UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re: Elysium Health-ChromaDex Litigation	17-cv-7394 (LJL)
	OPINION AND ORDER

LEWIS J. LIMAN, United States District Judge:

Plaintiff ChromaDex, Inc. ("ChromaDex") moves to exclude the opinions of Defendant Elysium Health's ("Elysium") survey expert, Brian Sowers, and damages rebuttal expert, Colin Weir, pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) and Federal Rules of Evidence 104, 401, 402, 403, 702, and 704. Dkt. No. 199. Elysium moves to exclude the reports of ChromaDex's survey expert, Bruce Isaacson; damages expert, Lance Gunderson; FDA regulation expert, Steven Weisman; and clinical studies expert, Kurt Hong, pursuant to *Daubert* and Federal Rule of Evidence 702. Dkt. No. 197. Familiarity with the Court's prior opinions setting out the facts of the case is presumed.

For the following reasons, the *Daubert* motions are each granted in part and denied in part.

LEGAL STANDARD

Under Federal Rule of Evidence 702, a witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion if:

> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. "[T]he proponent of expert testimony has the burden of establishing by a preponderance of the evidence that the admissibility requirements of Rule 702 are satisfied." *United States v. Jones*, 965 F.3d 149, 161 (2d Cir. 2020) (quoting *United States v. Williams*, 506 F.3d 151, 160 (2d Cir. 2007)). That rule requires the proponent to establish and the trial judge to find "that any and all scientific testimony or evidence admitted is not only relevant, but reliable." *Daubert*, 509 U.S. at 589. This "gatekeeping obligation" applies "to all expert testimony." *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 147 (1999).

"The objective of [the gatekeeping] requirement is to ensure the reliability and relevancy of expert testimony. It is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Id.* at 152. Relevancy is determined by whether the proffered evidence "has any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable." *Amorgianos v. Amtrak*, 303 F.3d 256, 265 (2d Cir. 2002). Reliability is determined by considering if (1) "the testimony is based on sufficient facts or data;" (2) "the testimony is the product of reliable principles and methods;" and (3) "the expert has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702; *see also Amorgianos*, 303 F.3d at 266 (citing this standard).

Courts are to adhere to a "liberal standard of admissibility for expert opinions," *Nimely v. City of New York*, 414 F.3d 381, 395–96 (2d Cir. 2005), beginning with "a presumption that expert evidence is admissible," *Chen-Oster v. Goldman, Sachs & Co.*, 114 F. Supp. 3d 110, 115 (S.D.N.Y. 2015) (citing *Borawick v. Shay*, 68 F.3d 597, 610 (2d Cir. 1995)). However, a court still must determine that the evidence is "sufficiently reliable so as to be admissible."

Amorgianos, 303 F.3d at 268. "In deciding whether a step in an expert's analysis is unreliable, the district court should undertake a rigorous examination of the facts on which the expert relies, the method by which the expert draws an opinion from those facts, and how the expert applies the facts and methods to the case at hand." *Id.* at 267. "[I]t is critical that an expert's analysis be reliable at every step." *Id.* Even "[i]f the witness is relying solely or primarily on experience, [he still] must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts." *Alto v. Sun Pharmaceutical Indus., Inc.*, 2021 WL 4803582, at *2 (S.D.N.Y. Oct. 13, 2021) (internal quotation marks omitted) (quoting *Pension Comm. of Univ. of Montreal Pension Plan v. Banc of Am. Sec., LLC*, 691 F. Supp. 2d 448, 473 n.148 (S.D.N.Y. 2010) (quoting Fed. R. Evid. 702 advisory committee's note)).

"[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by *ipse dixit* of the expert." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). But "many factors 'will bear on the inquiry' of whether Rule 702 is satisfied, . . . and . . . 'the inquiry envisioned by Rule 702 is a flexible one.'" *Jones*, 965 F.3d at 161 (quoting *Daubert*, 509 U.S. at 593–94) (alteration omitted).

DISCUSSION

I. The Survey Experts

Each party moves to exclude the survey expert of the other party—ChromaDex moves to exclude the report of Elysium's expert, Brian Sowers, and Elysium moves to exclude the report of ChromaDex's expert, Bruce Isaacson.

A. General Principles

A party seeking to exclude survey evidence from a jury trial shoulders a heavy burden. A survey is probative and may be admitted into evidence to establish actual confusion if it is "fairly

prepared and its results directed to relevant issues." *Sterling Drug, Inc. v. Bayer AG*, 14 F.3d 733, 741 (2d Cir. 1994) (quoting *Universal City Studios, Inc. v. Nintendo Co., Ltd.*, 746 F.2d 112, 118 (2d Cir. 1984)). As a general matter, "[e]rrors in methodology . . . properly go only to the weight of the evidence" and not to its admissibility. *See Schering Corp. v. Pfizer Inc.*, 189 F.3d 218, 227–28 (2d Cir. 1999); *see also Lois Sportswear, U.S.A., Inc. v. Levi Strauss & Co.*, 799 F.2d 867, 875 (2d Cir. 1986); *WIZKIDS/NECA, LLC v. TIII Ventures, LLC*, 2019 WL 1454666, at *13 (S.D.N.Y. Mar. 31, 2019) ("Although these arguments are not without merit, they again simply diminish the weight of the survey evidence rather than provide grounds for its exclusion."); *Playtex Prods., Inc. v. Procter & Gamble Co.*, 2003 WL 21242769, at *2 (S.D.N.Y. May 28, 2003) ("[T]he Second Circuit clarified in *Schering* that any methodological deficiencies in a survey properly relate to the weight afforded to the survey's conclusions rather than its admissibility, subject of, of course, to a Rule 403 relevancy analysis."), *aff'd*, 126 F. App'x 32 (2d Cir. 2005); *Friesland Brands, B.V. v. Vietnam Nat'l Milk Co.*, 221 F. Supp. 2d 457, 459 (S.D.N.Y. 2002) ("The Second Circuit in *Schering* made clear that such a survey's 'errors in methodology . . . properly go only to the *weight* of the evidence'—not to its admissibility." (omission in original) (quoting *Schering*, 189 F.3d at 228)); *Caché, Inc. v. M.Z. Berger & Co*, 2001 WL 38283, at *6 (S.D.N.Y. Jan. 16, 2001). To be admissible, a survey generally must, among other things, (i) properly define the target population; (ii) select a representative sample; (iii) use precise, non-leading questions; (iv) report data accurately; and (v) maintain objectivity. *See Schering Corp.,* 189 F.3d at 224–25; *see also* Manual for Complex Litig., Fourth, § 11.493; Shari Seidman Diamond, *Reference Guide on Survey Research*, *in* Reference Manual on Scientific Evidence 359, 359–425 (3d ed. 2011) "The key issues for the trier of fact concerning the design of the survey are the objectivity and relevance of the questions on the survey and the

appropriateness of the definition of the population used to guide sample selection." *Reference Guide on Survey Research* at 374.

B. Background

1. The Sowers Report

During discovery, Elysium produced the expert report of Brian M. Sowers ("Sowers"). Dkt. No. 201-2 ("Sowers Report"). Sowers is a principal of Applied Marketing Science, Inc., a market research and consulting firm, and has worked in the field of market research since 1996. *Id.* ¶ 1. He has personally designed and conducted hundreds of market research surveys over the course of his career, is a member of numerous industry and professional organizations, and has served as a testifying expert in federal and state court and before the Trademark Trial and Appeal Board. *Id.* ¶¶ 2–3.

Sowers was retained by Elysium to conduct a survey to test Elysium's allegation that ChromaDex advertising deceived customers into believing that the FDA reviewed ChromaDex's product, Tru Niagen, for efficacy. As a general matter, Sowers conducted his survey in a manner consistent with consumer surveys used in Lanham Act cases. He determined what he believed to be the appropriate universe of respondents, he used an internet survey to identify eligible respondents, he designed a survey to ask respondents what messages they took from ChromaDex's statements and whether they took a message regarding FDA review of Tru Niagen for efficacy and what that message was, and finally, he conducted a survey of a control group to eliminate "noise" from his survey (or factors that might introduce error or bias into the survey results). In particular, Sowers determined that the appropriate universe to survey was "potential purchasers of products to support cellular health." *Id.* ¶ 17. To obtain a pool of qualified respondents, Sowers then developed an internet survey, which was sent to panel members of Prodege Market Research, a market-research firm with whom Sowers contracted and that

maintains a panel of over six million active members in the United States. *Id.* ¶¶ 18–20. Sowers divided eligible respondents into two groups—a test group and a control group. Members of the test group were shown the Tru Niagen homepage as it appeared at that time. *Id.* ¶¶ 7, 24. The homepage contained statements regarding FDA involvement in Tru Niagen, including the phrases "3 FDA Safety Notifications" and "reviewed and accepted by . . . US FDA." Dkt. No. 239 at 2. The control group was shown the same stimulus but with the following disclaimer added: "The Food and Drug Administration has not reviewed Tru Niagen for effectiveness." *Id.* ¶¶ 24, 33. Both sets of respondents were asked to review the homepage as if they were considering whether or not to purchase the product. *Id.* ¶¶ 24, 33.

Sowers' survey began with a series of screening questions to determine if the respondent was a member of the relevant population and qualified to participate in the survey, including questions to ensure that actual people were taking the survey, that they were using an electronic device that permitted them to view the stimulus, that they lived in the United States, and that they were paying attention. *Id.* ¶¶ 26–30. The main part of the questionnaire, to be answered only by respondents who passed the screening questions, was directed to the message respondents took from the webpage, which was described as a webpage "for a product that supports cellular health." *Id.* ¶ 32. Respondents were asked a total of seven questions. First, they were asked if they could view the webpage clearly; respondents who were unable to view the webpage clearly were not permitted to continue. *Id.* ¶ 36. Then, respondents were asked the open-ended question: "What is the main message communicated to you by the webpage?" (Q1) and were able to respond either in a text box or by selecting "Don't know/Unsure." *Id.* ¶ 37. If they responded with an answer, they were then queried: "What other messages, if any, are communicated to you by the webpage?" (Q2) and were given the option of inserting an answer in

a text box or selecting "No other messages." *Id.* Regardless whether they answered Q1, all respondents were directed to the next question, which asked: "Does the webpage communicate anything about whether or not the FDA has reviewed the Tru Niagen product for effectiveness?" (Q3). *Id.* ¶ 38. Respondents were given the option of selecting one of three answers:

- Yes, the webpage does communicate something about whether or not the FDA has reviewed the Tru Niagen product for effectiveness
- No, the webpage does not communicate anything about whether or not the FDA has reviewed the True Niagen product for effectiveness
- Don't know/Unsure.

Id. ¶ 38. The first two response options were rotated to avoid any potential response bias. *Id.*

Only respondents who answered yes to Q3 were permitted to go on to answer the remaining questions. Respondents who answered "No" or "Don't know/Unsure" were brought directly to the end of the survey where they were thanked for their time and told that they had completed the survey. *Id.* ¶ 38. For the remaining respondents, the fourth question asked: "What does the webpage communicate about whether or not the FDA has reviewed Tru Niagen for effectiveness?" (Q4), and respondents were given the option of providing an answer in a blank text box or selecting "Don't know/Unsure." *Id.* ¶ 39. The next question asked respondents to select one of four propositions, indicating whether they believed "[b]ased on the webpage" that:

- The FDA has reviewed the Tru Niagen product for effectiveness
- The FDA has not reviewed the Tru Niagen product for effectiveness
- No opinion
- Don't know/Unsure

(Q5). Once again, the first two response options were rotated to avoid any potential response bias. *Id.* ¶ 40.

Respondents who responded that the FDA had reviewed the Tru Niagen product for effectiveness were then asked: "You previously mentioned that, based on the webpage, you believe that the FDA has reviewed the Tru Niagen product for effectiveness. What do you believe effectiveness means in this context?" (Q6). *Id.* ¶ 41.

Sowers concluded that a net of 23.3% of respondents—after subtracting the percentage of respondents in the control group who took away the same belief—took away from the stimulus the belief that the FDA had reviewed Tru Niagen for effectiveness. *Id.* ¶ 11. Sowers also concluded: "[B]ecause testing the Tru Niagen homepage was a conservative approach, the survey results suggest that consumers are also likely to be deceived by other Tru Niagen advertising that more overtly communicates FDA review and approval." *Id.* ¶ 12c.

2. The Isaacson Report

ChromaDex's expert is Bruce Isaacson ("Isaacson"). Isaacson is President of MMR Strategy Group, a marketing research and consulting firm. Dkt. No. 205-3 ("Isaacson Report") ¶ 20. He has designed, conducted, and analyzed many hundreds of research studies over the course of his career and has provided expert testimony in numerous matters, including in cases in federal and state court, before the Trademark Trial and Appeal Board, and in many other venues and before other authorities. *Id.* ¶ 21.

Isaacson's survey tested four sets of marketplace communications from Elysium: (1) the homepage of Elysium as it appeared in February 2019; (2) a video posted on Elysium's Facebook page on May 14, 2019 that stated, among other things, "Inside this bottle is 25 years of research"; (3) a statement from Elysium's 2017 homepage and mission page that states, "We conduct rigorous safety studies for a new dietary ingredient (NDI) submission to the FDA"; and

(4) a post on a social media website that displays a jar of Basis and states, "Basis is clinically proven to increase NAD+ levels, which decline with age." *Id.* ¶ 4. The statements that he tested were: (1) "Clinical trials have demonstrated that the supplement described on the webpage is safe" (asked of respondents shown the 2019 homepage); (2) "The company described on the Facebook page with the video conducted 25 years of research on aging" (asked of respondents shown the Facebook Page and Video); (3) "The company described on the webpage demonstrated their supplement's safety by submitting a new dietary ingredient (NDI) notification to the FDA" (asked of respondents shown the 2017 homepage and mission page); and (4) "The supplement described on the webpage is clinically proven to slow the effects of aging." *Id.*

In broad form, Isaacson's methodology tracks that of Sowers. Isaacson defines a universe of respondents to be surveyed, identifies respondents who fit the profile, and then surveys them after displaying the message, using a control group to eliminate noise. Isaacson's population, however, differs from Sowers, as does the way he used his control group and the form of the questions he used in the survey. Isaacson's survey defines the population to be surveyed as persons who purchased in the past twelve months, or were likely to purchase in the next twelve months, dietary supplements to improve cellular health, provide energy, increase endurance, and/or promote healthy aging. *Id.* ¶ 11. Those criteria were used to locate and recruit prospective respondents through an online panel provided by Prodege Market Research. *Id.* ¶ 63. Like Sowers, Isaacson screened prospective respondents on criteria such as whether they had participated in more than one survey about dietary supplements in the past three months, whether they worked for certain types of companies where they could have gained unusual knowledge, and whether they would take the survey on a desktop computer, laptop computer, or tablet and—for those who were surveyed about questions on Facebook page and video—whether they had

visited Facebook in the prior three months, so that only those who answered affirmatively to this question were queried on the materials on Facebook page and video. *Id.* ¶¶ 35–37. Respondents who were shown the 2017 homepage and mission page were instructed to look at the webpage as the respondent normally would if he or she came across it while online; respondents who were shown the Facebook page and video were shown the video three times before they were asked if they wanted to view it again. *Id.*

Respondents were randomly assigned to one of two separate groups: a group shown the test materials and a group shown a set of control materials that were altered to remove or modify the text disputed by ChromaDex as follows:

Materials	Test Materials	Control Materials
2019 Homepage	**Clinical Trial Results Published** Our scientific article presenting the results of our study on the safety and efficacy of Basis was published in *Nature Partner Journals: Aging and Mechanisms of Disease*, a peer-reviewed journal covering the world's most important research in the fields of aging.	**Research Results Published** Our article presenting the results of our study was published in *Nature Partner Journals: Aging and Mechanisms of Disease*, a peer-reviewed journal covering important research in the fields of aging.
Facebook Page and Video	Inside this bottle is 25 years of research.	Inside this bottle is years of research, that was conducted by us and others.
2017 Homepage and Mission Page	**FDA NDI Submission** We conduct rigorous safety studies for a new dietary ingredient (NDI) submission to the FDA.	**FDA NDI Submission** We are conducting rigorous safety studies for a new dietary ingredient (NDI) submission to the FDA. (We have not yet submitted an NDI to the FDA.)
Post	**Try Basis.** Basis is clinically proven to increase NAD+ levels, which decline with age.	**Try Basis.** Basis may increase NAD+ levels, which decline with age.

Id. ¶¶ 9–10.

For each set of stimulus materials, Isaacson's first two questions were virtually identical to Sowers' first two questions. Respondents were first asked: "What are the main messages communicated or implied by the [material] that you just viewed? If you don't know, please select the box labeled 'I don't know.'" *Id.* ¶ 49. If a respondent gave an answer other than "I don't know" to the first question, that respondent was asked a second question: "What other messages, if any, does the [material] communicate or imply? If you don't know, please select the box labeled 'I don't know.'" *Id.* ¶ 50. After the first two questions, the form of Isaacson's questions differed from Sowers' questions. While Sowers asked respondents in an open-ended fashion whether the stimulus communicated anything about a particular subject (e.g., whether the stimulus conveyed anything about safety), Isaacson's survey asked a more leading question by framing a particular proposition or statement (e.g., that clinical trials demonstrated that the supplement was safe) and asking whether the communication at issue communicated or implied that statement. *See id.* ¶ 51. For each statement, respondents were given the option to answer "Yes, the [material] does communicate or imply this statement," "No, the [material] does not communicate or imply this statement," or "I don't know." Certain of the statements related to those alleged by ChromaDex to be false and misleading in this case; others were "distractor" statements. *Id.* In total, the third question asked each respondent about three or four statements, including one test statement and two or three distractor statements. *Id.* ¶¶ 52–53.

The fourth and fifth questions asked about the materiality of the messages and were asked only of the respondents shown the test materials. *Id.* ¶ 54. They were not asked of the control group. *Id.* The fourth question asked, "If you learned that the statement below is not true, would that change your likelihood of purchasing this supplement?" and gave one of three options for an answer: "Yes, it would change my likelihood of purchasing this supplement," "No, it would not

change my likelihood of purchasing this supplement," or "I don't know." *Id.* ¶¶ 54–56. Respondents who answered with a "yes," were then asked a fifth question: "You indicated that if you learned that the statement below is not true, that it would change your likelihood of purchasing this supplement. If you learned that the statement below is not true, would you be more likely or less likely to purchase the supplement shown in the [material], or you don't know?" *Id.* ¶ 57. Respondents could give one of three answers: "I would be more likely to purchase this supplement," "I would be less likely to purchase this supplement," or "I don't know." *Id.* ¶ 58. Once again, "more likely" was rotated at random with "less likely." *Id.* ¶ 57 n.34. Respondents who were asked about the test statement in the fourth and fifth questions were also asked about two additional statements including "The supplement described on the [material] is available in a white container" and "The supplement described on the [material] is also sold in Canada" which were intended as control statements.[1] *Id.* ¶¶ 55, 61.

Each set of materials was viewed by between 102 and 110 respondents. *Id.* ¶ 66. After adjusting for the controls, Isaacson concludes: (1) a net percentage of 13% of the respondents who were shown the test 2019 homepage believed that it communicated or implied that clinical trials had demonstrated that Elysium's product was safe; (2) a net percentage of 38.9% of the respondents believed that the test Facebook page and video communicated or implied that the company conducted twenty-five years of research on aging; (3) a net percentage of 21.9% of the respondents who were shown the test 2017 homepage and mission page believed that it communicated or implied that Elysium submitted an NDI to the FDA; and (4) a net percentage of

[1] According to Isaacson, these statements are not likely to make a respondent less likely to purchase the supplement and thus are intended to tease out from the survey results those respondents who simply answer reactively yes to a question whether the falsity of that proposition would make them less likely to purchase the product.

32.4% of the respondents who were shown the test post believed that it communicated or implied that Elysium's product was clinically proven to slow the effects of aging. *Id.* ¶ 18(i). He also concluded that, in response to the fourth question, a substantial percentage of respondents answered that, if they learned that certain statements containing disputed text were not true, it would change their likelihood of purchasing the supplement and that, based on the answers to the fifth question, a substantial percentage of those respondents whose decision to purchase the supplement would likely be affected by the falsity of a certain statement and would be less likely to purchase the supplement. *Id.* ¶ 18(ii)–(iii).

C. Analysis

1. Admissibility of the Sowers Report

Elysium has satisfied its burden to show that the Sowers survey is admissible.[2] As a general matter, the survey follows generally accepted principles of survey research, as set forth in the Federal Judicial Center's Manual for Complex Litigation, "Reference Guide on Survey Research." It identifies an appropriate population and queries that population in an objective and clear-to-understand manner that does not suggest to the respondent the answer that the respondent should give; it also contains an appropriate control group. As to the survey design, it employs well-accepted techniques in moving from the general to the specific. *Reference Guide on Survey Research* at 395–96 ("As a rule, . . . surveys are less likely to be subject to order effects if the questions move from the general . . . to the specific.") Moreover, the questions themselves do not suggest the answers; they were worded neutrally to avoid directional

[2] Although the survey is not excluded on *Daubert* and Rule 702 grounds, in an accompanying Opinion and Order the Court has rejected Elysium's challenges to ChromaDex's statements that do no more than convey the FDA status of ChromaDex's products. As such, the survey is no longer relevant to any remaining question in the case and is therefore excluded on Rule 403 grounds.

language. *See id.* at 388–91. Respondents also were told not to guess, and each question included explicit "Don't know/Unsure" and "No opinion" response answers. "By signaling to the respondent that it [wa]s appropriate not to have an opinion, the question reduce[d] the demand for an answer and, as a result, the inclination to hazard a guess just to comply." *Id.* at 390.

ChromaDex's arguments provide insufficient bases to exclude the Sowers Report. ChromaDex moves to exclude Sowers' opinions under *Daubert* and Federal Rules of Evidence 104, 401, 402, 403, 702, and 704 on the following grounds: (1) the questions were biased and lacked objectivity because Sowers did not analyze the responses to the open-ended (non-leading) questions in his survey and asked the closed-ended leading questions that mentioned "effectiveness" eight times and "FDA" seven times even to those persons who did not identify the FDA and effectiveness in their responses to the open-ended questions about what messages they took away from the tested statement; (2) the survey used an inappropriate population; and (3) it employed the current homepage, which was the wrong stimulus. The Court addresses each of these in turn.

First, ChromaDex argues that Sowers should not have proceeded to ask respondents directly whether they believed the FDA had reviewed Tru Niagen for effectiveness after none of the respondents identified that as the "main" message conveyed by the webpage or thought to mention it as another message that was conveyed by the webpage. "The advantage of open-ended questions is that they give the respondent fewer hints about expected or preferred answers." *Reference Guide on Survey Research* at 392. "Open-ended questions are more appropriate when the survey is attempting to gauge what come first to a respondent's mind." *Id.* at 394. But the object of Sowers' survey was not just to determine the message that came

immediately to the respondents' mind but also to understand whether, even if it did not come immediately to mind, the respondent would have taken away a misleading impression from the stimulus. Elysium has shown that the survey adequately tested for that question. In particular, a closed-ended question may "remind respondents of options that they would not otherwise consider or which simply do not come to mind as easily." *Id.* at 392. There is no *a priori* rule that a survey may only ask open-ended questions or may ask closed-ended questions only if a sufficient number of respondents mention the proposition to be tested in response to an open-ended question. "[T]he value of any open-ended or closed-ended question depends on the information it conveys in the question and, in the case of a closed-ended question, in the choices provided." *Id.* at 394. Thus, "[a]n open-ended question presents the respondents with a free-recall task, whereas a closed-ended question is a recognition task." *Id.* at 392 n.148. Sowers did not suggest the answer to the question whether the website conveyed the message that the FDA had reviewed Tru Niagen for safety; he simply asked the question whether, if the respondent had not previously thought about the issue, the website did convey a message on that subject and what that message was. In the choices provided, he left the respondent the option of saying that the website did not convey a message at all or that the respondent did not know.[3] "The probative value of any given survey is a fact specific question that is uniquely contextual. While certain types of survey questions may be appropriate to discern the message of one advertisement, they may be completely inapposite with regard to another." *Johnson & Johnson * Merck Consumer Pharmaceuticals Co. v. Smithkline Beecham Corp.*, 960 F.2d 294, 300–01 (2d Cir. 1992). It is

[3] In any event, ChromaDex may cross-examine Sowers on whether any respondent volunteered the FDA safety connection without being prompted and whether the failure of any respondent so to mention it decreased the saliency or the force of the message.

the role of the finder of fact to "weigh the evidence, and in particular the opinion research." *Id.* (quoting *Am. Home Prods. Corp. v. Johnson & Johnson*, 577 F.2d 160, 167 (2d Cir. 1978)).

ChromaDex's next attack—that the survey repeatedly mentioned the FDA and effectiveness—is misleading. The first two survey questions did not mention the FDA or effectiveness at all. The third survey question mentioned the terms, but it did so no more than necessary to ask the question whether the webpage communicated anything about whether or not the FDA had reviewed Tru Niagen for effectiveness and to ensure that the respondents would have a clear choice among answers. It was only if and after the respondent answered Q3 in the affirmative that the respondent was directed to the additional questions that used "effectiveness" and "FDA," and those questions too used the terms no more than necessary to convey the query clearly, directly, and impartially. The option to select "Don't know/unsure" ensured that each survey question was not overly suggestive. Indeed, ChromaDex has not suggested how Sowers should have asked his questions other than exactly how he asked them.

Next, although ChromaDex argues that Sowers tested the wrong universe, its challenge presents the paradigmatic jury issue. It does not provide a basis for excluding the survey from the jury. Sowers defined the appropriate population as consumers looking to purchase products supporting cellular health. ChromaDex's expert would have defined the population as persons who purchased in the past twelve months, or were likely to purchase in the next twelve months, dietary supplements to improve cellular health, provide energy, increase endurance, and/or promote healthy aging. Dkt. No. 201-3 ¶ 11. ChromaDex argues that Sowers' population was both overinclusive and underinclusive. It was overinclusive in that it included products and was not limited to supplements. It was underinclusive because it limited qualified respondents to those seeking products to support cellular health.

Numerous courts have held, however, that within bounds, questions regarding the appropriate universe to be surveyed goes to the weight of the evidence and not to its admissibility. *WIZKIDS/NECA*, 2019 WL 1454666, at *13 ("Although these arguments are not without merit, they again simply diminish the weight of the survey evidence rather than provide grounds for its exclusion"); *Playtex Prods.*, 2003 WL 21242769, at *2 ("[T]he Second Circuit clarified in *Schering* that any methodological deficiencies in a survey properly relate to the weight afforded to the survey's conclusions rather than its admissibility, subject of, of course, to a Rule 403 relevancy analysis."); *Friesland Brands*, 221 F. Supp. 2d at 459 ("The Second Circuit in *Schering* made clear that such a survey's 'errors in methodology . . . properly go only to the *weight* of the evidence'—not to its admissibility." (omission in original) (quoting *Schering*, 189 F.3d at 228)); *Caché*, 2001 WL 38283, at *6; *see also, e.g.*, *Rise-N-Shine, LLC v. Duner-Fenter*, 2015 WL 876470, at *3 (S.D.N. Y. Feb. 28, 2015) (finding arguments that universe of respondents was defined incorrectly in consumer survey "d[id] not rise to the level of destroying all relevance, and thus . . . any flaws bear exclusively on the weight of the results rather than their admissibility"); *Coty Inc. v. Excell Brands*, LLC, 277 F. Supp. 3d 425, 451–52 (S.D.N.Y. 2017) (failure to exclude "higher-end" consumers affected weight to be given survey results but did not "strip them of probative value"). Sowers' selection of the appropriate universe, if it is flawed at all, is not so flawed in methodology that its probative value is substantially outweighed by its prejudicial effect. *See Schering*, 189 F.3d at 228; *Starter Corp. v. Converse, Inc.*, 170 F.3d 286, 297 (2d Cir. 1999); *Arche, Inc. v. Azaleia, U.S.A., Inc.*, 882 F. Supp. 334, 336 (S.D.N.Y. 1995); *see also* Fed. R. Evid. 403.

Finally, ChromaDex argues that Sowers' report should be excluded because he used the wrong stimulus. He tested the current ChromaDex webpage for Tru Niagen rather than the

historical webpage referenced in the complaint. As Sowers explained, however, the choice of the current webpage is, if anything, conservative. Although it mentions that there are "3 FDA Safety Notifications" and contains language "reviewed and accepted by . . . US FDA," ChromaDex's other advertising contained more explicit language and more overt references suggesting that the FDA reviewed Tru Niagen for effectiveness. Dkt. No. 201-5 at 42.

Accordingly, ChromaDex's motion to exclude Sowers' expert testimony is denied.

2. Admissibility of the Isaacson Report

Elysium moves to exclude two portions of the Isaacson Report.

a. Isaacson's Conclusions

First, Elysium moves to exclude the conclusions expressed in paragraphs 18 and 129 of the Isaacson Report as irrelevant. Those conclusions relate both to the deception portion of the survey—that tests whether the challenged statements deceive consumers into believing a particular allegedly false message about Basis—and the materiality portion of the survey—that tests whether the challenged statements are material, meaning likely to influence consumers' purchasing decisions. In paragraph 18, Isaacson concludes:

- "In response to Question 3, a substantial percentage of respondents indicated that the materials they were shown communicate or imply certain messages." Isaacson Report, ¶ 18(i).
- "In response to Question 4, a substantial percentage of respondents answered that, if they learned that certain statements containing disputed text were not true, it would change their likelihood of purchasing the supplement." *Id.* ¶ 18(ii).
- "In response to Question 5, a substantial percentage of respondents answered that, if they learned that certain statements containing disputed text were not true, they would be less likely to purchase the supplement." *Id.* ¶ 18(iii).

In paragraph 129, Isaacson states: "Based on the results from my survey, I conclude that:"

- "A substantial percentage of respondents indicated that the materials they were shown communicates or implies certain messages." *Id.* ¶ 129(i).

- "A substantial percentage of respondents answered that, if they learned that a certain statement is not true, it would change their likelihood of purchasing the supplement." *Id.* ¶ 129(ii).

- "A substantial percentage of respondents answered that, if they learned that a certain statement is not true, they would be less likely to purchase the supplement." *Id.* ¶ 129(iii).

Various subsections of paragraph 18 and the entire paragraph 130 of the report provide specific response percentages for each of the challenged statements and each of the questions but offer no opinions as to whether those specific percentages are substantial. *Id.* ¶¶ 18(i)(a)–(d), 18(ii)(a)–(d), 18(iii)(a)–(d), 130.

At deposition, Isaacson was asked about his conclusion that "a substantial percentage of respondents indicated that the materials they were shown communicate or imply certain messages" and was asked to what specific messages that conclusion related. His testimony made clear that his opinion was based on the cumulative results of the responses of respondents to all of the statements and that he was not expressing an opinion about the portion of respondents who reacted to any specific message. He testified:

> Q. Which specific messages did a substantial percentage of respondents indicate that the materials they were shown communicated or implied?
>
> . . .
>
> A. Yeah, so I haven't – as you pointed out in 29 [sic], Roman number I, I haven't indicated which specific messages the measures were substantial for and which specific messages the measures were not substantial for, and I'll leave that to the Court to evaluate.
>
> Q. Well, I need to understand what your opinion is, sir.
>
> You said: "A substantial percentage of respondents indicated that the materials they were shown communicates or implies certain messages."
>
> I want to know which messages in your expert opinion do you believe a substantial percentage of respondents indicated that the messages they were shown communicated or implied.

> A. And I haven't provided an opinion on that in the report, and I'll leave that to the Court to evaluate.
>
> Q. So you will offer no opinion in this case as to what message that consumers – substantial percentage of respondents indicated that they materials they were shown communicate or imply?
>
> A. I haven't offered an opinion in my report on which of these specific measures are substantial and which of these specific measures are not, and I'm going to stay – I'm going to maintain that position.

Dkt. No. 205, Ex. D, at 24–25. Isaacson's further testimony explains that the same is true for all of his conclusions about substantial percentages in his report:

> A. I haven't provided any opinions about individual percentages relating to specific measures from the survey. I have provided an opinion about the measures from the survey as a whole.
>
> Q. So if I go through each of the percentages listed on paragraph 130, would your answer be the same, and asked you if they were a substantial percentage, would your answer be the same?
>
> A. My answer would be that I haven't provided an opinion about any of the specific numbers – any of the individual numbers from the survey and I'm relying on my experience and some rule of thumb to evaluate the numbers as a whole.

Id. at 30.

Isaacson's survey relates to two questions at issue in this case: (1) whether specific challenged statements were misleading to consumers; and (2) whether specific challenged statements were material to consumers, meaning likely to influence their purchasing decisions. There is no reason why either of these questions should be analyzed in the aggregate. There is no claim that Elysium combined each of the statements in a single advertisement or promotion or that any consumer would have seen the statements all together. The statements were made at different times and on different platforms. For each specific category of challenged statements—i.e., statements allegedly conveying that Basis is safe; statements allegedly conveying that Elysium conducted twenty-five years of research on aging; statements allegedly conveying that

Elysium submitted an NDI notification to the FDA; and statements allegedly conveying that Basis is clinically proven to raise NAD+ levels—to be actionable under the Lanham Act, that category must individually be both false and material, not false and material when viewed as part of a broad advertising campaign consisting of many unrelated types of statements, some of which may be false or material and some of which may not. That the results for all four statements when added together reflect that a substantial percentage of respondents believed the materials they were shown communicated a certain message or that they would be less likely to purchase the supplement if they learned that a certain statement was not true says nothing about whether, with respect to any one of the four messages at issue, a substantial percentage of the respondents who were exposed to that statement would take away the allegedly false message or would be moved in their purchasing decisions by the truth or falsity of that message.

ChromaDex argues that Isaacson "offered his opinions 'as a whole' because the items he tested are 'representative of a series of marketplace communications' and 'ChromaDex maintains that the other marketplace communications from Elysium contain the same or substantially similar messages.'" Dkt. No. 283 at 8 (citing Isaacson Report ¶ 4). That the tested communications are each representative of a series of marketplace communications reflecting the same or substantially similar messages may explain why a conclusion about one of the specific statements could extend to similar statements that were not tested but convey the same message; however, the four tested statements do not themselves "contain the same or substantially similar messages." In fact, Isaacson's survey methodology is incompatible with a belief that the four statements "contain the same or substantially similar messages"; for each of the challenged statements, his survey asked *different* questions of respondents as to whether they took away a specific belief from that statement. Isaacson Report ¶ 13. Respondents who viewed one

challenged statement were asked whether it communicated or implied that Basis is safe; respondents who viewed another were asked whether it communicated or implied that Elysium conducted twenty-five years of research on aging; respondents who viewed the third were asked whether it communicated or implied that Elysium had submitted a NDI notification to the FDA; and respondents who viewed the last challenged statement were asked whether it communicates or implies that Basis is clinically proven to slow the effects of aging. *Id.* The survey does not contend that each of the challenged statements communicated or implied the same or a substantially similar message; each is representative of a different category of statements that ChromaDex challenges under the Lanham Act. As such, Isaacson's opinions about the results of the survey "as a whole," for all of the challenged statements collectively, as opposed to for each category individually, are not helpful in assisting the factfinder to determine whether any category of tested statements is deceptive or is material, and they therefore are inadmissible.

ChromaDex's citation to the district court's opinion in *Church & Dwight* for the proposition that "it was reasonable to infer that *every* consumer who bought the competing product was exposed to at least part of the competitor's marketing campaign because the parties were direct competitors and the other side presented no persuasive evidence that some subset of consumers was unaffected by the false advertising" is unavailing. Dkt. No. 283 at 9 (citing *Church & Dwight Co., Inc. v. SPD Swiss Precision Diagnostics GMBH*, 2018 WL 4253181, at *6 (S.D.N.Y. Sept. 5, 2018)). Even if such an inference were reasonable here, it would not save Isaacson's conclusions—even if every consumer was affected by *some part* of Elysium's challenged advertising, that does not mean that every consumer was affected by *every part* of Elysium's advertising or Elysium's entire advertising campaign as a whole and thus does not mean deception and materiality can be properly determined for all of that advertising as a whole.

It certainly would be unreasonable to infer that every consumer was affected by *all* of Elysium's challenged advertising, and Isaacson himself disclaims that theory—"I'm not suggesting when I say 'aggregation' that the effect is accumulative, in that a consumer would see all four of these. I haven't provided an opinion that it – and my measures don't depend on a consumer seeing more than one of the sets of materials that were tested in my survey." Dkt. No. 205, Ex. D, at 182.

Finally, ChromaDex argues that Elysium's challenge is "a red herring" because "all the resulting percentages with respect to each of the tested materials and respective messages are listed in paragraphs 18 and 130 of the Isaacson Report (and supported by extensive data)." Dkt. No. 283 at 9. Elysium's challenge is only to "the conclusions" drawn in paragraphs 18 and 129—that the percentages were "substantial"—not to the individual percentages, devoid of any conclusions about whether or not those individual results are substantial. Isaacson's conclusions, which relate only to the survey results as to all of the challenged statements as a whole, are excluded.

b. Materiality Survey

Elysium also challenges the entirety of Isaacson's materiality survey, the results of which are described in paragraphs 18(ii)–(iii), 99–120, and 121–130 of his report. Elysium argues the materiality survey contains many methodological flaws that collectively render it unreliable. It concedes that challenges to survey methodology typically go to the weight of the survey rather than its admissibility but argues that the "cumulative effect" of these flaws renders the entire survey unreliable and requires exclusion. Dkt. No. 208 at 21; *see also Malletier v. Dooney & Bourke, Inc.*, 525 F. Supp. 2d 558, 563 (S.D.N.Y. 2007) ("While errors in a survey's methodology usually go to the weight accorded to the conclusions rather than its admissibility, the Second Circuit has made clear that this is 'subject, of course, to Rule 403's more general prohibition against evidence that is less probative than prejudicial or confusing.' Although it is

the exception, 'there will be occasions when the proffered survey is so flawed as to be completely unhelpful to the trier of fact' and 'its probative value is substantially outweighed by its prejudicial effect.'" (first quoting *Schering*, 189 F.3d at 228; and then quoting *Trouble v. Wet Seal, Inc.*, 179 F. Supp. 2d 291, 307 (S.D.N.Y. 2001))). The flaws Elysium identifies fit into five broad categories: (1) the survey asked leading questions; (2) the survey utilized improper controls; (3) the survey questions were vague; (4) the survey tested an improper universe of respondents; and (5) the survey data is contradictory and does not support Isaacson's conclusions. The Court considers each category of flaws in turn.

i. Leading Questions

Elysium first challenges the survey questions—and the design thereof—as biased and leading and as creating "demand effects," meaning that the language of the questions signaled to respondents how the survey sponsor wanted them to answer, causing respondents to give what they perceived as the "correct" answer. It highlights that the materiality questions, which asked respondents whether learning that a particular message was untrue would impact their purchasing decisions, were asked only after the deception questions, which asked respondents whether the statement conveyed that message. It argues that this sequence effectively drew the respondents' attention to a message that—in the absence of the first question—the respondent may not have otherwise noticed or focused upon. This sequence, Elysium argues, led respondents to the "correct" answer—that the thing they were asked to notice mattered. Elysium further argues that respondents were led to the "correct" answer because the materiality portion of the survey, which came after the deception portion of the survey, utilized different controls than the deception portion did, such that a respondent could recognize that the statement remaining consistent between the two sections—the challenged statement—was the statement being tested. In other words, respondents were able to recognize, when they got to the materiality portion of the

survey, which was the test message and which was the control and could therefore deduce that the "correct" answer was that learning that the test message was untrue would affect their purchasing decisions.

Elysium's two arguments that the survey design led respondents to the "correct" answer suffer from the same flaw. It is true that a properly conducted survey should minimize demand effects. *Cf.* 6 McCarthy on Trademarks and Unfair Competition § 32:172 (5th ed. 2021) ("*The Need to Minimize Demand Effects.* 'Demand Effects' in a survey are produced when respondents use cues from the survey procedures and questions to infer the purpose of the survey and identify the 'correct' answers. As professors Simonson & Kivetz remark: 'The respondents may then provide what they perceive as the correct or expected answers, to make sure that the results "come out right."'"). However, while both features of the survey design Elysium identifies—first, that the deception questions focused the respondents on a particular message and second, that the varying controls between the deception portion of the survey and that the materiality portion of the survey allowed respondents to identify the statement being tested and the statement that was a control—did enable an attentive respondent to deduce *what* the survey was testing, they did not provide a respondent with any cues regarding what the "correct" answer was.[4] A respondent might know that the survey sought to test the materiality of the specific message asked about, rather than any other message the statement could be interpreted to convey, but that does not tell the respondent whether the survey's purpose was to demonstrate that the message was material or that it was not material. He or she might know what the question was directed to, but not what the "correct" answer to that question was. Similarly, a

[4] While the fact that the deception questions focused the respondents on a particular message does not lead the respondents to the "correct" answer to the materiality questions, it does raise a different potential flaw with the survey—focalism—which is addressed below.

respondent might know that the survey sought to test the materiality of the challenged statement rather than the controls, but that does not tell the respondent whether the survey's purpose was to demonstrate that the challenged statement was material or that it was not material.[5] Thus, the survey's cues did not create any "demand effect" with respect to the question whether a particular message would affect a respondent's purchasing decisions—the respondents did not know what the survey sponsor wanted to hear and what the survey sought to demonstrate and thus were not more likely to provide that response.

Elysium identifies a separate problem with the sequence of questioning that has greater merit: Respondents were asked about materiality only after they were asked questions about deception that drew their attention to a particular message conveyed by the statement, causing "focalism." Elysium explains that focalism is "a phenomenon that causes consumers to pay more attention to a product attribute than they would during the purchasing process and, thus, increases the relative subjective value they place on that attribute." Dkt. No. 208 at 22. Elysium argues that the sequence of questioning drew the respondents' attention to a particular message conveyed by the challenge statement, thereby increasing the value respondents placed on that message and making them more likely to indicate that the message mattered to them. This argument does raise a potential flaw with the survey.

ChromaDex responds that the sequence of questioning utilized, far from being improper, is actually an element of a well-designed survey. It asserts that the question that asks respondents if they believe a statement conveys a specific message operates as a "filter question

[5] That the respondents could deduce which messages were controls might lead to a different flaw—it might have caused such respondents to disregard the controls entirely and to not take the questions asked about them seriously, thus minimizing the effectiveness of the controls. Elysium does not articulate this flaw in its *Daubert* motion; regardless, this flaw goes only to the weight of the survey's conclusions and not its admissibility.

designed to remove respondents who did not notice the messages being asked about in Questions 4 and 5 of the survey." Dkt. No. 283 at 11. Without the question, "respondents who did not notice the message and therefore have no opinion about it would be asked questions about that message and might either guess or provide a biased response." *Id.* ChromaDex's response, while true, does not fully address Elysium's argument. The problem with Isaacson's survey design was that the language and sequence of his questions may have amplified the importance of the message that the survey questions highlighted in the respondents' minds. Thus, while it may be true that the question asking respondents if they believe a statement conveys a specific message does operate as a filter question for the materiality survey, removing respondents who do not believe that message is conveyed at all, that does not meet Elysium's point. The question may have served as a filter. However, it could also have had the effect that Elysium identifies—of drawing the respondents' attention to a particular message such that the message took on disproportionate significance in their minds.

Survey questions that may lead to such results could conceivably be corrected with proper controls. However, as the Court addresses below, Isaacson's controls do not address this potential flaw.

ii. Improper Controls

The second category of flaws Elysium identifies relates to the survey controls. Elysium identifies two perceived flaws with regard to the survey controls. First, it argues that the controls were flawed because "they were innocuous statements—things consumers were *not* likely to care about." Dkt. No. 208 at 23. It contends that "[t]his caused an artificially inflated net percentage, because respondents were more likely to respond that they would change their purchasing decisions as to the Challenged Statements than they would as to the control statements." *Id.* at 23–24. This challenge misunderstands the purpose of the control group in the experiment.

"In designing a survey-experiment, the expert should select a stimulus for the control group that shares as many characteristics with the experimental stimulus as possible, with the key exception of the characteristic whose influence is being assessed. . . . Nor should the control stimulus share with the experimental stimulus the feature whose impact is being assessed." *Reference Guide on Survey Research* at 399. In Isaacson's survey, the characteristic whose influence is being assessed is the nature of the messages—the purpose of the survey was to test whether those messages are material or whether they are "innocuous statements—things consumers were *not* likely to care about." Dkt. No. 208 at 23.

In this respect, the controls thus properly put before the respondents an innocuous message about the product and asked whether learning that message was not true would have made a difference in the respondents' purchasing decisions. The controls effectively identified and removed from the survey results the portion of respondents who would reflexively answer that learning the message was false would affect their purchasing decision about any message about the product, no matter how innocuous, due perhaps to background noise, wording of the survey questions, or preexisting beliefs. A respondent who answered that learning the innocuous control statements were untrue would impact their purchasing decisions would likely give the same answer for *any* statement. The answer would not depend on the nature of the particular message being tested. As Isaacson explained at deposition,

> when we get to Question 4, the purpose of a control is to control for false positives. What we're looking for in a control for 4 is something that had you – had you known about it, it wouldn't have been likely to change your likelihood of purchasing. . . . So, in other words, what we're looking to identify in 4 and 5 are false positives, or noise in the survey. And in 4 what I'm looking to identify is, I'm looking to compare the responses for the test measures versus respondents that are not likely to change someone's likelihood of purchasing.

Dkt. No. 205-4 at 49.

Elysium's second challenge to the controls has greater merit. It argues that the controls were flawed because they appeared for the first time only in the materiality portion of the survey: Respondents were asked about the challenged statements twice—in the first portion of the survey when they were asked whether the statement contained a particular message and then again in the materiality portion of the survey when they were asked whether learning that message was false would make a difference in their purchasing decision. By contrast, they were only asked about the control messages in the materiality portion of the survey. In other words, respondents were shown the challenged statements, asked to consider what messages those statements conveyed to them and whether they conveyed a particular message, and then asked whether learning that specific message was untrue would impact their purchasing decisions. In contrast, respondents were shown the control messages and immediately asked whether learning those messages were untrue would impact their purchasing decisions, without the intermediate steps of viewing an advertising statement, being asked whether that statement conveys a particular message, and then being asked materiality questions about that particular message. Respondents were never shown an advertising statement conveying the control message.

Elysium's complaint about the study design is well-founded. A proper control should be as similar to the experimental stimulus as possible, because if there are multiple differences between them, it may be impossible to determine which of those differences caused any disparity between the respondents' reactions to them. Here, there were multiple differences between the control messages and the tested messages. First, the nature of the message was different. This, as discussed above, was not necessarily improper—the purpose of the survey was to test whether the messages conveyed in the challenged statements were material. The difference in the statements weeded out those who would believe that any message was material. However, the

control messages also differed from the tested messages in that they were not the subject of the earlier survey questions, particularly the question which asked the respondents whether they took away a specific message from a challenged statement. As a result, the survey design failed to correct for the potential flaw identified above—that respondents would overweight the significance of what they were earlier asked to notice with regard to the test messages, when no parallel existed with the control messages. It failed to correct for potential "focalism."

The fact that the controls appear only in the materiality portion of the survey leads to another problem. As Elysium explains it, "the control [was] incapable of accounting for the number of respondents who indicated that they would change purchasing behavior only because they felt deceived, rather than because the subject matter of the statement tested was important to them," because as a result of the study design "respondents were less likely to feel deceived when answering the [sic] whether the control statements were likely to impact their purchasing decisions" than when asked the same question about the challenge statements. *Id.* at 23. By the time the survey got around to asking whether learning that a message was untrue would affect a purchasing decision, there was a critical difference between the test message and the control message. The earlier portion of the survey presented an advertising statement to the respondents. It asked them to consider what messages that statement conveyed—in other words, what messages the advertiser was trying to get them, the viewer, to believe—and then asked them to focus on a specific message. Respondents only got to the second portion of the survey if they agreed that the advertising statement conveyed the message that would now be asked about. When the respondents were then asked how they would feel if they learned the messages were untrue, they may have felt deceived, and they may have reacted to that feeling of deception rather than to the nature of the message when answering whether learning that the message was

untrue would have an impact on their purchasing decisions. In contrast, the control messages were presented for the first time in the materiality portion of the survey; respondents were never asked to consider them in the context of advertising statements, nor were they asked to consider whether the advertiser sought to convey those specific messages. The controls thus failed to correct for this second potential flaw in the survey.

The Court is not persuaded that either of these potential flaws *necessarily* affected the survey responses, but the nature of the survey controls renders it impossible to detect whether the results were at least partially attributable to one or both of these, rather than to the element the survey was designed to test—the nature of the statement.

iii. Vague Questions

Next, Elysium challenges the survey questions as overly vague. It argues that the challenged statements being tested contained multiple facts, but respondents were just asked generally: "If you learned that the statement below is not true, would that change your likelihood of purchasing this supplement?" It provides an example:

> [F]or the Facebook Page and Video, the Challenged Statement tested was "The company described in the Facebook page and video conducted 25 years of research on aging." Yet, for those respondents who indicated they would change their purchasing decisions if they learned the statement was untrue, it is not clear why they gave this answer—whether it was because they thought another company did *some* of the research, another company did *all* of the research, there was no research, there was only *20 years* of research, the research did not pertain to aging—because they simply did not like being deceived, or something else entirely. Because ChromaDex is not claiming in this action that the entire statement is deceptive, the survey data cannot be relied upon to identify what, if anything, about the test statements is material to consumer behavior.

Dkt. No. 208 at 24. ChromaDex responds that "[t]he question of why consumers hold a particular belief, or which element of a complex stimulus causes them to hold a particular belief, is not relevant to materiality." Dkt. No. 283 at 14. It contends that the relevant question is

whether a consumer believed that an advertising statement as a whole was important and not the particular reasons why that statement was important.

ChromaDex's response misunderstands the nature of Elysium's concern and the ultimate question the Lanham Act asks: The ultimate question is not whether a particular advertisement would have been important to consumers but whether, when a statement includes several different and independent elements, the portion of the statements which is false was material. An advertisement or promotion can convey numerous different messages—about the product, about the company that is manufacturing it, and about competitors and the like. It does not follow that simply because a statement is false in some insignificant respect that it is untrue in all respects or, more importantly, that a Lanham Act claim lies when the statement is true in all respects that would matter to a consumer. The plaintiff has to prove both that the message is untrue or misleading and that the particular message that is untrue or misleading is material.

The example highlighted by Elysium well illustrates the point. The message "[t]he company described in the Facebook page and video conducted 25 years of research on aging" can be untrue in at least two entirely different ways: (1) the company did not do twenty-five years of research on aging but instead another company did that research; or (2) no one did twenty-five years of research on aging. The two different messages, and two different ways they were false, are entirely different. It could be important to a consumer that someone did twenty-five years of research without it being important that the "company described in the Facebook page and video" was the same company that did that research. The materiality portion of Isaacson's survey did not distinguish among respondents who answered that the untruth of the statement would have made a difference in their purchasing decision because twenty-five years of research was not done and those who answered the same question positively because Elysium

itself had not conducted the twenty-five years of research. The deception portion of Isaacson's survey provides an important contrast. In that portion, the statement tested was, "Inside this bottle is 25 years of research," and the control statement was, "Inside this bottle is 25 years of research, conducted by us and others." It thus sought to pinpoint the particular aspect of the statement that was being tested. The materiality portion of the survey did not do this. It provided no way to accurately measure those consumers who would have thought it important that Elysium did the research from those who would have thought it important that twenty-five years of research was done, regardless of who did it.

iv. Survey Universe

Elysium next argues that with respect to the Facebook page and video and the social media post, the universe of respondents was overinclusive because it included purchasers of dietary supplements for reasons other than healthy aging. As with ChromaDex's challenges to Elysium's survey, these arguments go to weight and not materiality, and are more appropriately evaluated by the trier of fact.

v. Survey Conclusions

Last, Elysium argues that "the survey data does not support Isaacson's conclusions that a 'substantial percentage' of respondents would change their behavior if a statement were untrue." Dkt. No. 208 at 25. The Court has already excluded Isaacson's conclusions on this front; as such, this objection is moot.

vi. Admissibility of the Materiality Survey

Although, as set forth above, while challenges to a survey's methodology ordinarily go to weight and not to admissibility, "the Second Circuit has made clear that this is 'subject, of course, to Rule 403's more general prohibition against evidence that is less probative than prejudicial or confusing.'" *Malletier*, 525 F. Supp. 2d at 563 (quoting *Schering*, 189 F.3d at

228). In this instance, the survey's failure to correct for the potential focalism as well as the fact that survey respondents may have reacted to feeling deceived rather than to the nature of the test messages in considering whether learning those messages were false would affect their purchasing decisions, as well as the survey's vague questions which render it impossible to determine whether the aspect of the message that is alleged to be false itself is material, make the survey "'so flawed as to be completely unhelpful to the trier of fact' and 'its probative value is substantially outweighed by its prejudicial effect.'" *Id.* (quoting *Trouble*, 179 F. Supp. 2d at 307). As such, the materiality portion of the survey is excluded.

II. The Damages Experts

A. General Principles

"[A] plaintiff who establishes false advertising in violation of § 43(a) of the Lanham Act [is] entitled only to such damages as were caused by the violation." *Burndy Corp. v. Teledyne Indus.*, 748 F.2d 767, 771 (2d Cir. 1984). "Although a court may engage in some degree of speculation in computing the *amount* of such damages, particularly when the inability to compute them is attributable to the defendant's wrongdoing, causation must first be established." *Id.* (internal citations omitted). "[I]t is a plaintiff's burden to demonstrate causation between the misleading advertisements and resulting damages." *Dependable Sales & Serv., Inc. v. TrueCar, Inc.*, 311 F. Supp. 3d 653, 656 (S.D.N.Y. 2018). Plaintiff's lost profits "can be calculated by estimating the plaintiff's revenues lost as a result of the unlawful conduct and subtracting any expenses associated with the lost revenues." *Merck Eprova AG v. Brookstone Pharmaceuticals, LLC*, 920 F. Supp. 2d 404, 428 (S.D.N.Y. 2013) (citing *GTFM, Inc. v. Solid Clothing, Inc.*, 215 F. Supp. 2d 273, 305 (S.D.N.Y. 2002)); *cf. Victoria Cruises, Inc. v. Changjiang Cruise Overseas Travel Co.*, 630 F. Supp. 2d 255, 262 (E.D.N.Y. 2008) ("Lost profits are calculated by estimating

the revenue lost due to the infringing conduct and subtracting what it would have cost to generate that revenue.").

B. Background

1. The Gunderson Report

ChromaDex offers Lance Gunderson ("Gunderson") as an expert to provide opinions regarding ChromaDex's damages and "various damages aspects pertaining to this dispute." Dkt. No. 209-1 ("Gunderson Report") ¶ 1. Gunderson is a managing director with Echelon Analytics LLC, a financial consulting firm that provides corporate, individual, and law firm clients with financial analyses of intellectual property and other corporate assets in dispute and non-dispute settings. *Id* ¶ 2. He purports to provide opinions on ChromaDex's damages resulting from the alleged wrongful acts by Elysium, including ChromaDex's lost profits on Tru Niagen if any and ChromaDex's lost profits on Niagen, as well as Elysium's profits on Basis sales.

Gunderson's analysis is simple. He asserts that but for the alleged wrongful acts, Elysium would have made no sales of its Basis product and the Basis product would be removed from the market. He also opines—based on the facts that ChromaDex and Elysium are direct competitors, that the marketing and promotional documents of both companies similarly point out benefits offered by the products at issue, that the companies have obtained "notable" sales of the NR products at issue, and that NR capsule products have gained success, industry recognition, and awards—that if Elysium had not been able to sell Basis, all of the sales it made would instead have been made by ChromaDex, either through sales of Tru Niagen or sales of its Niagen product through authorized resellers. This is because ChromaDex had the capacity (or would have had the capacity) to manufacture the amount of NR necessary to satisfy Elysium's customers. Finally, he asserts that ChromaDex would have earned a profit margin on the sales of Tru Niagen and Niagen equal to the gross profits it historically made on each product for the

period from January 2017 to June 2020 less the incremental operating costs that it would have incurred with the additional sales.

Based on the fact that Elysium's net sales of Basis products from March 2017 to June 2020 totaled approximately $78.3 million, and its sales of bottles of Basis products totaled approximately 1.8 million, Gunderson opines that ChromaDex lost approximately $33.2 million in revenue on its Tru Niagen products and would have sold approximately [redacted] of additional Niagen product for [redacted] in revenue or $4.1 million in profit leading to a total damages figure of $37.3 million. *Id.* at 7–8, 49–52. In the alternative, he concludes that Elysium earned incremental profit of $36.3 million on sales of the Basis products from March 2017 through June 2020. *Id.* at 9, 52–54.

2. The Weir Report

In response to the Gunderson Report, Elysium offers Colin B. Weir ("Weir") as a rebuttal expert witness on damages. Dkt. No. 201-7 ("Weir Report"). Weir is vice president at Economics and Technology, Inc., a research and consulting firm specializing in economics, statistics, regulation, and public policy. *Id.* ¶ 1.

The Weir Report proceeds in two parts. It first challenges the basis for and validity of Gunderson's damages calculations, and it then outlines Weir's own damages calculation derived from his regression analysis. Weir challenges Gunderson's damages calculation because Gunderson does not seek to identify what impact the challenged statements had on Elysium's sales, but rather assumes that but for the challenged statements, Elysium would have made no sales at all, and accordingly reallocates 100% of those sales to ChromaDex and its resellers. *Id.* ¶¶ 16, 20. Weir also opines that Gunderson's calculation (1) fails to analyze how any one of the challenged statements individually affected Elysium's sales or ChromaDex's damages; (2) assumes that all of Elysium's sales were attributable to the challenged statements but fails to

consider: whether all Elysium customers saw those statements or cared about those statements, when those statements occurred (including that Elysium made sales of Basis prior to the challenged statements, such that those sales had to be attributable to something else), and whether any other factor could be driving sales; and (3) implausibly assumes that all of Elysium's sales would otherwise have been made by ChromaDex, opining that ChromaDex would not need to spend any additional advertising money to capture this market, and that every Elysium sale would otherwise have been made by ChromaDex or its resellers rather than accounting for the fact that Elysium customers may not have otherwise purchased such a product or may have purchased other, non-NR products with the same effects.

Weir's own analysis of the impact of the challenged statements is based on a regression analysis, which he defines as "an econometric tool commonly used by economists" and which "identifies and quantifies the relationship between two or more variables, and is used to identify the variation in the so-called 'dependent variable' (such as the sales of Basis) through its relationship with one or more 'independent' or 'explanatory' variables (such as, *e.g.*, a Challenged Statement)." *Id.* ¶ 72. Weir's regression model "use[d] the sales of Basis as the dependent variable, and include[d] as independent variables Elysium's selling expense, advertising and marketing expenses, G&A, pricing, level of competition, the presence of ChromaDex's Tru Niagen in the retail NR market, and each of the Challenged Statements," and "also include[d] a time series variable to control for fixed effects and a month-of-the-year variable to control for any possible seasonality." *Id.* ¶ 82. Weir's report does not provide more information about the model he used. Exhibit 3 to the Weir Report provides Elysium's financial data that Weir used in his model, and Exhibit 4 to the report provides the results of the regression model. Based on these results, Weir opines that "the model shows that in no instance did any of

the Challenged Statements have a positive impact [on] Elysium's sales of basis, and in certain instances, may have had a detrimental impact on Elysium's sales." *Id.* ¶ 83.

At deposition, Weir testified at length about his regression model and the data he input into the model. *See generally* Dkt. No. 201-8 at 49–155. In relevant part, at the outset of this discussion, Weir was asked to explain what a "regression analysis" is, as well as the distinction between a "linear regression" and a "nonlinear regression." *Id.* at 49–50. In response, Weir explained that a "linear regression" is "a model that looks basically at the linear relationship between the underlying variables," whereas a "nonlinear regression" is a model that "would usually involve the transformation of one of more variables into a nonlinear scale, such as a logarithmic scale." *Id.* When asked where his report discloses whether he conducted a linear or a nonlinear regression analysis, he responded that the kind of regression he used is "implied by the description of the variables where instead of saying I used the log of the sales of Basis, it says I used the sales of Basis as the dependent variable. The same thing with the descriptions of the other variables, plus the nature of those other variables in the underlying exhibit as well as the final results shown in Exhibit 4." *Id.* at 50. When asked for more detail as to what in the report indicates that, Weir responded:

> Right, again, I would look very plainly at the description of the variables, which spell out what they are. So sales of Basis as the dependent variable. Independent variables include Elysium's selling expense; advertising and marketing expense; general and administrative, which is an implied expense, and again, referenced in the exhibit; pricing; level of competition; and then the others really aren't variables where there would be linear versus nonlinear conversions. Again, I feel like the descriptions there make plain how the data is being used in the regression.

Id. at 51–52. Weir was asked follow-up questions regarding whether dependent and independent variables could be used in a nonlinear regression; he explained that the question "almost sounds nonsensical," because any regression analysis would require at least one dependent variable and one independent variable. *Id.* He explained that "it is the nature of those variables that would

cause the regression to be linear versus nonlinear," and that one could "look at the description of the variables and see variables that would be listed in a linear fashion" and "understand that it would be a linear regression as opposed to transformations that would take those variables into a nonlinear capacity." *Id.* at 53.

Weir was also asked about his conversations with two Elysium employees, which he included in the list of data he relied upon in his analysis. *Id.* at 125; *see also id.*, Ex. 2 at 2. When asked how he used the "information [from these employees] as part of [his] analysis," Weir explained that they told him that "the majority of Basis customers were purchasing with a subscription and that the typical duration on average would be somewhere in the neighborhood of nine months." *Id.* at 126. Based on this, he explained that "[t]he regression model introduces a lag between . . . the initial presence of the statements and their . . . potential impact in the marketplace of six months reflecting that at any given moment when a statement becomes available in the marketplace a large percentage of existing customers will be already committed to a subscription, which would prevent the statement from having an impact on their purchase decision, if at all, for a period of time." *Id.* at 127. When asked where this lag is disclosed in his report, Weir responded that "it's going to be paragraph 82 which references the challenged statements and, again, my conversations with those two people, which relate to the idea of the subscription model" and added that "it's the combination of the challenged statements, I guess the reference to paragraph 81 with their timeline from the third set of interrogatories, and again, the conversations with those two people." *Id.* at 127–28.

C. Analysis

1. Admissibility of the Gunderson Report

Elysium argues that Gunderson report should be excluded under Rule 702 and *Daubert* because it relies on insufficient facts or data or because it is not the result of the application of a

reliable method. Elysium argues that Gunderson either improperly assumed or assumed without any factual or evidentiary support that: (1) Elysium's alleged misstatements were the cause for every sale of Basis and, absent the alleged unlawful acts, Basis would be removed from the market; (2) every sale of Basis that was made by Elysium would have been made by another company (and that Elysium's sales and marketing of Basis therefore did not grow the market but rather simply stole share from others) and thus is properly apportioned to another party; and (3) each sale of Basis product should be apportioned only to ChromaDex or to a ChromaDex-authorized reseller using Niagen because the only substitutes for Basis would have been a NR capsule and not a product other than a NR capsule.

ChromaDex has not satisfied its burden that Gunderson's damages analysis is reliable. It agrees that the only lost profits it is entitled to as damages are those profits it would have enjoyed in the but-for world in which Elysium had not used the advertisements that it contends are misleading. In his deposition testimony, however, Gunderson admitted that he did not view his engagement or his report as "a true but for analysis." Dkt No. 209-2 at 103. He expressed the mistaken understanding that in a false advertising case the court views damages as "more of a punishment for the . . . wrongful act," *id.*, and that "the Court is attempting to punish the bad act" and do it through "either a . . . lost profits method or a disgorgement method." *Id.* at 103–04. He testified the damages available under the Lanham Act are "to punish the false advertiser" by subjecting the sales sold pursuant to false advertising to either a lost profits or disgorgement theory. *Id.* at 86.

His report thus does not analyze or measure the sales lost by ChromaDex as a result of Elysium's alleged false advertising but assumes those lost sales. He testified that he did not do an analysis of whether ChromaDex's sales of Niagen or Tru Niagen decreased as a result of the

statements at issue in the case. *Id.* at 44. He also did not do any independent analysis on how the allegedly deceptive statements in the case affected Elysium sales, relying instead on Isaacson, who did not analyze the issue. *Id.* at 50. Nor did he do an analysis of how any individual alleged false statement would have affected Elysium sales of Basis. *Id.* at 50. He also did not conduct an analysis of the impact of any particular statement on ChromaDex's damages. *Id.* at 55.

Gunderson's report is plagued with assumptions that are not supported by the evidence. The report assumes that Elysium would not have made any sales of Basis but for the alleged misleading advertisements, but he admitted that Elysium in fact made sales of Basis in 2015 and 2016 before it used any of the statements alleged in this case to be misleading and that he did not look at any of those sales for purposes of his report. *Id.* at 35. He testified that "the critical elements of [Elysium's] marketing do contain the false and misleading statements," and that "the false and misleading advertisements are what were driving the sales of Elysium," *id.* at 46, but he admitted that the statements alleged to be misleading were the only Elysium statements of which he was aware, *id.* at 42, and that not all of Elysium's statements regarding safety and efficacy were false and misleading, *id.* at 70. In other words, he believed that the allegedly false and misleading statements were the critical elements of Elysium's marketing—a belief fundamental to his assumption that all sales of Basis were attributable to those statements—but he looked at none of Elysium's marketing beyond those statements to draw that conclusion. His report assumes that the "very essence" of Basis and "[t]he elements that are critical to the sale of the product" are the alleged false and misleading statements, but the only basis he had for that assumption was "reading through" the report of ChromaDex's expert Bruce Isaacson, *id.* at 47—which does not analyze the essence of Elysium's advertising—and his non-specific "general

experience" having "been involved with cases like this before and been involved in . . . false advertising claims and . . . sales of these types of products," *id.* at 48, or, as he put it elsewhere in the deposition, his "general experience . . . in these types of cases," *id.* at 50. He testified to the belief that "the people that purchased [Basis] were driven to the website based on the false and misleading advertisements," *id.* at 48, but the only support he was able to offer for that proposition was that Elysium spent thirty to forty percent of its revenue on sales and marketing and that Basis is "not a product that . . . kind of sells itself," *id.* at 49. He did not do any analysis of how other advertising by Elysium that is not at issue in the case affected Elysium sales. *Id.* at 69, 74–75. Other than the fact that consumers went to the Elysium website to purchase Basis, he had no reason to believe that any consumers were exposed to any of the alleged false advertising in the case other than what was in the Isaacson Report, which does not address the issue. *Id.* at 60. He assumed "that at the end of the day, Elysium did make false and misleading statements and that those statements were at the heart of their campaign and drove sales of their Basis product," *id.* at 51, but he did not do any analysis to support that assumption. His assumption was that the false and misleading statements permeated Elysium's advertising and his methodology depended on the false and misleading advertising not only being a critical element of Elysium's advertising but also that consumers were exposed to it from March 2017 through June of 2020, but he did not know when any of the statements were made. *Id.* at 63, 65–66.

Gunderson's report further assumes that all of the persons who purchased Basis as a result of Elysium's advertising, would—in the but-for world where there was no Elysium advertising—have purchased Tru Niagen or other Niagen-containing products, but Gunderson also admitted that the market grew as a result of Elysium's advertising and that certain of the customers who purchased Basis would not have purchased any NR-containing product in the

but-for world where there was no Elysium advertising. He failed to make any adjustment for that. *Id.* at 122–23.

Gunderson also assumed that persons who purchased Basis did so because it had NR and they were looking for the benefits of NR; that assumption was not based on fact or analysis but rather on the circular reasoning that customers who purchased Basis necessarily purchased NR. *Id.* at 147–48. Gunderson admitted, however, that there were other benefits of Basis including increased endurance and increased energy. *Id.* at 156. He also admitted that one of the attributes of Basis—as opposed to ChromaDex's products—was that Basis contained pterostilbene ("PT") but admitted that "I didn't really concentrate on PT frankly, so I don't know a lot about the PT market," *id.* at 160, and that, while there are companies that sell PT and consumers who buy PT, he did not "know how many or in what volumes" but he knew that Elysium believed "there's nothing clinically proven there," *id.* at 162.

Dependable Sales, 311 F. Supp. 3d 653, is on point. In that case, the court granted the defendant's *Daubert* motion to exclude expert testimony on damages and causation on the ground that the testimony was not reliable or relevant under Rule 702. The plaintiffs there asserted, as ChromaDex does here, that the defendant's false advertising diverted business from them to the defendant and that they were entitled to damages under the Lanham Act for their lost profits. The expert calculated lost profits damages by assuming that each of the purchases made through the defendant was motivated by the alleged false and misleading advertisement. *Id.* at 659–60. He then allocated each of the defendant's sales to a competing plaintiff who was located within the same geographic area of the defendant. *Id.* at 657. Finally, he multiplied the lost sale by the average net profit for the sale of the product to arrive at a lost profits figure. *Id.* at 658.

The court rejected the analysis under *Daubert* as unreliable. It concluded that the expert's "analysis suffers from the fundamental problem that he fails to support his conclusion that 100% of sales effectuated through [the defendant] were motivated by the allegedly false 'no haggle' claim," noting that the defendant's "advertisements touted multiple other features," and that the expert "did not weigh any of these features." *Id.* at 660. The court also found that the "analysis did not account for the possibility that a consumer might have been influenced by external considerations in deciding to purchase from a [dealer affiliated with the defendant], such as their past interactions with that dealership or the plaintiff dealership, personal recommendations, or non-defendant promotions." *Id.* The court further noted that a study the expert purported to rely upon contradicted his conclusion that 100% of the sales were motivated by the allegedly false claim; the study found that 70% of respondents—not 100%—responded favorably to the message of a negotiation-free way to save money on a new car. *Id.* at 661. The court also faulted the expert for not analyzing sales for the periods of time when the defendant was not making the false advertisement. Those sales showed that the false advertisement did not have a discernible impact on the defendant's sales. *Id.* at 661–62. Finally, the court noted that the plaintiffs' analysis did not account for sales made through channels other than those that used the false advertisement and made unsupported assumptions about where the lost sales would have gone. *Id.* at 662–63.

Gunderson's report and analysis suffer from the same flaws. Gunderson assumed but did not support that Elysium would have lost all of its sales but for the allegedly false and misleading advertising. He also assumed, but did not support, that those sales would have gone to another supplier of Niagen or to Tru Niagen. In the end, then, his report is no more reliable than the report held to be unreliable and therefore inadmissible in *TrueCar*. Other courts have similarly

excluded testimony where an expert assumed, without analysis, that plaintiff would have made every one of defendant's sales. *See Compania Embotelladora Del Pacifico, S.A. v. Pepsi Cola Co.*, 650 F. Supp. 2d 314, 319 (S.D.N.Y. 2009) (excluding expert testimony that "in a 'but for' world," plaintiff "would have made each and every one of [the] sales that were made by bottlers or distributors other than [plaintiff]"); *Am. Home Prod. Corp. v. Johnson & Johnson*, 682 F. Supp. 769, 771 (S.D.N.Y. 1988) (dismissing false advertising claim where theory of injury relied on the "highly questionable premise[]" that a product's entire sales decline "is attributable to false and misleading advertising by" the defendant); *Verisign, Inc. v. XYZ.com LLC*, 848 F.3d 292, 300–01 (4th Cir. 2017) (upholding exclusion of expert testimony where expert's market share allocation "assume[d] rather than demonstrate[d]" that every lost sale was the result of the alleged false advertising).[6]

ChromaDex relies upon the district court decision in *Church & Dwight*, 2018 WL 4253181, at *3, but that case is distinguishable. That case involved "a competitive market in which the parties own[ed] the top two brands; and there is one key distinguishing feature between the [accused] Product and similar test sticks—a feature that was the subject of false advertising directed at both consumers and retailers." *Id.* at *6. Moreover, the defendant "pervasively falsely advertised the Product from its launch, [and] never advertised it in a truthful

[6] Gunderson also provides an alternative disgorgement analysis; however, a Lanham Act plaintiff has no entitlement to disgorgement if it cannot independently demonstrate causation and injury, either through a presumption of injury or evidence of the same. *See Dependable Sales & Services, Inc. v. TrueCar, Inc.*, 394 F. Supp. 3d 368, 372 (S.D.N.Y. 2019) ("[T]he Court concludes that plaintiffs' failure to come forward with evidence of injury precludes their disgorgement claim . . . ."); *see also Salon Fad v. L'Oreal USA, Inc.*, 2011 WL 4089902, at *11 (S.D.N.Y. Sept. 14, 2011) (requiring plaintiffs to demonstrate "generalized link between the defendants' profits from diversion and the injury" to invoke remedy of disgorgement). Because Gunderson's opinions provide no evidence of causation or injury, his disgorgement analysis will only be relevant to the extent that ChromaDex can independently demonstrate those. As the Court holds in an accompanying Opinion and Order, it cannot.

manner." *Id.* at *11. In short, it involved a claim that a single advertisement that was used pervasively from the launch of the accused product to the present was false and misleading, and there was evidence that the advertisement pertained to the key distinguishing feature between the product and its competitors (i.e., its ability to determine the age of a pregnancy using the measure that a doctor would use). This case by contrast involves many advertisements with different themes, none of which ran throughout the launch of the product; there is no evidence that they pertained to the key distinguishing feature between the products or that, indeed, they had salience at all in attracting consumers to Basis. In these circumstances, to permit a jury to render a verdict based on Gunderson's analysis would be—as he himself put it—a "punishment," and it would not be a measure of ChromaDex's damages or lost profits. Elysium's motion to exclude Gunderson's expert testimony is therefore granted.

2. Admissibility of the Weir Report

ChromaDex argues that Weir's opinions should be excluded for three reasons: (1) Weir's report does not disclose the details of his regression model; (2) Weir's regression analysis is based on unreliable data, because he relied upon Elysium's interrogatory responses to identify the time periods when the challenged statements he tested were in the marketplace; and (3) Weir's criticism of Gunderson's "market share allocation analysis" conflicts with settled law accepting such analyses. The Court first considers the two arguments for exclusion of Weir's regression analysis and then turns to the argument for exclusion of Weir's critique of Gunderson's analysis.

c. Admissibility of Weir's Regression Analysis

The Federal Judicial Center's Reference Guide on Multiple Regression provides that:

> In evaluating the admissibility of statistical evidence, courts should consider the following issues:

> 1. Has the expert provided sufficient information to replicate the multiple regression analysis?
> 2. Are the expert's methodological choices reasonable, or are they arbitrary and unjustified?

Daniel L. Rubinfeld, *Reference Guide on Multiple Regression*, *in* Reference Manual on Scientific Evidence 305, 328 (3d ed. 2011). In considering whether statistical evidence at issue—here, Weir's regression analysis—meets this standard, courts consider not only the challenged expert report but also the expert's relevant deposition testimony explaining his report. "Ideally, an expert report would contain every fact, conclusion, and detail of the planned testimony. However, 'section 26(a)(2)(B) does not limit an expert's testimony simply to reading his report. The rule contemplates that the expert will supplement, elaborate upon, explain, and subject himself to cross-examination upon his report.'" *In re Methyl Teriary Butyl Ether (MTBE) Prods. Liability Litig.*, 643 F. Supp. 2d 471, 482 (S.D.N.Y. 2009) (internal alterations omitted) (quoting *Thompson v. Doane Pet Care Co.*, 470 F.3d 1201, 1203 (6th Cir. 2006)).

ChromaDex raises several specific critiques of Weir's disclosure—or, in its view, lack thereof—regarding his regression model. ChromaDex argues that "[o]ther than identifying the independent and dependent variables he claims to have used, Mr. Weir does not disclose any of his methodologies." Dkt. No. 201 at 20. It critiques Weir's report for failing to disclose "the specifications he used for his model, the underlying software or programming used, or a description of how he determined the 'outputs,'" as well as for the failure to disclose some of his inputs, such as the six-month time lag discussed at deposition, and lastly, for the failure to conduct further evaluation of whether independent variables are correlated with each other. *Id.* at 20–21. Elysium responds that "to the extent ChromaDex had questions about the regression analysis in the Weir Report, Mr. Weir answered those questions at his deposition." Dkt. No. 239 at 17. Elysium is correct that, to the extent that Weir's report did not adequately disclose the

form of model he used, his deposition clarified that he used a linear model, and to the extent that Weir's report did not adequately disclose his time-lag input, he disclosed and explained that input at deposition. ChromaDex is left with two outstanding critiques of the Weir's testimony: (1) that he does not disclose what software or programming he used, and (2) that he did not conduct further evaluation of whether independent variables are correlated with each other.

With regard to the first, ChromaDex had the opportunity at deposition to ask Weir what software or programming he used to run his regression model and did not do so. The Reference Guide on Multiple Regression provides that:

> the following suggestions are useful requirements that can substantially improve the discovery process: . . . 2. A party that offers data to be used in statistical work, including multiple regression analysis, should be encouraged to provide the following to the other parties: . . . (d) computer programs that were used to generate the data. . . . The documentation should be sufficiently complete and clear so that the opposing expert can reproduce all of the statistical work.

Reference Guide on Multiple Regression at 330–31. Although Weir's report does not disclose what specific software he used to run his model, his testimony makes clear that he ran a standard linear regression analysis and outlines what inputs he used. Weir provides the variables he tested and the results of his analysis in Exhibit 4 to his report. He was never asked to disclose the specific software—at deposition, he was asked only "where in your expert report do you disclose which software you used," and responded that "[i]t doesn't make a difference which software is used. Any regression software will produce identical results. So I don't make a statement as to which software was used. Any regression software will produce identical results." Dkt. No. 201-8 at 143. The suggestion in the Reference Guide on Multiple Regression that providing the computer program used would be helpful to improve the discovery process does not warrant excluding an otherwise reliable regression analysis simply for failure to provide that information,

particularly where the party advocating for its exclusion had the opportunity to request that information at deposition but did not do so.

With regard to correlated variables, the Reference Guide on Multiple Regression explains how to analyze whether regression results are robust. It explains that:

> The issue of robustness--whether regression results are sensitive to slight modifications in assumptions (e.g., that the data are measured accurately)--is of vital importance. If the assumptions of the regression model are valid, standard statistical tests can be applied. However, when the assumptions of the model are violated, standard tests can overstate or understate the significance of the results.
>
> The violation of an assumption does not necessarily invalidate a regression analysis, however. In some instances in which the assumptions of multiple regression analysis fail, there are other statistical methods that are appropriate. Consequently, experts should be encouraged to provide additional information that relates to the issue of whether regression assumptions are valid, and if they are not valid, the extent to which the regression results are robust. The following questions highlight some of the more important assumptions of regression analysis.

Reference Guide on Multiple Regression, at 322. One of the highlighted questions is: "To what extent are the explanatory variables correlated with each other?" *Id.* at 324. The Guide explains:

> It is essential in multiple regression analysis that the explanatory variable of interest not be correlated perfectly with one or more of the other explanatory variables. If there were perfect correlation between two variables, the expert could not separate out the effect of the variable of interest on the dependent variable from the effect of the other variable. In essence, there are two explanations for the same pattern in the data. Suppose, for example, that in a sex discrimination suit, a particular form of job experience is determined to be a valid source of high wages. If all men had the requisite job experience and all women did not, it would be impossible to tell whether wage differentials between men and women were the result of sex discrimination or differences in experience.

Id. Here, the independent variables that are potentially correlated are the various challenged statements. As such—without further analysis of their correlation—ChromaDex is correct that the model does not distinguish between the effects of the independent variables. Had it found some effect, it would be impossible to determine to which independent variable or variables that effect was attributable. However, Weir's regression model found *no* effects from the challenged

statements; as such, this critique does not challenge the validity of Weir's results such that exclusion is warranted.

ChromaDex's second challenge to Weir's regression analysis—that Weir's analysis is unreliable because he relied on what ChromaDex considers unreliable data, i.e., the Elysium interrogatory responses—is unavailing. "When facts are in dispute, experts sometimes reach different conclusions based on competing versions of the facts. The emphasis in the amendment on 'sufficient facts or data' is not intended to authorize a trial court to exclude an expert's testimony on the ground that the court believes one version of the facts and not the other." Fed. R. Evid. 702, advisory committee notes to the 2000 Amendment. That ChromaDex disputes the contents of Elysium's sworn interrogatory responses may give rise to questions on cross-examination; it does not render Weir's expert testimony unreliable such that it should be excluded under Rule 702.

d. Admissibility of Weir's Critique of Gunderson's Report

Last, ChromaDex argues that "Mr. Weir's opinion on the market share allocation methodology conflicts with settled law." Dkt. No. 201 at 23. It argues that "although [Weir] was adamant that Mr. Gunderson's analysis was improper, Mr. Weir did not even know what a market share allocation meant outside of the context of this case," *id.*, and on this basis and because Weir has not published in a journal or otherwise authored any peer-reviewed publications, that "[i]t is abundantly clear that Mr. Weir lacks the training, expertise, or experience to comment on Mr. Gunderson's use of the market share allocation method," *id.* at 24–25. ChromaDex's arguments are moot—because the Gunderson Report is excluded, so is Weir's critique of that report.

D. Steven Weisman

1. Background

ChromaDex offers Steven M. Weisman ("Weisman") as an expert to provide opinions and offer testimony regarding FDA regulation of dietary supplements and the regulatory pathways of Niagen and Basis. Dkt. No. 209-3 ("Weisman Report") at 1. The Weisman Report first provides an overview of the relevant FDA regulations. Weisman traces the statutory and regulatory background of Generally Recognized as Safe ("GRAS") status, explaining that "[u]nder the 1958 Food Additives Amendment, any substance intentionally added to food is considered a 'food additive' and must undergo premarket approval by the FDA, subject to certain exemptions." *Id.* at 4 (citing 21 U.S.C. § 321(s)). One such exemption is for "food ingredients found by qualified experts to be 'generally recognized as safe' (GRAS) for their intended use based on scientific procedures or common use in food prior to 1958." *Id.* Weisman then explains the current procedure for obtaining GRAS status: "Under a final FDA rule issued in 2016, and under prior draft guidelines, the FDA allows companies to have a substance obtain GRAS status by submitting a dossier of historical and scientific evidence of safety to an independent panel of experts and having that panel find the substance to be GRAS." *Id.* at 5 (citing 81 Fed. Reg 54,960 (Aug. 17, 2016) (codified at 21 C.F.R. pts. 20, 25, 170, 184, 186, 570)). The evidence of safety is submitted to a "GRAS expert panel [which] is comprised of unbiased qualified experts who independently evaluate whether the available scientific data, information, and methods establish that an ingredient is safe under the conditions of its intended use." *Id.* at 6. Once the GRAS expert panel issues a finding, that finding "can then be voluntarily submitted to the FDA ('Notified GRAS') or the company can choose not to submit the GRAS finding to the FDA ('Self-Affirmed GRAS')". *Id.* at 6–7. If the finding is submitted to the FDA, the FDA "evaluates whether the submitted notice is sufficient for a GRAS

determination or whether the information in the notice (or otherwise available) raises potential questions on whether the substance is indeed GRAS." *Id.* at 7. The FDA responds either by issuing a "no objection" letter or by concluding that the notice is insufficient to provide evidence of a GRAS conclusion. Alternatively, if the finding is not submitted to the FDA, the Self-Affirmed GRAS status "*should* be of the same scientific rigor as a GRAS notification submitted to the FDA." *Id.* In that case, "the basis for the independent GRAS conclusion should be made publicly available by placing a document analogous to the GRAS notice and/or a report of any GRAS panel on the sponsor's website." *Id.*

Next, Weisman explains the regulatory scheme for New Dietary Ingredients ("NDI"s). He explains that an NDI is defined as "a dietary ingredient that was not marketed in the United States before October 15, 1994." *Id.* (internal quotation marks omitted) (quoting 21 U.S.C. § 350b(c)). Under the federal Food, Drug, and Cosmetic Act, "the manufacturer or distributor of an NDI, or of the dietary supplement that contains the NDI, must submit a premarket safety notification (an "NDI Notification" or "NDIN") to the FDA at least 75 days before introducing the product to market, unless the NDI and any other dietary ingredients in the dietary supplement 'have been present in the food supply as an article used for food in a form in which the food has not been chemically altered.'" *Id.* at 8 (quoting 21 U.S.C. § 350b(a)(2)). When a manufacturer or distributor submits an NDIN, the notification must contain the information based on which they believe that the dietary supplement with the NDI "will reasonably be expected to be safe." *Id.* (internal quotation marks omitted) (quoting 21 U.S.C. § 350b(a)(2)). If an NDIN is not submitted to the FDA at least seventy-five days before the NDI or supplement containing the NDI is introduced into interstate commerce, the NDI is considered "adulterated," which Weisman explains to mean "lacking in adequate information to provide reasonable assurance of

safety," and the Food, Drug, and Cosmetic Act provides for seizure of such products and injunctions against those manufacturing and distributing them. *Id.* at 9. When the FDA receives an NDIN, the notifier receives a letter within seventy-five days acknowledging receipt of the NDIN. The letter may be a letter of acknowledgement without objection; a letter listing deficiencies in the notification; an objection letter raising specific safety concerns based on information in the NDIN, gaps in the history of use, or other safety evidence; or a letter raising other regulatory issues with the NDI or supplement containing the NDI. *Id.* at 10. Weisman notes that "[o]f the 1,078 substantive FDA responses since 1995, only 288 have been letters acknowledging an NDIN without objection, compared with nearly 800 letters from the FDA objecting to notifications due to safety or other concerns." *Id.*

Weisman also opines that "[a] company may not just rely on an existing GRAS assessment or NDIN for its own product," and that with limited exceptions, "dietary supplement manufacturers or distributors must submit separate notifications for each supplement that contains an NDI and cannot rely on a previously-submitted notification from a different manufacturer or distributor." *Id.* at 11. He further explains that "a new NDI notification is warranted if a dietary supplement combines a previously-notified NDI with another active ingredient," and that "any changes to the marketing process that alter the identity of the ingredient will convert a previously marketed dietary ingredient into an NDI." *Id.* Sponsors submitting NDINs may rely on data from other NDINs only if they submitted the previous notification, the notification is public, or the previous sponsor authorizes such reliance. *Id.* A similar principle is true for GRAS: "[N]ew information may result in reconsideration of GRAS status." *Id.* at 12.

Weisman's report next turns to current Good Manufacturing Practice regulations ("cGMP"), which are "regulations enforced by the FDA that help ensure the safety and efficacy of dietary supplement products through proper manufacturing, packaging, and labeling." *Id.* He explains that a company's noncompliance with cGMP regulations means that any product it produces is considered "adulterated." *Id.* at 13. He cites a ConsumerLab report stating that of U.S. facilities inspected in 2019, "52% received citations for GMP noncompliance." *Id.*

The second half of Weisman's report shifts from an overview of FDA regulations in general to an explanation of ChromaDex's products, Niagen and Tru Niagen, and Elysium's product, Basis, and their compliance—or noncompliance—with the regulations outlined above.

First, Weisman turns to ChromaDex's products—Niagen, "a patented and proprietary ingredient that is composed of NR," which is "a form of vitamin B_3, and a precursor to nicotinamide adenide dinucleotide (NAD+), an essential molecule found in every living cell," and Tru Niagen, a dietary supplement marketed directly to consumers. *Id.* at 14. Weisman states that in August 2016, Niagen was successfully GRAS notified to the FDA. *Id.* He outlines the safety package that ChromaDex submitted to the FDA, which included information about the product and its manufacturing process, analysis of multiple batches of Niagen, and published study results related to the safety of NR. *Id.* at 14–15. He states that an "independent panel of experts in toxicology" evaluated this information, and it determined that Niagen is "safe for its intended conditions of use"—that is, GRAS. *Id.* at 15. ChromaDex submitted its dossier and the panel's finding to the FDA, who in response provided ChromaDex with a letter stating that it had "no questions at this time regarding ChromaDex's conclusion that NR is GRAS under the intended conditions of use." *Id.* at 16. Based on this, Weisman states: "It is my opinion that ChromaDex had a rigorous regulatory submission package for the NIAGEN® GRAS

determination." *Id.* Weisman also notes that ChromaDex submitted two NDINs to the FDA for Niagen, one in 2015 and one in 2017, and the FDA acknowledged both NDINs without objection. *Id.* at 16–17.

Weisman then turns to Elysium's product, Basis, which "combines NR with pterostilbene (PT), a polyphenol related to resveratrol." *Id.* at 18. He states that while Elysium sourced both NR and PT from ChromaDex when it launched Basis, since 2016 it "has utilized at least five different manufacturers for its NR and at [sic] two different manufacturers for its PT" and that Elysium's 30(b)(6) witness, Mark Morris, "confirmed that Elysium has never submitted an NDIN for Basis or either of its ingredients." *Id.* Elysium prepared GRAS assessments for NR and PT, but "Mr. Morris testified that Elysium's PT [GRAS] assessment was not reviewed by an independent panel," and Elysium did not submit either GRAS assessment to the FDA. *Id.* at 18–19. Weisman cites ChromaDex's allegations of Elysium's false or misleading representations about Basis's safety, purity, and regulatory status, *id.* at 19, and then provides his own overview and opinions regarding Basis's regulatory status. He opines that Elysium's 2017 NR GRAS notification "relies on ChromaDex's data in all substantive aspects," and that in his experience, "this is highly unusual" and "it is inappropriate for Elysium to claim that the NR in Basis 'enjoys Generally Recognized as Safe status' based upon NIAGEN's GRAS status." *Id.* at 20. Significant manufacturing changes, he explains, "can affect the identity or conditions of use of a food substance," and "thus, the properties may not match the information considered in a prior GRAS assessment, rendering the previous determination of GRAS status inapplicable." *Id.* He provides a chart from Elysium's GRAS assessment comparing the specifications of Elysium's NR with ChromaDex's NR, and he opines that it "demonstrates important differences in the specifications, solvents, by-products (including acetamide), and impurity specifications." *Id.* at

21–22. He further notes that Elysium's GRAS assessment for NR was not submitted to the FDA; as outlined above, while this is permissible, if a GRAS assessment is not submitted to the FDA, it should be made publicly available on the sponsor's website. *Id.* at 23. He states that he has "reviewed Elysium's website and it does not appear as if its GRAS assessment of NR was made publicly available." *Id.* Weisman further notes that Elysium's GRAS assessment of PT raises safety concerns, *id.* at 23, was not reviewed by an independent panel of experts, *id.* at 24, and was not submitted to the FDA yet does not appear to be publicly available on Elysium's website, *id.*

Regarding NDINs, Weisman opines that Basis is not covered by ChromaDex's NDINs because its notifications "specified the intended use for NIAGEN® . . . as the sole active ingredient in a dietary supplement capsule, whereas Elysium combines its NR with PT in Basis." *Id.* Last, regarding Elysium's cGMP compliance, Weisman opines that "assuming that each of the facilities [in China] that Elysium employed met GMP standards appropriate for China, they likely did not meet GMP standards appropriate for the United States," and that "based upon [his] understanding of GMP standards, for Elysium to assert that their NR is manufactured in a facility that is GMP compliant may be misleading." *Id.* at 25.

2. Analysis

Elysium seeks to preclude Weisman's expert testimony in its entirety, arguing that his opinions are "either legal conclusions, mere recitation of ChromaDex's allegations of which Weisman has no specialized knowledge, or mere speculation not supported by facts and data." Dkt. No. 208 at 9. Specifically, Elysium challenges (1) the portion of Weisman's report that outlines FDA regulations including GRAS and NDIN as "consisting entirely of legal conclusions based upon his interpretation of FDA regulations and guidance," *id.*; (2) the portion of Weisman's report related to Niagen's and Basis's regulatory pathways as "factual narrative" of

subjects as to which "Weisman has no prior experience . . . , or awareness of," *id.*; (3) Weisman's opinion about the propriety of Elysium's GRAS for NR, because it argues that he "backtracked" and "pivoted" from this opinion at his deposition, *id.* at 10; (4) Weisman's opinions regarding Elysium's GRAS for PT as irrelevant, because he "identifies what he considers to be shortcomings in Elysium's process for obtaining GRAS determination for PT" but does not "offer any opinion that the alleged shortcomings render the GRAS *invalid*," and the legal issue is whether the statement that "[b]oth primary ingredients in Basis are GRAS" is false or misleading, *id.* at 11; and (5) Weisman's opinions regarding the impact of Elysium's manufacturer changes on the regulatory status of Basis and his opinions on cGMP compliance as speculative, *id.* at 12. The Court addresses each of these in turn.

The first half of Weisman's expert report does not address the specific products at issue in this litigation, but rather outlines the relevant FDA regulations and guidance at play here. Elysium argues that "[t]his is not the proper subject for expert testimony," and that Weisman's testimony improperly offers legal conclusions; ChromaDex counters that "[s]uch testimony is permitted in a complex case to help the jury understand unfamiliar terms and concepts," and that Weisman does not opine on any of the ultimate legal issues in the case—namely, whether Elysium's advertising was false or misleading. Both parties rely on *U.S. v. Bilzerian*, 926 F.2d 1285 (2d Cir.), *cert denied*, 502 U.S. 813 (1991) to support their positions. Dkt. No. 208 at 9; Dkt. No. 232 at 16. In *Bilzerian*, the defendant argued that the trial court erred in admitting expert testimony "regarding the requirements of Schedule 13D concerning disclosure of the source of funds and arrangements and understandings with others." *Id.* at 1294. The Second Circuit noted that:

> Particularly in complex cases involving the securities industry, expert testimony may help a jury understand unfamiliar terms and concepts. Its use must be carefully

> circumscribed to assure that the expert does not usurp either the role of the trial judge in instructing the jury as to the applicable law or the role of the jury in applying that law to the facts before it.

Id. The Second Circuit also noted that "[a]s a general rule an expert's testimony on issues of law is inadmissible" but distinguished between "factual conclusions that may be included in an expert's testimony—though they embrace an ultimate issue to be decided by the jury—and opinions embodying legal conclusions that encroach upon the court's duty to instruct on the law." *Id.* The court held that the challenged expert "did not give his opinion as to whether [the defendant's] actions violated the securities laws" but rather testified about "general background on federal securities regulation and the filing requirements of Schedule 13d." *Id.*

Here, too, Weisman's testimony regarding the relevant FDA regulatory schemes does not consist of opinions as to whether Elysium's advertising was false or misleading as a matter of law. Rather, Weisman outlines the general background of FDA regulation and the specific requirements and regulations pertaining to obtaining GRAS status and submitting NDINs. Much like the testimony at issue in *Bilzerian*, this testimony "may help a jury understand unfamiliar terms and concepts," and does not encroach on the roles of judge or jury. As such, the testimony is admissible.

The second half of Weisman's report addresses Niagen's and Basis's regulatory pathways. Elysium challenges various portions of this testimony on various different grounds; its first challenge, however, relates to Sections III.A through H as a whole. Elysium argues that this testimony is improper because it consists of a factual narrative that recites ChromaDex's allegations, and regarding which Weisman has no prior experience or awareness. Elysium relies on *Haritatos v. Hasbro, Inc.*, in which a court in the Northern District of New York rejected an expert's testimony as "consist[ing] mostly of recitations of the law" and summarily rejected the remainder because it "consists of recitations of plaintiff's versions of the facts, conclusions based

on her application of plaintiff's version of the facts to her version of the law, and various unsupported legal conclusions." 2007 WL 3124626, at *2 (N.D.N.Y. Oct. 23, 2007). As ChromaDex points out, *Haritatos* is inapposite. Weisman's proposed testimony outlines his own analysis of ChromaDex's and Elysium's regulatory submissions and pathways. These opinions do not merely rehash ChromaDex's factual allegations, nor do they offer legal conclusions inappropriate for expert testimony. The one exception to this is Section III.H, which simply states that ChromaDex's Second Amended Complaint "alleges that Elysium makes several false or misleading representations regarding Basis, including about the product's safety, purity, and regulatory status" and provides "examples of allegedly false or misleading representations." Weisman Report at 19–20. This Section offers nothing more than a recitation of ChromaDex's factual allegations and is therefore excluded.

Next, Elysium challenges Weisman's opinion about the propriety of Elysium's GRAS for NR. Weisman's report opines that "[i]t is inappropriate for Elysium to claim that the NR in Basis 'enjoys Generally Recognized as Safe status' based upon NIAGEN's GRAS status." Weisman Report at 20. He further opines that a chart in Elysium's GRAS assessment "demonstrates important differences in the specifications, solvents, by-products (including acetamide), and impurity specifications" between Elysium's NR and ChromaDex's NR, such that "Elysium could and should not have relied upon the NIAGEN® GRAS assessment for assurance of safety given the differences in specifications and impurity profiles." *Id.* at 21–23. Elysium contends that at his deposition, Weisman "backtracked, conceding there is 'absolutely nothing inappropriate' about Elysium citing ChromaDex's prior GRAS notification for NR," and "pivoted and opined that the GRAS determination for Elysium's NR would not support an 'implication that Elysium's Basis or NR has uniquely defined GRAS status for its unique

product.'" Dkt. No. 208 at 10 (quoting Dkt. No. 209-4 at 104–06) (internal alterations omitted)). Elysium's argument selectively quotes and misconstrues Weisman's deposition testimony, which is entirely consistent with the opinions he expressed in his report. The full, relevant excerpt of Weisman's deposition testimony, with Elysium's quotations italicized, is as follows:

> A. What I'm saying is that the statement is that Elysium's product enjoys a status, but that status is defined by a totally different company's product and production methods.
>
> Q. Why do you think ChromaDex's NR product is totally different than Elysium's product?
>
> A. So I did not say that.
>
> . . .
>
> Q. So you're saying that it's not a different product, but just a different company; is that right?
>
> A. No, that's not correct. . . . What I was saying is that the statement that this product, Elysium's product, enjoys a status suggests that the product of Elysium was what was certified and deemed to be GRAS, as opposed to what the GRAS report was, which was a regurgitation of the ChromaDex submission that basically says that NR has a GRAS status. So they overexaggerate the claim and suggest that Elysium uniquely has met a standard based on studies that it has done.
>
> Q. Okay. So ChromaDex's Niagen product is NR; right?
>
> A. That is correct.
>
> Q. Okay. And Elysium's product is also NR; right?
>
> A. I believe that is correct, yes.
>
> Q. Okay. And so why is it inappropriate for Elysium to cite published studies and data relating to NR?
>
> A. *So absolutely nothing inappropriate was citing published studies relating to NR.* That's not what's at issue here. You know, what is at issue here is, is there a unique and different GRAS notification for the Elysium product, because if the Elysium product is NR, as you've alluded to, NR is NR, then there is no need for a GRAS application. They could just market the product, but the fact that they said theirs was GRAS adds it to a higher standard, and *the implication is that it has uniquely defined GRAS status for its unique product.*

> Q. Okay. So I want to just kind of understand your most recent testimony where you say: If NR is NR, then there is no need for a GRAS application. What do you mean by that?
>
> A. I mean, that it would be inappropriate to say that this product was GRAS because a GRAS notification or a dossier would not be required if it was the exact same product, but the truth of the matter is that it's not the exact same product and they deemed it not to be the exact same product and, hence, the reason they completed a GRAS process.
>
> Q. Okay. Are you rendering an opinion as to whether or not ChromaDex's NR is the same product as Elysium's NR?
>
> . . .
>
> A. It's clearly not the same product. I mean, there are different formulations, different manufacturing facilities, different marketing, etc., so they're clearly different products.

Dkt. No. 209-4 at 104–6. Weisman's testimony at his deposition was thus that while it would be appropriate for Elysium to simply rely on ChromaDex's GRAS assessment if they were utilizing the same product, the products are not the same—which is why a new GRAS assessment is required—and in conducting that GRAS assessment, it was not appropriate to simply re-utilize the same data as in ChromaDex's GRAS assessment, because that data does not support a conclusion about the GRAS status of Elysium's NR specifically. This testimony is consistent with the opinions expressed in his report; as such, Elysium's argument that "Weisman withdrew his opinion about the propriety of Elysium's GRAS for NR," Dkt. No. 208 at 10, is rejected.

Elysium's next argument is that Weisman's opinions about the shortcomings in Elysium's GRAS assessment for PT are irrelevant because Weisman does not ultimately opine that the GRAS assessment is therefore invalid, as relevant to the at-issue question whether the statement that "[b]oth primary ingredients in Basis are GRAS" is false or misleading. This argument, too, is unavailing. As ChromaDex identifies, "Weisman opines that Elysium never submitted a GRAS for PT to FDA and took shortcut [sic] regarding its self-GRAS," Dkt. No.

232 at 20; notably, those shortcuts included failing to submit its GRAS assessment for review by an expert panel, *id.* at 24, a fatal flaw according to Weisman's description of the GRAS process. That Weisman never explicitly states that these flaws rendered the GRAS assessment invalid does not negate the relevance of his testimony at least to the question whether the ingredients in Basis had GRAS status.

Last, Elysium argues that Weisman's opinions regarding the impact of Elysium's manufacturer changes on the regulatory status of Basis and his opinions on cGMP compliance are speculative. Elysium's argument is well-taken. These portions of Weisman's report opine, respectively, that "changes to Elysium's manufacturers, specifications, and purity profiles *may* necessitate new assessments," and that "for Elysium to assert that their NR is manufactured in a facility that is GMP compliant *may* be misleading." Weisman Report at 24–25 (emphasis added). Proper expert testimony under Federal Rule of Evidence 702 is that which "will help the trier of fact to understand the evidence or determine a fact in issue." Under Federal Rule of Evidence 403, "the court may exclude relevant evidence if its probative value is substantially outweighed by a danger of . . . unfair prejudice, confusing the issues, [or] misleading the jury." Weisman's indefinite and uncertain opinions are too speculative to assist the trier of fact in determining any fact in issue. Moreover, "[t]hese tentative conclusions offer little in the way of probative evidence. What little value they have is far outweighed by the danger that the jury would accord too much weight to such opinions because they come from the mouth of a . . . professional." *Tchatat v. City of New York*, 315 F.R.D. 441, 447 (S.D.N.Y. 2016).

E. Kurt Hong

1. Background

ChromaDex offers Kurt Hong ("Hong") as an expert to provide opinions and testify regarding "the history of the development of NR as a human vitamin supplement, history of

resveratrol and pterostilbene, Elysium's published studies, and safety concerns related to Basis." Dkt. No. 209-5 ("Hong Report") at 1. Hong is a Professor of Clinical Medicine at USC Keck School of Medicine, where he holds a joint appointment with the USC Davis School of Gerontology. *Id.* at 2. He also serves as the Executive Director of the Center for Clinical Nutrition at USC. *Id.* The first twelve pages of Hong's report discuss the history of the development of NR as a human vitamin supplement and the history of resveratrol and pterostilbene. *Id.* at 3–13. There is then one page that identifies what Hong terms "key differences" between Tru Niagen and Basis. *Id.* at 13–14. It states that Tru Niagen has a single active ingredient—NR—and is currently sold to consumers in capsules of 150mg or 300mg, with a recommended daily intake of 300mg of NR and that Basis contains 250mg of NR and 50mg of PT. *Id.* Hong's opinions are contained in the last five pages of his report. He opines that Elysium has not performed sufficient toxicology and safety studies for Basis primarily because Elysium did not study PT and the combination of NR and PT, that Elysium's claim of a synergistic effect between NR and PT has not been the subject of any human studies, and that the increase in NAD+ level in Basis is likely attributed solely to the effect from NR and that there are safety concerns with the combination of PT with NR in Basis. *Id.* at 13–18. He also opines that the acetamide levels in some batches of Basis exceed the "no significant risk" levels under California Proposition 65 and, if Basis containing that NR were sold in California, it would require a warning to consumers that the product contains a chemical known to the State of California to be potentially carcinogenic. *Id.* at 18–19.

2. Analysis

Elysium first argues that Sections IV.A and B of Hong's report, where he recites the history of NR, PT, and resveratrol, should be excluded because they rehash evidence of which Hong has no personal knowledge and which would be more helpfully presented to the jury

through the testimony of fact witnesses, including Dr. Charles Brenner (of ChromaDex) and Dr. Leonard Guarante (for Elysium). Dkt. No. 208 at 13–14. ChromaDex counters that Hong "employed his experience and expertise to explain complex scientific articles and clinical studies that are relevant to ChromaDex's false advertising claims, and which the jury will not necessarily understand without assistance." Dkt. No. 283 at 23. The challenged sections of Hong's report consist of a narrative explaining what NAD+ is, the relationship between NAD+ and NR, Dr. Guarente's and Dr. Brenner's contributions to the field and the significance of those contributions; a description of various studies conducted on ChromaDex's NR; and a narrative recounting the history of PT and resveratrol. This testimony is based on Hong's examination of the pleadings, the relevant studies, various produced documents, and deposition transcripts of Dr. Guarente, Dr. Brenner, Ryan Dellinger, and Frank Jaksch. Hong Report, Ex. 2. "[T]estimony by fact witnesses familiar with those documents would 'be far more appropriate . . . and renders the expert witness' secondhand knowledge unnecessary for the edification of the jury.'" *LinkCo, Inc. v. Fujitsu Ltd.*, 2002 WL 1585551, at *2 (S.D.N.Y. July 16, 2002) (alteration adopted) (quoting *Media Sport & Arts s.r.l. v. Kinney Shoe Corp.*, 1999 WL 946354, at *3 (S.D.N.Y. Oct. 19, 1999)). This portion of his report "does no more than counsel for plaintiff will do in argument"—it merely recites facts that other witnesses have firsthand knowledge of and "propound[s] a particular interpretation of" those facts. *Id.* (internal quotation marks omitted and alteration adopted) (quoting *Primavera Familienstifung v. Askin*, 130 F. Supp. 2d 450, 530 (S.D.N.Y. 2001), *abrogated on other grounds by Casey v. Merck & Co., Inc.*, 653 F.3d 95 (2d Cir. 2011)); *see also In re Rezulin Prods. Liability Litig.*, 309 F. Supp. 2d 531, 551 (S.D.N.Y. 2004) (excluding expert testimony that consisted of a narrative of the background of the case, because "[s]uch material, to the extent that it is admissible, is properly presented through

percipient witnesses and documentary evidence," and "the glosses that [the expert] interpolates into his narrative are simple inferences drawn from uncomplicated facts that serve only to buttress plaintiffs' theory of the case"). To the extent that Hong's testimony is intended to "address technical questions that may be difficult for a juror to comprehend," *see LinkCo*, 2002 WL 1585551, at *2, a review of the report demonstrates that it does not do so. One example is illustrative. Several pages of Hong's report are devoted to summarizing the relevant studies of Niagen. With regard to the Conze study, Hong's report states:

> In an 8-week study published in 2019 (Conze, 2019), researchers evaluated the kinetics and dose-dependency of NR oral availability and safety in overweight but otherwise healthy men and women. The study showed that consumption of 100, 300 and 1000mg of NR dose-dependently and significantly increased whole blood NAD+ levels (*i.e.*, by 22%, 51% and 142%, respectively) within 14 days. These levels were sustained throughout the remainder of the 8 week study in the 300mg and 1000mg participants (*i.e.*, by 48±8% and 139±19%, respectively) as compared to baseline blood NAD+ levels.

Hong Report at 10. The study itself contains the following abstract, in bold and on the first page of the paper:

> To evaluate the kinetics and dose-dependency of NR oral availability and safety in overweight, but otherwise healthy men and women, an 8-week randomized, double-blind, placebo-controlled clinical trial was conducted. Consumption of 100, 300, and 1000 mg NR dose-dependently and significantly increased whole blood NAD+ (i.e. by 22%, 51% and 142%) and other NAD+ metabolites within 2 weeks. The increases were maintained throughout the remainder of the study.

Dkt. No. 230-15 at 1.

In the "Results" section, the study states that "[a]t day 56, the blood NAD+ levels of the same 100 mg, 300 mg and 1000 mg participants were sustained at increases of 10% ± 4%, 48% ± 7% and 139% ± 19% with respect to their baseline blood NAD+ levels." *Id.* at 6. Hong's description—which uses virtually identical phrasing and vocabulary to that of the study itself—does not say anything that a jury could not understand for itself simply by reading the study's

abstract, or by hearing testimony from two of the study's authors, Dr. Brenner and Claire Kruger, both of whom gave depositions in this case and presumably can be offered as fact witnesses.

Next, Elysium argues that the opinion Hong expressed at his deposition that his conclusion that "there is currently no evidence that PT is actually more bioavailable than resveratrol in humans" is "important potentially to consumers" should be excluded because Hong did not perform or review any surveys of such "potential" importance to consumers. Dkt. No. 208 at 14 (citing Hong Tr. at 69). ChromaDex counters that the "focus of Hong's opinion" about PT is found in his report, which does not mention anything about the potential importance of his summary of the available research on PT to consumers. Dkt. No. 283 at 24. To the extent that ChromaDex intends to offer Hong's testimony about such potential importance, that testimony is excluded as his "subjective belief or unsupported speculation," *Daubert*, 509 U.S. at 590, since his report contains no basis from which he could draw conclusions about what or is not important to consumers.

Elysium further argues that Section IV.C of Hong's report is inadmissible because Hong identifies what he calls "key differences" between Tru Niagen and Basis but conducted no surveys as to what consumers consider key differences. This portion of Hong's report merely recites the active ingredients of Tru Niagen and Basis, how much of each ingredient is in each supplement, and that Elysium initially sourced its NR and PT from ChromaDex but ceased to do so in 2016 and subsequently changed manufacturers of those ingredients several times. Hong offers no opinions or insights beyond these basic facts, nor does he explain anything that the factfinder would not otherwise understand; as such, these facts are not the proper subject of expert testimony.

Elysium challenges the opinions expressed in Section IV.D.1 of Hong's report regarding whether their clinical surveys were "sufficient" because Hong testified at deposition that he meant sufficient for "consumers" and "healthcare providers" but did not test consumers' or healthcare providers' attitudes toward the sufficiency of Elysium studies. Dkt. No. 209-6 at 79. He further testified that his opinion that "it would be important to see that there is a human safety study of the ingredients in Basis which is NR plus PT" was "just based on [his] personal opinion," and that his opinion that "ideally," "both a toxicology study and a human clinical trial should be performed on a product prior to selling it" was also "just [his] personal opinion." Dkt. No. 209-6 at 79–80. Federal Rule of Evidence 702 requires that expert testimony be "the product of reliable principles and methods." Fed. R. Evid. 702(c). Expert opinion testimony that does no more than assert that something is insufficient because it is the expert's "personal opinion" that it is insufficient cannot meet this requirement and is thus inadmissible. *See Joiner*, 522 U.S. at 146 (1997) ("[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by *ipse dixit* of the expert.").

Elysium further argues that Hong's opinion in Section IV.D.2 of his report regarding the absence of a synergistic effect between NR and PT on NAD+ levels is irrelevant because Elysium predicted that the combination of the two ingredients would have a synergistic effect in supporting a healthy cellular aging process generally and not on NAD+ levels specifically. "Rule 702 . . . requires that the evidence or testimony 'assist the trier of fact to understand the evidence of to determine a fact in issue.' This condition goes primarily to relevance." *Daubert*, 509 U.S. at 591 (quoting Fed. R. Evid. 702). "Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful." *Id.* (internal quotation marks omitted)

(quoting 3 Weinstein & Berger ¶ 702, p. 702–18). Hong's testimony about the absence of a synergistic effect between NR and PT on NAD+ levels is not relevant to the truth of Elysium's claims of an expected synergistic effect between NR and PT on cellular health generally; it thus fails the *Daubert* "fit" test, *see* 509 U.S. at 591, and is inadmissible.

Next, Elysium argues that Hong's opinion that the PT in Basis presents significant safety concerns is flawed and unreliable because it reflects only his personal views on what the studies reveal and not either a prevailing wisdom or the views of the scientists who authored the study upon which he bases his opinion, was not based on sufficient facts, and makes an unsupported analytical leap from an increase in LDL levels to the conclusion that the increase in LDL levels presents "significant safety concerns." The relevant portion of Hong's report recites the findings of two studies regarding increases in LDL levels and then opines that:

> Given the finding in Riche 2014 demonstrating that PT adversely impacts lipid profile (in particular, increasing LDL levels), and the finding in Dellinger 2017 demonstrating that the NRPT combination similarly adversely impacts lipid profile, there are significant safety concerns for chronic supplementation with PT in humans. The associations of LDL with cardiovascular disease and coronary heart disease mortality are well-delineated. In addition, across multiple ethnicities and age groups, an increase in LDL levels is significantly associated with coronary heart disease, risk for myocardial infarction, and strokes.

Hong Report at 17. The report provides no basis for the conclusion that "there are significant safety concerns for chronic supplementation with PT in humans," and provides no analysis of the specific increases found in either the Riche study or the Dellinger study and the connection between such increases and any safety concerns. Hong's opinion appears to be supported only by his general assertions about "the associations of LDL." His opinion about the safety concerns of Basis is thus connected to existing data only by his own *ipse dixit* and is inadmissible. *See Joiner*, 522 U.S. at 146.

Finally, Elysium argues that Hong's testimony regarding Proposition 65 is inadmissible because Hong has no prior experience with Proposition 65 and was unable to articulate what "no significant risk level" means and because the testimony is impermissibly hypothetical because there is no evidence that Elysium ever sold Basis containing acetamide in California. Hong's report states that:

> I understand that multiple batches of NR manufactured by PCI, Elysium's manufacturer, had acetamide levels in excess of 100 ppm. If Basis containing that NR was sold in California, Proposition 65 would require a warning to consumers that the product contains a chemical known to the State to be potentially carcinogenic.

Hong Report at 19. ChromaDex argues that "[w]hether Elysium sold Basis with high acetamide levels in California is beside the point," because "the evidence shows that Elysium's executives worried about Prop 65 and thus sold tainted product outside of California, which certainly goes to the issue of whether or not Basis was and is safe." Dkt. No. 283 at 25 (citing Dkt. No. 257, Ex. 13). ChromaDex's argument proves too much. If Proposition 65 is relevant because of evidence indicating that Elysium's executives were aware of and concerned about it and deliberately sold product that would exceed the Proposition 65 threshold outside of California—and the possible implications of such evidence on the issue of whether or not Basis is safe—that evidence is the proper vehicle to raise this issue before the jury, rather than expert testimony which offers only the expert's interpretation of the proposition and the tautological opinion that if Elysium sold product that fell under that proposition in California, it would be subject to the requirements of that proposition in California. Such testimony "is a simple inference drawn from his review" of the Proposition 65 threshold and evidence about acetamide levels in Basis, *Rezulin*, 309 F. Supp. 2d at 550; there does not appear to be any question about the relevant threshold requiring expert clarification, *see* Dkt. No. 257, Ex. 13, at 125–27 (deposition testimony of Elysium executive confirming the same numbers that Hong's report recites), and

the evidence about acetamide levels in various batches of Basis is evidence "which, if admissible, plaintiffs' counsel may present directly to the fact-finder while arguing his or her view as to their significance," *Rezulin*, 309 F. Supp. 2d at 550.

CONCLUSION

The *Daubert* motions are each GRANTED IN PART and DENIED IN PART.

SO ORDERED.

Dated: February 11, 2022
New York, New York

LEWIS J. LIMAN
United States District Judge