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I. INTRODUCTION

1. I am a Professor of Marketing at the Leonard N. Stern School of Business, New York University ("NYU Stern"), where I have taught since January 1989. During the academic year just ended, I was on sabbatical and served as a Visiting Scholar at the University of Pennsylvania Carey Law School. Prior to my sabbatical, I served as NYU Stern’s Vice-Dean for Doctoral Education from August 2012 to September 2021. Overlapping that interval, I also served as the Acting Chairperson of the school’s Accounting Department from August 2016 to August 2019. Prior to my promotion to Vice Dean, I was the faculty director of the Stern School Doctoral Program for five years, from May 2007 to July 2012. Earlier I served as the Chairperson of NYU Stern’s Marketing Department for six years, from July 1998 to June 2004. I have also held either permanent or visiting faculty appointments at the Graduate School of Business, Columbia University; the Anderson Graduate School of Management, U.C.L.A.; the School of Management, Yale University; and the Wharton School, University of Pennsylvania. I received my B.A. summa cum laude from Columbia University in 1977, and M.B.A. (with distinction), M.A., and Ph.D. degrees from the Wharton School, University of Pennsylvania in 1979, 1980, and 1982, respectively. I was elected to Phi Beta Kappa at Columbia University and Beta Gamma Sigma at the Wharton School. These are the national honor societies for the respective disciplines I studied at these institutions.

2. I was the Founding President of the INFORMS (Institute for Operations Research and Management Science) Society on Marketing Science ("ISMS"), the foremost professional group for the development and application of management science theory
and tools in marketing. In addition, I am a member of the American Marketing Association, the American Statistical Association, the Association for Consumer Research, the American Psychological Association, the American Association for Public Opinion Research, and the Society for Consumer Psychology.

3. My fields of specialization within marketing include marketing research methodologies such as survey design and analysis, marketing and branding strategies, the relationship between marketing research and marketing strategy, managerial decision-making, and consumer decision-making. I am an author of five books and over 60 articles and book chapters. In the course of my scholarly research, teaching, and consulting work, I have studied issues of marketing research and its role in consumer choice and marketing strategy.

4. One of the books I co-authored is a textbook entitled *Marketing Research*. This book was adopted at several of the country’s major business schools.

5. I have sat on the editorial boards of many major journals over the years. From July 2010 until March 2017, I served as a co-Editor-in-Chief of the journal *Marketing Letters*. In that capacity, I evaluated over 200 research studies each year for over six and a half years. I served as a gatekeeper, deciding which articles were published in the journal, and which were not. As such, my evaluations of the scientific reliability and validity of each research study were subject to the scrutiny of the academic community. The community considers any study that appeared in the journal that did not conform to the scientific standards of my profession as a black mark on my record. I consider the fact that the journal’s publisher, the international firm, Springer-Verlag, kept me on long past the expiration of my term (July 2014) as validation of my performance in evaluating
research. My professional qualifications are described further in my curriculum vitae attached to this report.

6. During the course of my professional career, I have designed, conducted, supervised, and/or evaluated well over 1000 marketing research studies. In that work, I have formulated sampling strategies, designed questionnaires, analyzed data, and interpreted results. I have also evaluated similarly purposed survey work performed by others. During my career, I have taught M.B.A. students about, written textbook chapters on, published research papers about using, and lectured executives on marketing research.

7. My rate of compensation for this assignment is $1,200 per hour.

II. BACKGROUND

8. I understand that the U.S. Food and Drug Administration (‘‘FDA’’) in authoring a document referred to as “Draft Guidance”\(^1\) recommended that all plant-based beverages that use the term “milk” either in their names or in comparison to cow’s milk and do not meet the minimums for nine nutrients present in cow’s milk should display a disclaimer on the front of the package describing the nutritional differences between them and cow’s milk.\(^2\)

9. I further understand this recommendation was (at least partially) based on six consumer research reports. Finally, I understand that the Plant-Based Food Association (‘‘PBFA’’)


\(^2\) Draft Guidance, p. 15.
objects to this recommendation (at least partially) on the basis that these six research reports do not contain any scientifically valid findings of consumers being confused about the nutritional content of plant-based milk alternatives. More specifically, the PBFA disputes the FDA’s contention that these six reports “suggest inadequate knowledge of and misunderstanding of nutrients in plant-based milk alternatives. The reports reviewed further indicate that those who always or often purchase plant-based milk alternatives seem more likely than non-purchasers to believe these alternatives are nutritionally equivalent or superior to milk.”

10. I have been asked by PBFA to provide professional and scientific commentary on the six consumer research reports upon which the above beliefs and recommendations were (at least partially) based. In particular, I was asked to look into the quality of the research, the clarity of the reports with respect to the research, and the degree to which the reports support the notion that consumers are confused about or do not understand the relative nutritional content of dairy milk and plant-based milk alternatives.

11. I believe PBFA is correct in its belief that the six reports at issue do not support the above highlighted notion for reasons which I shall detail later in this report.

12. To complete my assignment, I studied the six reports at issue:


3 FDA Summary, p. 3.

• “Focus Groups on Consumer Understanding and Behaviors Related to Plant-based Products and Foods: Final Report, August 2019,” (“RTI Focus Groups Report”); and

• “Plant-Based Diets are Here to Stay!, Proprietary consumer insights based on results from ‘Plant-Based Eating’ and ‘Plant-Based Behaviors & Motivations: Online Anthropology, conducted by HealthFocus® International and MotiveQuest, respectively, ” (“HealthFocus Anthropology Report”).

13. In addition to the above reports, I reviewed the following documents:

• Draft Guidance; and

• Memorandum detailing “Summary of consumer research reports on consumers’ perceptions and understanding of plant-based milk alternatives,” dated February 2, 2023, U.S. Food & Drug Administration, (“FDA Summary”).

III. THE REPORTS

14. In this section, I focus on two aspects of each report: the methodology used in the research contained in the reports and the major conclusions as they pertain to consumer perceptions of plant based milk alternative nutrients relative to those of cow’s milk.

CR Report

15. The plant-based milk survey commissioned by Consumer Reports was a phone survey administered to a sample of 1003 U.S. adults as part of an omnibus survey. Respondents were recruited through a random digit dialing process. The survey asked respondents “(c)ompared to cow’s milk, do you think unsweetened plant-based milks have MORE,
the SAME, or LESS nutrients (i.e. protein, calcium, vitamin A, and potassium) than cow’s milk?"\(^4\)

16. The survey results indicated that respondents were completely divided in how they answered that question. In particular,

- 27 percent of respondents say plant-based milks have more protein, calcium, vitamin A, and potassium than cow’s milk;\(^5\)
- 25 percent of respondents say plant-based milks have the same amount of protein, calcium, vitamin A, and potassium than cow’s milk;\(^6\)
- 26 percent of respondents say plant-based milks have more protein, calcium, vitamin A, and potassium than cow’s milk;\(^7\) and
- 20 percent of respondents do not know whether plant-based milks are nutritionally equivalent to cow’s milk.\(^8\)
- Nearly half (48%) of respondents who purchase plant-based milk alternatives do so because it has more nutrients that they need than cow’s milk.\(^9\)

**NDC Report**

17. This report summarizes an online survey that appears to have been administered by IPSOS in two phases. The first phase was administered to a “nationally representative” sample of 2010 adults in August 2018.\(^{10}\) The second phase was administered to a sample

\(^{4}\) CR Report, p. 4.
\(^{5}\) CR Report, p. 2.
\(^{6}\) Id.
\(^{7}\) Id.
\(^{8}\) Id.
\(^{9}\) CR Report, p. 8.
\(^{10}\) NDC Report, Phase I, p. 3.
of 2006 adults the following October. The questions in the survey most relevant to my objectives are from Phase I. In that part of the study, respondents were asked for their perceptions of milk and milk alternative products via both open and closed ended questions. Specifically, they were instructed to think about Almond, Soy, and Coconut Milk, and for each variety indicate how much protein, sugar, vitamins, key nutrients (e.g. calcium, potassium), calories, and fat that variety of milk alternative contains relative to cow’s milk. Respondents were given choices ‘more than dairy milk’, ‘same as dairy milk’ and ‘less than dairy milk’.

18. In Phase II, respondents were asked “Thinking about dairy milk and plant-based milk, would you say that plant-based milk contains..”more nutrients than dairy milk/same number of nutrients than dairy milk/less nutrients than dairy milk/not sure.

19. Phase I found that the majority of respondents perceive almond, soy, and coconut milks as having at least as many key nutrients and protein as cow’s milk. In particular:

- 78% of respondents indicated that almond milk has the same or more vitamins as dairy milk; 77% indicated that almond milk has the same or more protein; 68% responded that it had the same or more key nutrients (e.g. calcium, potassium); 
- 73% of respondents indicated that soy milk has the same or more vitamins as dairy milk; 75% indicated that soy milk has the same or more protein; 66% responded that it had the same or more key nutrients (e.g. calcium, potassium);

11 NDC Report, Phase II, p. 3.
12 NDC Report, Phase I, p. 3.
14 NDC Report, Phase II, p. 17.
71% of respondents indicated that coconut milk has the same or more vitamins as dairy milk; 62% indicated that coconut milk has the same or more protein; 68% responded that it had the same or more key nutrients (e.g. calcium, potassium);17 and

23% of general population respondents believed that plant-based milk alternatives had more nutrients than dairy milk; 20% believed they had the same, and 19% believed they had less. 38% were not sure.18

DMI Report

20. The DMI Report presents the result of an online survey designed to assess perceptions and usage of specific Dairy and Plant-Based beverage products, focusing primarily on almond milk.19 One of the objectives of this research was to see whether the perception of plant beverages is affected by the product name (i.e. milk or something else).20

21. The survey was described as being fielded on April 9, 2018 to a nationally representative sample of Americans aged 18+ (n=1000).21

22. Among the learnings reported by the DMI were

- Dairy Milk, Almond Milk and Almond Beverage are all perceived as nutritious by the general population;22

- The general population is more likely to rank Almond Milk as healthier or equally healthy as Dairy Milk.23 Only people who buy Dairy Milk exclusively view Dairy Milk as the healthier option. Others perceive Almond Milk as healthier by a large margin; and

17 NDC Report, p. 15.
18 NDC Report, Phase II, p. 17.
19 DMI Report, p. 2.
20 Id.
21 Id.
22 DMI Report, p. 3.
23 Id.
In an apparent contradiction to the previous bullet point, Dairy Milk had nutritional advantages over Almond Milk related to Calcium, Vitamin D, and its Role in Building Bones. Its advantage in responses to being a “good source of calcium” is 65 percent to 33 percent. Its advantage in ‘helps build and maintain strong bones & teeth’ is 60 to 27 percent. Finally, its advantage in perceptions of “contains vitamin D” is 59 to 22 percent. On the other hand, Dairy Milk and Almond Milk are approximately equally perceived to be nutritious (50 percent to 50 percent), good sources of protein (38 to 39 percent), good sources of vitamins (33 to 32 percent), is vitamin and mineral fortified (24 to 24 percent), and a good source of minerals (22 percent to 22 percent). The only clear advantage for Almond Milk was in “contains fiber” (18 to 6 percent).24

Mintel Report

23. Mintel is an independent market analysis company.25 The Mintel Report at issue in this matter represents an aggregation of data and results related to the non-dairy milk product category. In general, Mintel uses five main sources to assemble information on a range of markets and marketing issues. These sources are:

- Consumer research
- Social media research
- Desk research
- Trade research
- Statistical forecasting.26

24. For the primary consumer research Mintel develops the questions and uses specialty research firms for data collection.27 The survey results included in this report were

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24 DMI Report, p. 4.
26 Id.
27 Id.
apparently collected by a firm called Lightspeed.\textsuperscript{28} Mintel surveys are generally done online with quotas based on gender, age, household income, and region.\textsuperscript{29} This supposedly ensures that the Mintel consumer survey samples are demographically representative of the U.S. adult internet population.

25. It is important to note that the Mintel Report, produced in 2017, is a syndicated industry level resource that presents data and results for the industry as a whole. The research reported therein focuses on the market (its breakdown, forecasts, the external environment, etc.), the key participants (company and brands, etc.), and the consumer (market penetration of different types of non-dairy milk alternatives, purchase incentives, health perceptions, attitudes, and usage contexts, etc.). The research was not custom designed to address the issues at hand; i.e. consumer perceptions of the nutrient content of plant-based milk alternatives relative to dairy/cow’s milk. Rather, the research in the report was designed for general industry consumption and for industry participants to use in making marketing decisions. As such, there is little in the report that directly addresses the issue at hand.

26. Among the findings that do not directly relate to the issues at hand are:

- Respondents to the Lightspeed online survey generally believe that cow’s milk is healthier than plant based milk alternatives. Among plant based milk alternatives, almond milk is seen as the healthiest;\textsuperscript{30}

- Vitamins/minerals are important to 35 percent of the respondents in making the choice between dairy and non-dairy milk;\textsuperscript{31}

\textsuperscript{28} Mintel Report, p. 68, p. 84.

\textsuperscript{29} Mintel Report, p. 83.

\textsuperscript{30} Mintel Report, p. 11.

\textsuperscript{31} Mintel Report, p. 46.
• Vitamins and minerals are important to 42 percent of non-dairy milk consumers and 36 percent of dairy milk consumers;\textsuperscript{32}

• In answering “(w)hich words or phrases do you think best describe each of the following types of milk?” 54 percent of respondents associated “nutritious” with any dairy milk and 28 percent associated “nutritious” with any non-dairy milk;\textsuperscript{33}

• In answering “(w)hich words or phrases do you think best describe each of the following types of milk?” 46 percent of respondents associated “contains vitamins and minerals” with any dairy milk and 24 percent associated “contains vitamins and minerals” with any non-dairy milk.\textsuperscript{34}

\textbf{RTI International Focus Group Report}

27. The FDA requested that RTI International conduct 12 focus groups in three cities (Bethesda MD, Portland OR, and Raleigh NC) to understand usage, attitudes and perceptions of plant-based products, with an emphasis on beverages.\textsuperscript{35} Four groups were conducted in each city. The groups were segmented so that each city had a low education/non-parent group as well as a high education/non-parent, a low education/parent, and a high education/parent group.\textsuperscript{36} Of note, the groups were homogeneous and all individuals in each group were in the same combination of education and parent status. All group members were between the age of 18 and 65,

\begin{itemize}
\item \textsuperscript{32} Mintel Report, p. 47.
\item \textsuperscript{33} Mintel Report, p. 63.
\item \textsuperscript{34} Mintel Report, p. 63.
\item \textsuperscript{35} RTI Focus Groups Report, p. 4.
\item \textsuperscript{36} RTI Focus Groups Report, p. 5.
\end{itemize}
prepared household meals, and had purchased a plant-based beverage within the last six months.\textsuperscript{37}

28. A moderator presided over each group and prompted group discussion with several questions as described in a discussion guide.\textsuperscript{38} The critical question for our purposes is question 12.

- What is in plant-based products [e.g. ingredients, nutrients]?
  
  a) To what extent are they or are they not, equal to cow’s milk? [e.g. Lower fat/calorie content? Lactose?]
  
  b) How do they differ in calcium, protein, fat, vitamins (A, D, B)?

29. Prior to the group discussion, participants were asked to complete a rating sheet that listed a range of statements. Participants were asked to rate each statement from 1 (strongly disagree) to 5 (strongly agree). Among the statements respondents were asked to react to were “Plant-based beverages have the same nutrients as cow’s milk”, “Plant-based beverages are less-nutritious than cow’s milk”, and “Plant-based beverages are more nutritious than cow’s milk.”\textsuperscript{39}

30. Among the insights and results RTI International derived from the groups were:

- Participants in most groups (8 out of 12) said the products were less nutritious than cow’s milk,\textsuperscript{40}

- Ten groups mentioned reasons why they felt that plant-based milk alternatives were not healthy or less healthy than dairy milk. The reasons were fewer nutrients (e.g.,

\textsuperscript{37} Id.

\textsuperscript{38} RTI Focus Groups Report, Appendix B.

\textsuperscript{39} RTI Focus Groups Report, p. 33.

\textsuperscript{40} RTI Focus Groups Report, p. 5, p. 13.
calcium or vitamin D; 4 groups), less protein (3 groups), more additives (3 groups), or more sugar (4 groups);⁴¹

- In a seeming contradiction to the last bullet point, more groups (n=8) said that plant-based milk alternatives were superior to cow’s milk. Reasons included better nutritional characteristics (e.g. less fat, less calories, more calcium, and more protein);⁴²

- The pre-group mean ratings for “Plant-based beverages have the same nutrients as cow’s milk”, “Plant-based beverages are less-nutritious than cow’s milk”, and “Plant-based beverages are more nutritious than cow’s milk” were 2.8, 2.2, and 3.3 respectively.⁴³

**Healthfocus Anthropology Report**

31. The Healthfocus Anthropology Report consists of three components. The first component describes an online study of 1009 respondents.⁴⁴ ⁴⁵ The primary purpose of this study was to create market segments using the proprietary DuPont Health & Wellness Segmentation Model.⁴⁶ Related to my focus (i.e. consumer perceptions of plant-based milk alternative nutrient contents relative to dairy milk nutrient contents), this online study asked “How much more would you be willing to pay for (milk alternatives) if it had added plant-based ingredients?”⁴⁷

32. The results of the first component of the report suggest:

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⁴¹ RTI Focus Groups Report, p. 5, p.17.
⁴² RTI Focus Groups Report, p. 19.
⁴³ RTI Focus Groups Report, p. 33.
⁴⁴ Healthfocus Anthropology Report. (This report does not have numbered pages)
⁴⁵ The report does not make clear whether the respondents were from the United States or other countries.
⁴⁶ Id.
⁴⁷ Id.
• The market for plant-based foods consists of six segments. They are referred to as Health Helpers, Weight Strugglers, Health Wise, Taste Driven, Good Life, and Just Food;\textsuperscript{48} and

• Respondents who feel having plant-based ingredients is Somewhat Important, Important, Very Important, or Extremely Important for milk alternatives were willing to pay 15 percent more for products with them. Of course this varied by segment, ranging from 9 percent for Goodlife to 23% for Health Helpers.\textsuperscript{49}

33. The second component of the Healthfocus Anthropology Report involved what the authors of the presentation called an “online anthropology approach.”\textsuperscript{50} This component contains most of the research in this report that relates to nutritional comparisons between dairy milk and plant-based milk alternatives.

34. The research analyzed 35 months of unprompted online conversations from forums, blogs, review sites, public Facebook pages, and YouTube video commentary in order to answer specific questions related to (among other things) consumer perceptions.\textsuperscript{51} This general approach has gained acceptance in the marketing academy and practitioner community.\textsuperscript{52}

35. The analysis began with approximately 5.8 million English-language conversations mentioning terms related to plant-based food and beverage consumption. These conversations were then “cleaned” by identifying and excluding false positives, and non-personal discussions resulting in just over 3 million conversations about behaviors and

\textsuperscript{48} Id.

\textsuperscript{49} Id.

\textsuperscript{50} Id.

\textsuperscript{51} Id.

thoughts on plant-based food and beverage consumption aspirations, habits, and experiences.\textsuperscript{53}

36. Analysis of these conversations showed that 4.2 percent of the 279,918 plant-based beverage conversations (.042 x 279,918 = 11,777) made a nutritional comparison with dairy milk. These comparisons focused largely on protein, fat, and sugar. Dairy milk seems to be perceived as having more protein than plant based beverages.\textsuperscript{54}

37. The third component of the Healthfocus Anthropology Report appears to be a presentation focused on DuPont’s business and not consumer behavior. It makes mention of primary consumer research, but does not present it or its findings.\textsuperscript{55}

\textsuperscript{53} Healthfocus Anthropology Report. (This report does not have numbered pages)

\textsuperscript{54} \textit{Id.}

\textsuperscript{55} \textit{Id.}
IV. THE SIX RESEARCH REPORTS, INDIVIDUALLY AND COLLECTIVELY, DO NOT CONTAIN VALID SCIENTIFIC EVIDENCE ABOUT HOW CONSUMERS PERCEIVE THE NUTRIENT CONTENTS OF PLANT BASED MILK ALTERNATIVES RELATIVE TO THOSE OF DAIRY OR COW’S MILK.

38. Drawing any conclusions about perceptions of relative nutrient content from the six research reports at issue can only be the result of what is often referred to as “confirmation bias” on the part of the FDA. Confirmation bias refers to the well-established principle that people asked to make a judgment about an individual, object, or event that harbor prior beliefs about that individual, object, or event, tend to look for and interpret new information that confirms those prior beliefs.\(^{56}\)

39. There are several reasons why any conclusions related to consumer perceptions of the relative nutrient content of plant-based milk alternatives and dairy milk based on the six research reports are unwarranted. These include:

- Not all the reports describe research designed to examine the issue at hand;
- The results presented in the six reports contradict each other. Two reports (DMI Report and RTI Focus Group Report) even can be seen as internally inconsistent on the issue;
- The reports and the studies they contain use ambiguous language;
- The research described in the reports is not contemporaneous with the current recommendations; and
- The reports lack the detail of the underlying research necessary to provide a scientific evaluation of the work.

These concerns apply to the collectivity of the reports. In addition, there are issues related to each one individually that I will address later.

**The Research Was Not Designed To The Issue At Hand**

40. Scientific research generally begins with a well-defined research objective. Specific objectives guide the research, give it focus, and help ensure objectivity. For example, in false advertising studies, for example, objectives typically are of the form ‘test whether [INSERT ALLEGEDLY MISLEADING STATEMENT] causes consumers to take away [INSERT SPECIFIC IMPRESSION] from a particular ad. Without precise well-defined objectives, it is difficult to draw precise well-defined conclusions.

41. Ideally, for purposes of examining consumer perceptions of relative nutrient content, a study would begin with a precise objective such as “to test whether consumers perceive the content of INSERT SPECIFIC NUTRIENTS in INSERT SPECIFIC PLANT BASED MILK ALTERNATIVES relative that of dairy or cow’s milk.” Then one or more studies would be designed to directly address this objective.

42. None of the six reports contain a research objective similar to this. In particular, the CR Report does not contain a research objective at all. Neither does the Mintel Report, nor the Healthfocus Anthropology Report. The NDC Report Phase I does a little better. It says, “DMI would like to better understand consumer perceptions toward Dairy Milk and Plant-Based Milk Alternatives, particularly regarding nutritional content.” The DMI Report states the objective “to assess perceptions and usage of specific Dairy and

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57 I shall explain later in the report why specific nutrients and specific plant based milk alternatives are needed.

58 As an industry summary, it is probably inappropriate for it to present a research objective.

59 NDC Report, Phase I, p. 2. Phase II has a very similar objective.
Plant-Based beverage products, focused primarily on the largest plant beverage, almond based beverages and the secondary objective “to assess how/if the perception of plant beverages is affected by the product name.” The closest the RTI Focus Group Report comes to a research objective is that “(t)he U.S. Food and Drug Administration (FDA) issued a request for more information (emphasis added) to examine consumer’s knowledge, attitudes, and beliefs about (plant-based milk alternatives). Additionally, FDA wanted to ensure that labeling-plant based products with names that include the names of dairy foods (e.g. milk or cheese) would not mislead consumers.”

The objectives stated in the NDC Report, the DMI Report, and the RTI Focus Group Report are generally vague. As my own textbook says, “research objectives should be both specific and limited. One of the greatest causes of dissatisfaction with research is vaguely worded or overly optimistic objectives, which are rarely achieved.” This is because a vague objective cannot provide specific direction for a research project. As a result, the project tends to disappoint.

Given that none if the reports contain an objective resembling the question I was asked to investigate, it becomes significantly less likely that they will contain research that addresses the issue in a scientifically valid manner. The FDA Summary tries to piggy-back on studies that, by and large, do not have objectives related to consumer perceptions of relative nutrient content. Of note, some of the reports’ studies do not even

60 DMI Report, p. 2.
61 Id.
have questions that directly address nutrient content. Instead, they focus on whether the beverages are ‘healthy.’ Of course nutrient content and health are related; but health is a much broader construct. For example, non-nutrient fat and sugar content are related to health. As such, making inferences about perceptions of relative nutrition from perceptions of which is healthier is dangerous indeed.

45. In the entire set of six reports, I could only find questions inviting respondents to directly compare the nutritional content of dairy milk and plant-based milk alternatives in three of them: the CR Report, the NDC Report (Phase I), and the RTI Focus Group Report. But, as I shall illustrate below, these studies and the questions they ask have other problems, not the least of which is a lack of consistent results.

**Contradictory Findings**

46. Social science has benefitted from the use of multiple studies using different research approaches. If one can study a phenomenon using multiple approaches, the results of the different approaches are consistent, and none of them are contradictory, one can establish convergent validity through “triangulation.” Triangulation, the use of multiple methods and data sources to study the same phenomenon, can overcome any potential bias resulting from the use of a single method or single source of data in a study and thereby increase the confidence in the conclusions regarding the phenomenon being studied.

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63 Triangulation refers to the use of multiple methods and data sources in the study of the same phenomenon. See for example, Brender, J., Framework for Meta-Assessment of Assessment Studies, in *Handbook of Evaluation Methods for Health Informatics*, 2006; and Patton, M.Q. (1999). Enhancing the quality and credibility of qualitative analysis. *Health Sciences Research*, 34, 1189–1208. The concept of convergent validity has long been accepted as a means of ensuring the validity of key findings in many fields of scientific inquiry. Its roots can be traced to a seminal article in the *Psychological Bulletin* by Campbell and Fiske (1959), “Convergent and Discriminant Validation by the Multitrait-Multimethod Matrix.”
studied. However, if the results of the various studies contradict each other, the questions of interest are still open. Unfortunately, that is the case here.

47. The six reports I studied present research using a variety of methods and approaches (e.g. consumer surveys, focus groups, social media analysis) in their study of the consumer perceptions of the relative nutrient content of plant based milk alternatives and dairy milk. Such diversity would lead to greater confidence in the results of each if they were consistent. However, they are not.

48. For example, the Phase I NDC Report respondents indicated that almond milk has the same or more vitamins, protein, and other key nutrients. There were similar results for soy milk and coconut milk.\textsuperscript{64} The results of the CR Report study suggests that Americans believe that plant-based milks have the same or more nutrients than cow’s milk.\textsuperscript{65}

49. In contrast, more respondents in the Lightspeed survey described in the Mintel Report associated “contains vitamins and minerals” with dairy milk than non-dairy milk.\textsuperscript{66} Furthermore, participants in 8 out of 12 of the RTI focus groups said that cow’s milk is more nutritious than plant based.\textsuperscript{67} \textsuperscript{68} Similarly, the online conversations in the

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\textsuperscript{64} DMI Report, p. 3.

\textsuperscript{65} CR Report, p. 4.

\textsuperscript{66} Mintel Report, p. 63.

\textsuperscript{67} RTI Focus Groups Report, p. 5, p. 13.

\textsuperscript{68} Curiously though, more groups (n=8) said that plant-based milk alternatives were superior. (RTI Focus Groups Report, p. 19). Furthermore, the pre-group mean ratings slightly favor the nutritional content of plant-based milk. (RTI Focus Group Report, p. 33)
Healthfocus Anthropology Report suggests that dairy milk is perceived as having greater protein content than plant-based beverages.\textsuperscript{69}

50. In a potentially internal contradiction, the DMI Report cited perceptions of Almond Milk as being equally healthy or more healthy than Dairy Milk. Yet, at the same time, Dairy Milk was perceived as having nutritional advantages over Almond Milk.\textsuperscript{70}

51. Clearly, no coherent consistent story about consumer perceptions of the nutritional content of plant-based milk alternatives relative to dairy milk emerges from the six reports. As such, there can be no scientifically valid conclusion on the subject from the six reports.

\textit{The Research Described In Each Report Is Not Contemporaneous With The FDA’s Recommendations.}

52. The FDA’s summary memo in which it states that it has “gained useful and relevant insight into consumers’ perceptions into consumers’ perceptions and understanding of plant-based milk alternatives”\textsuperscript{71} was written in 2023. Furthermore, the recommendations made in the Draft Guidance are for the present day.

53. However, the dates the research projects described in the six reports were conducted is as follows:

- The study conducted in the CR Report was administered in October 2018;

\textsuperscript{69} Healthfocus Anthropology Report. (This report does not have numbered pages.)

\textsuperscript{70} See paragraph 22, \textit{supra}. I note that this is not necessarily a contradiction as healthier and having nutritional disadvantages are not necessarily inconsistent. However, the results taken together raise questions of potential inconsistency which the DMI Report does not answer.

\textsuperscript{71} FDA Summary, p. 1.
• The data collected for the NDC Report were collected in August 2018\textsuperscript{72} and October 2018\textsuperscript{73};

• The survey described in the DMI Report was fielded in April 2018;\textsuperscript{74}

• The Mintel Report is dated September 2017 so the Lightspeed survey referred to therein must have been fielded prior to that;

• Similarly, the RTI Focus Group Report is silent as to when the focus groups were run. However, the report is dated August 2019 so they must have been run prior to that; and

• The online conversations analyzed in the Healthfocus Anthropology Report took place between January 2016 and November 2018.

54. Therefore, the data from which the FDA is gaining its ‘useful and relevant insight’ and on which it is basing its recommendations is at least four, most likely five, and in some cases as much as six or seven years out of date. I know of no marketing manager that would base product or advertising decisions on data that are that old. Those data could only be valid if consumer perceptions remained unchanged over the seven-year time period, an extremely unlikely occurrence, especially since the market was projected to grow by over 50 percent in that time period.\textsuperscript{75} Even if they were collected and reported properly and addressed the question of interest directly, the data that formed the basis of the six reports are as out of date as the Blackberry.

\textsuperscript{72} NDC Report, Phase I, p. 3.
\textsuperscript{73} NDC Report, Phase II, p. 3.
\textsuperscript{74} DMI Report, p. 2.
\textsuperscript{75} Mintel Report, p. 18.
**Ambiguous Language**

55. Survey questions need to be clear, precise, and unbiased. Even questions that appear clear can convey ambiguities to some respondents.\(^76\) Reliable survey research requires that each respondent understand the questions and that the understanding be uniform across respondents. It is well established in the survey literature that ambiguous questions “written with … words with various different meanings [are] … more difficult for respondents to interpret.”\(^77\) For example, in *The Art of Asking Questions*, Stanley Payne states, “[s]urvey questions ideally should be geared to embrace all levels of understanding so that they have the same meaning for everyone.”\(^78\) He (1951) adds:

> “The most critical need for attention to [survey] wording is to make sure that the particular issue which the questioner has in mind is the particular issue on which the respondent gives his answers.”\(^79\)

56. Two words used in the studies and the questions they ask are potentially ambiguous, ‘nutrients’ and/or ‘plant-based milks’. These words raise two questions: What nutrients are respondents thinking of when they see the word? Similarly what plant-based milks are respondents thinking of? Respondents may not be clear as to whether (say) proteins and vitamins are nutrients. Some websites even classify water as a nutrient. One says that there are 11 separate categories of nutrients.\(^80\) Similarly, there are numerous plant-

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\(^80\) Cf. https://draxe.com/nutrition/essential-nutrients/#What_Are_Nutrients
based milks. The FDA’s website enumerates several categories of plant based beverages:\footnote{https://www.fda.gov/consumers/consumer-updates/milk-and-plant-based-milk-alternatives-know-nutrient-difference?gclid=Cj0KCQjwho-lBhC_ARIsAMpgMoe2CKVL015aN01sv1zqfn4t_xQpgSsyS_5x0BDN9ZeqtXaEnl8lsgaAlmJEALw_wcB}

- **Grains** such as oat, quinoa and rice.
- **Legumes** such as pea and soy.
- **Nuts** such as almond, cashew, coconut, hazelnut, macadamia, peanut, pistachio and walnut.
- **Seeds** such as flax, hemp and sesame.

57. The critical question asked in the CR Report’s survey was “(c)ompared to cow’s milk do you think unsweetened plant-based milks have MORE, the SAME, or LESS nutrients (i.e. protein, calcium, vitamin A, and potassium) than cow’s milk?”\footnote{CR Report, p. 4.} Both ambiguities appear. The CR Report asks about and reports results for “plant-based milks”. The FDA correctly points out that “it is unknown whether beliefs about how plant-based milk alternatives compare to milk may differ between types of plant-based milk alternatives.”\footnote{FDA Summary, p. 10.} Furthermore, the question bundles four nutrients. Since there is only one question, it is not clear what a respondent should do if she thinks one type has more protein or less calcium. Also the question does not make clear whether these nutrients are the only ones to consider or just examples.

58. Giving examples of nutrients, as the CR Report does, and the NDC Report does in questions such as “Thinking about Almond Milk, would you say that almond milk
contains key nutrients (e.g. Calcium, Potassium)…?’,\textsuperscript{84} does not cure the ambiguity problem. Examples such as this tell you what are ‘key nutrients’, but they do not tell you what are not.

59. Unless given very specific and precise instructions about what nutrients and what plant-based milks to consider, respondents could interpret these words and therefore the questions differently. If that is the case, overall results will be uninterpretable and any conclusions drawn from them cannot be relied upon. Such is likely to be the case here.

\textbf{Critical Details Are Missing From The Reports.}

60. One of the cornerstones of science is replicability. In performing a scientific evaluation, I should be able to investigate and reproduce every detail of the research contained in the reports. I may not agree with all conclusions, but I should be able to completely examine how they were obtained. Without detailed descriptions of the research processes used, I cannot do that.

61. The FDA research memo recognizes that the study descriptions are incomplete. It says:

\begin{quote}
It is important to emphasize that most of the consumer research reports submitted did not contain detailed information about the methodology, sample characteristics, survey protocols/questions raw data, statistics used for data analyses, and some research contained biases/limitations that affect the reliability, validity, and usefulness of the findings.\textsuperscript{85}
\end{quote}

62. Despite these observations, the authors of the memo add, “(w)hile we often did not have sufficient information to conduct a thorough, critical review of these studies, we gained

\\[\text{\textsuperscript{84} NDC Report, Phase I, p. 13.}\]
\\[\text{\textsuperscript{85} FDA Summary, p. 1.}\]
useful and relevant insight into consumers’ perceptions and understanding of plant-based milk alternatives.”

63. I find that latter statement by the FDA Summary curious. The FDA appears to be accepting at least some results presented in the six reports without knowing how they were obtained. No scientist worth his or her salt would ever do that. This is especially dangerous for results in the NDC and DMI reports. These reports were sponsored and/or prepared by the Dairy Management, Inc. (“DMI”), a trade association affiliated with the National Milk Producers Federation and the American Dairy Association. These organizations exist to increase sales and demand for dairy product. As such, their objectivity is subject. Not knowing the details of how their studies were conducted inhibits the audience from evaluating any potential bias.

**Miscellaneous**

64. Apart from the above global problems, the studies and reports have several other problems. In this section, I describe some of those that were not addressed above.

65. *RTI Focus Group Report:* While the FDA summary concedes that the findings of the focus groups cannot be projected to the population as a whole (the participants essentially comprise a convenience sample), it fails to recognize other limitations. As I write in my *Marketing Research* textbook,

> The problems with focus groups are…numerous. First, the process depends heavily on the moderator’s ability to direct the discussion. Second, bad group dynamics (e.g. one loudmouth) can greatly reduce the value of the results. Third, interpreting the results requires considerable skill. A corollary to this is that the buyer of the research

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86 Id.
who does not observe a focus group either in person or on tape may lose much of the value of the session.\textsuperscript{87}

In other words, the focus groups would be much more valuable to the FDA if a member of the FDA actually observed them.

66. Furthermore, the focus groups conducted by RTI were essentially homogenous. The members of each group all came from the same city, had the same level of education, and were of the same parental status. In contrast, literature has recognized that focus groups are more effective when the participants come from a diverse range of backgrounds, views and experiences.\textsuperscript{88}

67. \textit{Healthfocus Anthropology Report}: The Healthfocus International Report lists the sources for the online conversations used in its analysis.\textsuperscript{89} Conspicuous by its absence on that list is Twitter. According to Pew Research Center,\textsuperscript{90} 24\% of U.S. Internet users were using Twitter by the end of 2016.\textsuperscript{91} It is hard to believe that some of the sources enumerated in the Healthfocus Anthropology Report contained more conversations about dairy and plant-based milk than Twitter.

V. SUMMARY


\textsuperscript{89} Healthfocus Anthropology Report (This Report has no page numbers).


68. The content of the six research reports relied upon by the FDA does not present valid scientific evidence that consumers do not understand the differences between dairy milk and plant-based milk alternatives. The research is flawed and the reports are incomplete. As a result, the reports present conflicting results.

69. The CR Report contains no research objective, uses ambiguous language (it contains only one question, which bundles both “nutrients” and “plant-based milks”), and is outdated.

70. The NDC Report and DMI Report were both sponsored by dairy trade associations and, according to the FDA, lack information about methodology, sampling, protocols and analysis, and are therefore potentially biased. Both reports contain vague research objectives and are outdated. The NDC report also used ambiguous language (e.g., “key nutrients”).

71. The Mintel Report was not designed to address consumer perceptions of nutrient content, is outdated, and also suggests findings that contradict the FDA’s conclusion (finding more respondents associated “contains vitamins and minerals” with dairy milk than non-dairy milk).

72. The RTI Focus Group Report, commissioned by the FDA, contains vague research objectives, is based on a convenience homogenous sample of participants, with the many problems inherent in focus groups, but likewise suggests findings that contradict the FDA’s conclusion (with 8 out of 12 participants saying cow’s milk is more nutritious than plant-based milk).

73. The HealthFocus Anthropology Report also lacks a research objective, is (according to the FDA) based on a “skewed” sample, but likewise suggests findings that contradict the
FDA’s conclusion (suggesting that dairy milk is perceived as having greater protein content than plant-based beverages).

74. In sum, the research reports cannot support the FDA’s conclusion that consumers are confused about the relative content of certain nutrients of dairy milk and plant based beverages. The research is flawed and the reports are incomplete. As a result, the reports present conflicting results.

75. The surveys conducted are not geared towards answering the question implicit in the FDA’s conclusion about what consumers do and do not understand. The data analyzed for the reports are out of date. The reports do not present sufficient details about how the research was conducted.