as community-based research, clinical research, and public health. This helps us stay up-to-date on research findings. It also allows us to examine publications (for the research questions, study design, results and conclusions) so we can apply the knowledge gained and lessons learned to the design of our own projects.

The next Journal Club meeting will be held at the PRC on the second floor of Griffin Hospital.

- **Tuesday, July 10th from 2:00 to 3:30 p.m.**
  Kahleova H, Matoulek M, Malinska H, Oliyarnik O, Kazdova L, Neskudla T, Skoch A, Hajek M, Hill M, Kahle M, Pelikanova T. *Vegetarian Diet Improves Insulin Resistance and Oxidative Stress Markers More Than Conventional Diet in Subjects with Type 2 Diabetes.* Diabetic Medicine 2011 May;28(5):549-59.

If you have questions or want to receive a PDF version of the article by email, contact Dr. Valentine Njike by email at valentine.njike@yalegriffinprc.org, or by phone at 203-732-1265 ext. 304.

Let's Stay in Touch

We want to hear from you – let us know what you are doing and how our research might assist you in your work. Please contact Beth Comerford, MS, Deputy Director (beth.comerford@yalegriffinprc.org) or any of the staff listed in this ***Newsflash.***

Yale-Griffin Prevention Research Center
130 Division Street
Derby, CT. 06418
Phone: (203) 732-1265
Fax: (203) 732-1264

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EXHIBIT C

The Yale-Griffin Prevention Research Center

Newsflash

May 2014

The PRC has prepared this electronic ***Newsflash*** to keep you informed about our work and invite you to take part in our research, education and outreach activities. It serves as a communication tool for our Community Committee members, and our colleagues in academia, education, clinical settings, and social service agencies. If you have ideas for working together on shared projects, please let us know.

This *Newsflash* issue includes:

PRC Updates
Current Projects
Project Findings
Grant Proposals and Awards
Presentations / Publications
Journal Club

For more information about the Yale-Griffin PRC:

Please visit our website at http://www.yalegriffinprc.org

PRC Updates

Our next Community Committee meeting will be held sometime in June or July. We will send out an announcement about the location, date, and time.

Dr. Katz Weighs in on What Diet is Best for Health - Since an unhealthful diet is a leading cause of premature death and chronic disease, and a healthful diet can lead to the opposite outcome, what specific kind of healthful diet is best to follow? PRC Director Dr. David Katz recently addressed this question in an article published in *Annual Reviews in Public Health* *(see "Publications" section of this Newsflash for citation).* He noted the competing claims for different diets, each with its own reputedly distinctive merits, and the commonalities among these diets in terms of their potentially healthful components. For now, given the absence of rigorous unbiased studies comparing these diets over a long period of time, the jury is still out on which specific diet is best. In the meantime, Dr. Katz recommends consuming a diet of minimally processed foods that are close to nature and mostly from plant sources.

Current Projects

NOW RECRUITING! Egg Ingestion in Adults with Type 2 Diabetes: Effects on Glycemic Control, Anthropometry, Diet Quality and Cardiometabolic Status. A Randomized, Controlled, Crossover Trial

- ***Study details:*** The PRC has received a $185,000 grant from the Egg Nutrition Center to assess the effects of daily intake of eggs for a 12-week period on diet quality and health outcomes in adults with diabetes. Eggs are low in fat, a low-cost source of protein, and a good source of micronutrients.

However, for many years, medical professionals have been advising patients at risk for cardiovascular disease (CVD), including those with diabetes, to limit intake of eggs because they are high in cholesterol. The prevailing view has been that dietary cholesterol intake could lead to elevated serum cholesterol, which could raise the risk for CVD. However, results of early studies that seemed to show a linear relationship between cholesterol intake and CVD are now being questioned due to study design flaws. More recent studies have not found an association between egg intake and CVD effects. The PRC's own studies have found no adverse effects of egg ingestion by 3 groups of adults (those who were healthy, those at risk for CVD, and those with coronary artery disease). Excluding eggs from the diets of patients with diabetes could potentially lead them to eat other foods high in starch and sugar, which could increase the risk of CVD due to the effects of elevated blood glucose on blood vessels over time. Therefore, we want to learn whether eggs can be included in the diets of people with diabetes. We are conducting a randomized controlled crossover study to compare the effects of two ad libitum diets (one that includes 10-14 eggs per week vs. one that excludes eggs) on hemoglobin A1C, fasting blood glucose, insulin levels, body composition, weight, waist circumference, and diet quality in adults with diabetes. A crossover study means that each participant will be assigned to both the intervention diet (which includes eggs) and the control diet (which excludes eggs) at different time points during the study. We expect to find that adults with diabetes who include eggs in their diets will have an improved diet quality, and improved health-related outcome measures, compared to when they exclude eggs from their diets.

- ***Who we're recruiting:*** 40 adults who have been diagnosed with Type 2 diabetes in the last 1 to 10 years, are overweight and have not had any advanced complications from diabetes. We are seeking men who are at least 35 years old, and women who are post-menopausal and not on hormone replacement therapy. Each person who completes the study will receive $400 in compensation. The time commitment is approximately 34 weeks. This will allow enough time for 12 weeks of each dietary phase, with a "wash-out period" of a few weeks before the start of each dietary phase.
- ***How to apply****:* If you or someone you know is interested in participating, contact Ms. Rockiy Ayettey by email at rockiy.ayettey@yalegriffinprc.org or by phone at 203-732-1265 ext. 300.

STILL RECRUITING! - Exploring Massage Benefits for Arthritis of the Knee (EMBARK)

- ***Study details****:* The National Institutes of Health (NIH) awarded a $2.75 million shared grant to Duke Integrative Medicine and its key research partners at the Yale-Griffin PRC and the University of Medicine and Dentistry of New Jersey to investigate the impact of massage therapy on people with osteoarthritis (OA) of the knee. The combined research team is conducting a randomized controlled trial over a 4-year period to definitively evaluate the impact of an 8-week course of Swedish massage on pain, stiffness, and physical function in people with OA of the knee, how long the effects last over a one-year period, and the cost-effectiveness of this treatment. OA, a slowly progressive, degenerative disease of the joints that afflicts up to 40 million Americans, can lead to chronic pain and disability. Conventional treatments are often associated with incomplete pain relief and/or side effects of medications, and surgery requires a long period of recovery. This study will recruit more than 200 participants at all three sites combined (66 at the PRC) who have OA of the knee, and will follow each participant for a full year. Participants will be randomly assigned to receive Swedish massage therapy, light touch bodywork, or conventional care. Outcomes of interest include: joint pain, stiffness, and flexibility; physical function; and health care utilization and cost. For those who qualify, treatments are available at the Integrative Medicine Center at Griffin Hospital in Derby, CT, Barnabas Health Ambulatory Care Center in Livingston, NJ, and Duke University in Durham, NC.
- ***Who we're recruiting:*** 2 more adults over 35 years of age with radiographically diagnosed osteoarthritis of the knee, who meet the American College of Rheumatology criteria for OA, are experiencing moderate pain, and are under the care of a board-certified primary care physician.

- ***How to apply:*** If you or someone you know is interested in participating, contact Gina Smith (email Gina.Smith@yalegriffinprc.org, phone 203-732-1265, ext. 305).

PROJECT UPDATE - Valley Initiative to Advance Health & Learning in Schools (VITAHLS)

This initiative, led by the PRC and Griffin Hospital in collaboration with Valley School Districts, involves developing, implementing, evaluating and sustaining a comprehensive Valley-wide school-based program focusing on nutrition and physical activity. The goal is to reduce the prevalence of obesity, and promote health and academic readiness, among students in grades PreK-12. Our partners are the Ansonia, Derby, Seymour, and Shelton school districts, and Emmett O'Brien Regional Technical School.

Since our last progress report in January, we have additional news to report:

- ***School gardens*** – This spring, a FoodCorps service member based at Massaro Farm is partnering with us to support interested schools in planning, ordering, and building their gardens. The PRC has supported the purchase of materials to start school gardens and will incorporate them into classroom lesson plans. These include: Ansonia Middle School; Bradley and Irving Elementary Schools in Derby; Sunnyside and Perry Hill School s in Shelton; and Shelton High School.
- ***Healthy cooking contest*** – This spring, the First Annual VITAHLS Health Cooking Challenge within/among the 4 school districts is underway. Sixth grade students have been invited to submit a healthy salad recipe, with the top 6 recipes entered in each district's own cooking competition. The winners from each district will soon compete against each other in a VITAHLS Cook-off on Monday, May 19th at the Molto Bene restaurant in Ansonia. Recipes are being judged based on originality, presentation, ease of preparation, taste, and healthy attributes. There are prizes for all those who compete, and a special prize for the winner.

Ansonia Middle School Chefs

Derby Middle School Chefs

If you would like to attend planning meetings of the VITAHLS working group or its subcommittees, contact Gina Smith (email Gina.Smith@yalegriffinprc.org, phone 203-732-1265, ext. 305).

PROJECT UPDATE - NuVal® Nutritional Scoring System in Ansonia Schools – During this school year, the Ansonia Public Schools has been implementing and evaluating the NuVal Nutritional Scoring System in school cafeterias, funded by a grant from the CT State Department of Education. PRC Research Associate Kim Doughty has been conducting the project evaluation. The NuVal system assigns a score of between 1 and 100 to foods based on their overall nutritional value (the higher the score, the better the nutritional value). In Ansonia, NuVal scores are now posted for the majority of menu items available to students in the cafeterias of all four schools, and also for vending machine items at the middle school and high school. The intervention has been in place for 8 weeks, and the PRC study team is collecting post-intervention data in the schools at the end of April and early May. Outcome measures include the types of foods selected by these students in the cafeteria line, and which foods they actually eat rather than discard in the trash. We also plan to conduct focus groups with students in grades 1-12 to learn about their awareness, understanding, and reported use of the system. Our Ansonia partners are Dominick Golia, Food Service Director, and Diana Brancato, School Readiness Coordinator. For more

information, contact Kim Doughty (email kim.doughty@yalegriffinprc.org, phone 203-732-1265, ext. 306).

Project Findings

Snacking, Satiety, & Weight: A Randomized, Controlled Trial

Purpose

Prior studies have found that people often fail to compensate for the calories consumed from snacks, leading to the perception that eating snacks could lead to weight gain. Yet when chosen judiciously, snacks can contribute valuable nutrients to the diet. If high in protein and/or fiber, snacks can also potentially contribute to satiety, which could help control overall calorie intake. Nuts are a good source of protein and fiber, and have been shown to improve lipid profiles without leading to weight gain.

Study Design / Hypotheses

This parallel-design randomized controlled trial compared the effects of eating either high-protein, high-fiber snacks (KIND snack bars with almonds) or conventional snacks (low in nutrients and fiber; e.g., cookies) on a daily basis for a 12-week period on health outcomes, diet quality, and self-reported satiety in a group of overweight adults. We recruited 34 adults, randomly assigned each adult to eat either KIND bars or conventional snacks for a 12-week period, and compared pre/post measures of weight, body mass index (BMI), body composition, waist circumference, blood pressure, lipid profile, diet quality/key nutrient intake, and their perceived hunger/satiety and quality of life. At the start of the study (baseline), both groups had comparable demographic characteristics and clinical measures.

Our hypotheses were that: snacking on nutrient-dense, highly satiating snack foods, compared to low-nutrient, conventional snack foods, would contribute to satiety, weight loss, and health improvements; and that these effects would be seen even when study participants receive clear guidance on the calorie content of the snack foods and on how to make room for those calories in their diets.

Results after 12 weeks of consuming either KIND snacks or conventional snacks

- Health outcomes
  The conventional snack group had significant gains in visceral fat, percent body fat, and systolic blood pressure (upper number on blood pressure readings), in comparison to the KIND snack group. There were no significant differences between the two snack groups with regard to changes in weight, BMI, diastolic blood pressure, total cholesterol, triglycerides, or HDL or LDL cholesterol.
- Self-reported quality of life
  There were no significant differences between the two snack groups with regard to changes in overall quality of life, or in individual measures (general health; vitality; physical or social function; physical or emotional role; mental health; or bodily pain) used to assess quality of life.
- Diet quality/key nutrient intake
  Based on self-reported food intake records, there were no significant differences between the two snack groups with regard to measures of diet quality. These included caloric intake; percent of calories from protein, carbohydrate, and fat; dietary fiber intake; or percent of calories from monounsaturated and polyunsaturated fat.
- Self-reported satiety
  Satiety (measured by levels of hunger, fullness, desire to eat, and anticipated amount of food that could be consumed at a given time point) did not significantly differ between the two snack groups.

Conclusions

Our data suggest that daily intake of high-protein, high-fiber snacks (KIND snack bars) for 12 weeks reduced body fat and had no adverse effects on weight, blood pressure, lipid profile, and quality of life

in this small sample of overweight adults, when compared to daily intake of conventional "empty calorie" snacks (cookies). Daily intake of conventional snacks adversely affected body fat, body weight, and blood pressure. A larger randomized controlled trial is warranted to replicate these findings.

Funding source: KIND LLC

Grant Proposals and Awards

UPCOMING SUBMISSIONS

We are currently having exploratory conversations with potential funders of some new clinical research studies, and will provide details when we have more information to report.

Presentations

David Katz, MD, MPH, FACPM, FACP, PRC Director, delivered the following presentations:

- *Feet, Forks and the Fate of Our Patients* on March 4th at the University of Connecticut Health Center in Farmington, CT.
- *Science, Sense, and Supplementation: Bridging the Gap of our Nation's Diet* on March 14th at a Prevention Carolinas event sponsored by NSA/Juice Plus in Charlotte, NC.
- *Feet, Forks, and the Fate of Our Families,* keynote presentation on March 20th at the NBTY Leadership Conference in Riverhead, New York.
- *Evidence-Based Integrative Medicine: Medicine, Miracles, and Myopia* on March 21st at Greenwich Hospital Grand Rounds in Greenwich, CT.
- *Weight Management: One Size Does Not Fit All* on April 3rd at the Women's Health 2014: 22nd Annual Congress in Washington, DC.
- *The Promise of Disease Proofing Ourselves,* Bob Rosum Memorial Lecture on April 7th at Greenwich Hospital in Greenwich, CT.
- Presentation on April 11th at the NSA/Juice Plus Conference in Phoenix, AZ.

Publications

Katz DL. *Brawn, Brains, and Grains of Truth.* Medscape Neurology. April 3, 2014:1-4.

Katz DL. *Are Our Children "Diseased"?* Child Obes. 2014 Feb;10(1):1-3.

Katz DL. *Diet and Diabetes: Lines and Dots.* J Nutr. 2014 Apr;144(4):567S-70S.

Katz DL, Meller S. *Can We Say What Diet is Best for Health?* Annu Rev Public Health. 2014 Mar 18;35:83-103.

Katz DL, Treu JA, Ayettey RG, Kavak Y, Katz CS, Njike V. *Testing the Effectiveness of an Abbreviated Version of the Nutrition Detectives Program.* Prev Chronic Dis. 2014 Apr 10;11:E57.

In-Service / Training Opportunities

You are invited to join us at our **Journal Club meetings**, usually held every other month. We review and critique publications on topics such as community-based research, clinical research, and public health.

This helps us stay up-to-date on research findings. It also allows us to examine publications (for the research questions, study design, results and conclusions) so we can apply the knowledge gained and lessons learned to the design of our own projects.

The next Journal Club meeting will be held at the PRC on the second floor of Griffin Hospital.

- Tuesday, May 13th from 1:00 to 2:30 p.m.
  Yang Q, Zhang Z, Gregg EW, Flanders WD, Merritt R, Hu FB. *Added Sugar Intake and Cardiovascular Diseases Mortality Among US Adults*. JAMA Intern Med. 2014 Feb 3.

If you have questions or want to receive a PDF version of the article by email, contact Dr. Valentine Njike by email at valentine.njike@yalegriffinprc.org, or by phone at 203-732-1265 ext. 304.

Let's Stay in Touch

We want to hear from you – let us know what you are doing and how our research might assist you in your work. Please contact Beth Comerford, MS, Deputy Director (beth.comerford@yalegriffinprc.org) or any of the staff listed in this ***Newsflash.***

Yale-Griffin Prevention Research Center
130 Division Street
Derby, CT. 06418
Phone: (203) 732-1265
Fax: (203) 732-1264

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EXHIBIT D

BURSOR & FISHER
P.A.

1990 N. CALIFORNIA BLVD.
SUITE 940
WALNUT CREEK, CA 94596
www.bursor.com

L. TIMOTHY FISHER
Tel: 925.300.4455
Fax: 925.407.2700
ltfisher@bursor.com

December 15, 2015

Via Hand Delivery

KIND, LLC
1372 Broadway
New York, NY 10018

Re: *Demand Letter Pursuant to California Civil Code § 1782 and Violation of U.C.C. §§ 2-313, 2-314*

To Whom It May Concern:

This letter serves as a preliminary notice and demand for corrective action by KIND, LLC pursuant to numerous provisions of California and New York law, including the Consumers Legal Remedies Act, Civil Code § 1770, including but not limited to subsections (a)(2), (3), (5), (7), and (9), and N.Y.G.B.L. §§ 349 and 350, on behalf of our clients, Steven Bailey and Courtney Dietrich. This letter also serves as notice pursuant to U.C.C. § 2-607(3)(A) concerning the breaches of express warranties described herein.

You have participated in the marketing and sale of KIND bars. The labels for KIND bars state that "[a] study by the Yale-Griffin Prevention Research Center indicates that eating two KIND bars a day helps prevent weight gain" (the "Misrepresentation"). That representation is false and misleading. The study conducted by the Yale-Griffin Prevention Research Center found no difference in weight gain between the subjects who consumed KIND bars and those who did not.

Mr. Bailey and Ms. Dietrich purchased KIND bars based on this representation on the label.

Mr. Bailey and Ms. Dietrich are acting on behalf of a class defined as all persons in the United States who purchased KIND bars containing the Misrepresentation on the label (the "Products"). Mr. Bailey is also acting on behalf of a subclass of persons who purchased the Products in the State of California and Ms. Dietrich is also acting on behalf of a subclass of persons who purchased the Products in the State of New York.

To cure these defects, we demand that you make full restitution to all purchasers of the Products of all money obtained from sales thereof.

We further demand that you preserve all documents and other evidence which refer or relate to any of the above-described practices including, but not limited to, the following:

1. All documents concerning the design, development, and/or testing of the Products;

2. All documents concerning the advertisement, marketing, or sale of the Products;

4. All documents concerning communications with purchasers of the Products, including but not limited to customer complaints related to its failure to reduce weight or body fat; and

5. All documents concerning your total revenue derived from sales of the Products in California, New York and the United States.

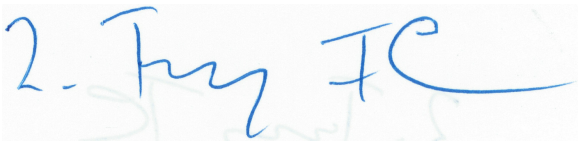
6. All documents produced in *Cohn v. KIND, LLC*, Civil Action No. 13-8365 (S.D.N.Y.).

If you contend that any statement in this letter is inaccurate in any respect, please provide us with your contentions and supporting documents immediately upon receipt of this letter.

This letter also serves as a thirty (30) day notice and demand under California Civil Code § 1782 for damages. Accordingly, should you fail to rectify the situation on a class-wide basis within 30 days of receipt of this letter, we will seek actual damages, plus punitive damages, interest, attorneys' fees and costs.

Please contact me right away if you wish to discuss an appropriate way to remedy this matter. If I do not hear from you promptly, I will take that as an indication that you are not interested in doing so.

Very truly yours,



L. Timothy Fisher