22-1059-cv(L), 22-1153-cv(XAP)

United States Court of Appeals

for the

Second Circuit

ELYSIUM HEALTH, INC.,

Plaintiff-Counter Claimant-Appellant-Cross-Appellee,

– v. –

CHROMADEX, INC.,

Defendant-Counter Defendant-Appellee-Cross-Appellant.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

BRIEF AND SPECIAL APPENDIX FOR DEFENDANT-COUNTER DEFENDANT-APPELLEE-CROSS-APPELLANT CHROMADEX, INC.

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CORPORATE DISCLOSURE STATEMENT
PURSUANT TO RULE 26.1 OF THE
FEDERAL RULES OF APPELLATE PROCEDURE

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure, ChromaDex, Inc., Appellee/Cross-Appellant in this appeal, states that its parent company is ChromaDex Corporation and that no publicly held corporation owns 10% or more of ChromaDex, Inc.'s or ChromaDex Corporation's stock

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PRELIMINARY STATEMENT

This appeal presents a case of buyer's remorse on the part of Appellant Elysium. After lengthy litigation spanning two jurisdictions, and while the parties' summary judgment and *Daubert* motions were pending, Elysium and ChromaDex struck a bargain to resolve these disputes. In an agreement negotiated between Elysium's General Counsel and ChromaDex's Senior Vice President of Business Affairs and legal counsel, the parties agreed to give up their respective rights in at-issue litigation; Elysium agreed to pay ChromaDex $2.5 million; and, if Elysium failed to pay timely, ChromaDex would be entitled to interest and attorneys' fees associated with collections. In an email, Elysium's General Counsel listed each material term and concluded: "we have an agreement."

Just a few hours later, before the parties had the chance to notify the district court of their negotiated resolution, the court issued orders on pending motions. Sensing a potential advantage, Elysium tried to renege, first claiming that the concluded agreement was on "hold," and later concocting a documentation requirement that was never discussed or made part of the agreement. With the benefit of hindsight, perhaps Elysium is unhappy with the bargain it struck. But litigants routinely assess similar risks when engaging in alternative dispute resolution. The law does not permit settling parties to wait and see what happens in

litigation before deciding whether they like the deal; a settlement agreement is not an option contract.

Now, Elysium demands that this Court both vacate the district court's order confirming the parties' settlement, and an earlier grant of summary judgment in ChromaDex's favor on Elysium's claims that an FDA Citizen Petition was somehow wrongful. Elysium's argument fails on multiple grounds. First, there was no error in the district court construing the contours of the settlement agreement applying the well-established *Winston* factors. Elysium's email confirming the parties' settlement was clear and unambiguous, and nothing in Elysium's writing conditioned enforceability on additional formalities. Second, by settling all claims in the litigation, Elysium gave up the right to adjudicate any error in the earlier grant of summary judgment.

But if this Court does not affirm the judgment, it should reach ChromaDex's conditional cross-appeal and reverse the district court's summary judgment and *Daubert* orders. With respect to at-issue Elysium advertising, the record is replete with evidence of falsity and injury. The district court disagreed, but that evaluation is one for a jury. The district court also misapplied this Court's precedent in excluding ChromaDex's survey, damages, and science experts. On Elysium's false advertising claim against ChromaDex's advertising, the record demonstrates that Elysium did not even try to demonstrate materiality or injury.

COUNTER-STATEMENT OF JURISDICTION

A. Elysium's Appeal

The at-issue settlement agreement, which Elysium challenges, covers "all claims and counterclaims raised in the New York action." Thus, contrary to Elysium's argument, if this Court affirms the district court's settlement order, there is nothing for Elysium to appeal.

B. ChromaDex's Conditional Cross-Appeal

The district court entered judgment based on its conclusion that the parties had already settled all claims and counterclaims in the action. ChromaDex filed a conditional cross-appeal to challenge the district court's summary judgment and *Daubert* orders.

If this Court affirms the settlement order, it need not reach ChromaDex's cross-appeal. However, if this Court reverses the Settlement Order, the cross-appeal would be ripe for review. *See Smith ex rel. Smith v. Half Hollow Hills Cent. School Dist.*, 298 F.3d 168, 170-72 (2d Cir. 2002) (dismissal of remaining claim and entry of final judgment "cured any jurisdictional infirmity" as to appellate jurisdiction over district court's prior order dismissing some claims, even without proper Rule 54(b) certification).

COUNTER-STATEMENT OF THE ISSUES ON APPEAL

ChromaDex does not agree with the issues presented in Elysium's opening brief. The proper issues in this appeal are:

1. Did the district court clearly err in finding that there was a binding settlement agreement between the parties?

2. Can Elysium raise arguments relating to enforcement of the at-issue settlement agreement for the first time on appeal, or are those arguments waived?

3. Does this Court have appellate jurisdiction to consider Elysium's arguments relating to the Citizen Petition Claims?

4. Only if the answer to Issue 3 is "yes," did the district court properly apply the "objectively baseless" standard under the "sham exception" to the *Noerr-Pennington* doctrine when it dismissed the Citizen Petition Claims?

STATEMENT OF THE ISSUES ON CONDITIONAL CROSS-APPEAL

1. Did the district court err in granting summary judgment for Elysium on ChromaDex's false advertising claim where the record abounds with evidence that establishes, and at the very least creates triable issues of fact as to, the falsity of Elysium's advertising claims and the injury to ChromaDex caused thereby?

2. Did the district court commit legal error by allowing Elysium's false advertising claim to survive in part despite Elysium's admission that it has no

evidence of materiality and no evidence of injury caused by ChromaDex's alleged false advertising?

3. Whether the district court abused its discretion in excluding expert reports and testimony offered by ChromaDex.

STATEMENT OF THE CASE

A. The History Between the Parties

Elysium sells a product called Basis, which is an anti-aging dietary supplement that consists of two primary active ingredients: pterostilbene ("PT") and synthetic nicotinamide riboside ("NR"). A-1258.[1] Elysium was originally ChromaDex's customer, and pursuant to this relationship, ChromaDex supplied NR (licensed from ChromaDex as NIAGEN®) and PT (licensed as pTeroPure®) to Elysium. *Id.* The business relationship between the parties ended in 2016, after Elysium, among other things, breached its supply agreement with ChromaDex and stole trade secrets (after compromising two high-level ChromaDex employees who eventually accepted employment at Elysium). ChromaDex thereafter began selling TruNiagen, its own direct-to-consumer anti-aging product, consisting of NR as its only active ingredient. A-1259.

[1] The following citation forms are used in this brief. Materials contained in the Appellant's appendix are cited "A-__." Materials contained in Appellee's supplemental appendix are cited "SA-__." Appellant's opening brief is cited as "Br."

ChromaDex and Elysium are parties to several different lawsuits pending in different federal courts. Contrary to Elysium's characterization of the facts in its opening brief, the instant action (the "New York Action") was actually commenced by Elysium (on September 27, 2017) when it sued ChromaDex for false advertising, trade libel, deceptive business practices and tortious interference with business relations for allegedly making a sham citizen petition to the United States Food & Drug Administration ("FDA"). A-1250. On October 25, 2017, ChromaDex also sued Elysium for false advertising also in the New York Action. Dkt. 171 at 2. The two cases were consolidated on November 3, 2017. Dkt. 27. On February 7, 2019, the district court in the New York Action granted ChromaDex's motion for summary judgment as to Elysium's citizen petition pursuant to the *Noerr-Pennington* doctrine. A-1270. Another action pending in the Central District of California (the "California Action") was commenced by ChromaDex in December 2016, in which ChromaDex brought claims for breach of contract, breach of fiduciary duty, and misappropriation of trade secrets and Elysium alleged counterclaims for alleged violation of a most-favored-nations clause, fraudulent inducement, patent misuse, and unjust enrichment. A-1400. In September 2021, after trial, a verdict was rendered in the California Action where the jury found for ChromaDex on certain of its claims and for Elysium on other claims, resulting in a total net award to ChromaDex of $1,100,658 with

prejudgment interest and attorney's fees yet to be decided, plus the possibility of additional post-trial motions and appeals. A-1400-01. Elysium retained a patent misuse counterclaim, which was bifurcated for a separate bench trial and stayed pending the outcome of the litigation in Delaware. A-1401. Finally, in 2018, ChromaDex sued Elysium for patent infringement in the District of Delaware (the "Delaware Action"). A-1401. Elysium filed a motion for summary judgment in the Delaware Action, that was granted on September 21, 2021. *Id.* That order is currently on appeal.

B. Facts Relevant to the At-Issue Settlement Order

1. The February 2022 Settlement Discussions

After lengthy discovery in this case, the parties each filed motions for summary judgment and *Daubert* motions. A-1401. On January 10, 2022, the district court heard oral argument on these motions. *Id.*

In January 2022, leading up to the oral argument and afterwards, the parties conducted settlement discussions to settle both this action (*i.e.*, the New York Action) and the California Action. *Id.* The parties generally agreed on a settlement amount of $2.5 million from Elysium to ChromaDex to settle both cases but did not reach agreement on the timing of the payments. *Id.* ChromaDex sought payment of the $2.5 million in a single lump sum; Elysium sought to split the payment into two equal installments. *Id.*

On February 2, 2022, after oral argument on the parties' motions for summary judgment and *Daubert* motions, William Carter, Senior Vice President of Business Affairs and legal counsel at ChromaDex, called Thomas Wilhelm, General Counsel for Elysium, to convey a settlement offer on behalf of ChromaDex (the "February 2 Call"). *Id.* The settlement offer (the "Offer") consisted of the following terms (the "Material Terms"): (1) the payment by Elysium of $2.5 million in two separate installments to resolve the entire New York Action and all outstanding issues in the California Action including the issue of prejudgment interest; (2) the filing of a stipulated judgment in the amount of $2.5 million in the California Action, with $1.25 million to be paid by Elysium in February 2022 and the second payment to be made one year from the first payment; (3) Elysium's agreement that interest would accrue on the second payment from the date of the settlement agreement but would be waived if payment was timely made and that ChromaDex would be entitled to seek attorney's fees incurred in collecting the second payment should Elysium fail to make it on time; (4) the parties' agreement not to seek attorney's fees or costs arising from the California Action and not to file any post-trial motions or appeals related to the claims and counterclaims tried to the jury in the California Action; and (5) the mutual dismissal with prejudice of all claims and counterclaims in the New York Action, with each side bearing its own attorney's fees and costs. A-

1401-02. Mr. Carter told Mr. Wilhelm that if Elysium agreed to the Material Terms the parties would have a deal and Mr. Wilhelm indicated that he understood the Offer and would discuss it with Elysium and get back to Mr. Carter as soon as possible. A-1402.

On Thursday, February 3, 2022, at 12:02 p.m., Mr. Wilhelm sent an email to Mr. Carter responding to the Offer (the "Acceptance Email"). A-1402-03. In the Acceptance Email, Mr. Wilhelm memorialized the Material Terms and stated: "I understand that now that we have an agreement you will get started on documentation." *Id.* There were no contingencies regarding pending motions. *Id.*

A little over two hours later, the district court issued orders on the pending motions. A-1403-04. Elysium then wrote asking that ChromaDex "hold off on drafting the documentation." A-1404. ChromaDex immediately wrote back stating: "I haven't seen the ruling either but the settlement structure and amount isn't impacted." *Id.* A week later, on February 10, 2022, Elysium reneged and claimed that it was open to "discussing new terms." A-1404-05.

2. Prior Settlement Discussions

In 2021, before trial in the California Action, the parties discussed a complex, global resolution that would have resolved *all claims* between the parties, including the Delaware Action. A-1405. That deal would have required –among other things—execution of several agreements memorializing a comprehensive,

multi-faceted, ongoing business arrangement: a supply agreement between the parties and third-party W.R. Grace ("Grace") (with pricing and royalty terms to be negotiated); research and development and other intellectual property coordination; ChromaDex's assistance in helping Elysium resolve *separate* patent litigation with Grace; global resolution of *all* litigation between the parties; and jointly authored public statements. A-1405-06. A term sheet was circulated in September of 2021, which stated "[a]ny agreement with respect to the matters set out in this term sheet would become binding on the parties only when and if the parties enter into one or more definitive agreements regarding such subject matter" and contained a proposal that the parties would reach two definitive agreements. A-1406-07. Ultimately, these discussions were unsuccessful. A-1407.

C. Facts Relevant to the Citizen Petition Order

Beginning in approximately August 2017, Elysium began manufacturing Basis using NR and PT from an unknown supplier. A-1259. ChromaDex thereafter conducted in-house testing of Basis, which revealed that the NR and PT Elysium was now using from the unknown supplier contained toluene, an industrial solvent that potentially poses "serious health concerns" when ingested. *Id.* Thereafter, ChromaDex filed a citizen petition (the "Citizen Petition") with the FDA, asking the agency, among other things, to "take all appropriate remedial action, including [ordering] that Elysium cease distribution of its Basis product and

take other appropriate enforcement action, including seizure of violating products and an injunction against the manufacturers and distributors . . . ." *Id.*

In response, Elysium initiated the New York Action on September 27, 2017, by filing a complaint alleging that the Citizen Petition was false, misleading, and filed for the sole purpose of harming Elysium. *Id.*

On October 26, 2017, ChromaDex moved to dismiss Elysium's Complaint under FRCP 12(b)(6). *Id.* ChromaDex argued that the Citizen Petition qualifies for protection under the *Noerr-Pennington* doctrine, which safeguards the First Amendment right to petition the government for a redress of grievances by immunizing citizens from liability attending to that right. A-1260-61. Elysium countered that ChromaDex's activity fell under *Noerr-Pennington's* narrow "sham exception." A-1261.

On January 16, 2018, ChromaDex submitted a supplemental citizen petition ("Supplemental Petition") to the FDA. *Id.* On January 25, 2018, Elysium submitted a comment to the Supplemental Petition, informing the FDA that it removed toluene from its new version of Basis. *Id.* Elysium explained that "Although [it] believes that the ICH Guidelines establish the safety of toluene at the minimal level previously found in Basis, Elysium elected to eliminate the presence of toluene from Basis as part of its continuing efforts to ensure superior product quality." *Id.*

On September 27, 2018, the district court denied in part ChromaDex's motion to dismiss and converted the remainder of the motion – the argument that ChromaDex was immune from liability under the *Noerr-Pennington* doctrine – to a motion for summary judgment. A-1261-62.

On February 7, 2019, the district court granted ChromaDex's motion for summary judgment. A-1270.

D. Facts Relevant to the MSJ/*Daubert* Order

On February 2, 2022, the district court issued its Opinion and Order on the parties' motions for summary judgment and its Opinion and Order on the *Daubert* motions. A-1403. The district court's summary judgment opinion dismissed in full ChromaDex's complaint and allowed Elysium's counterclaim to survive in part. A-1404. In its *Daubert* opinion, the Court granted Elysium's motion to exclude portions of the opinions of ChromaDex expert Bruce Isaacson, and excluded the testimony of ChromaDex experts Lance Gunderson and Kurt Hong in their entirety. *Id.*

SUMMARY OF ARGUMENT

First, the district court did not clearly err in finding there was a binding settlement agreement between the parties. The District Court correctly found that on the February 2 Call with Elysium, ChromaDex conveyed the Offer containing all Material Terms, and Elysium accepted the Offer in the Acceptance Email the

next day. Moreover, the district court correctly found, after reviewing the history and context of the parties' settlement negotiations, that there were no express reservations by any parties regarding the at-issue settlement. Finally, the district court correctly found that the at-issue settlement agreement did not need to be in writing, but in any event constituted a writing given the Material Terms were set forth in the Acceptance Email. In reaching its conclusion, the district court correctly found that Elysium's evidence did not refute ChromaDex's evidence that a binding settlement had been reached.

Second, Elysium has waived arguments it now sets forth for the first time, including its contention that the district court should have held an evidentiary hearing, and its new contentions as to the enforceability of the at-issue settlement agreement.

Third, there is no "inherent authority" test relevant to the at-issue order as posited by Elysium. Rather, *Winston* and its progeny set forth the standard by which a district court enforces a settlement agreement, and that standard does not change just because the at-issue settlement involves more than one case from different jurisdictions.

Fourth, this Court does not have appellate jurisdiction to consider Elysium's arguments relating to the Citizen Petition Claims because those claims are clearly subsumed by the at-issue settlement agreement that the district court enforced.

Fifth, the district court applied the correct standard in determining that ChromaDex's Citizen Petition was not objectively baseless because, among other things, it prompted Elysium to remove toluene from its product, which any objective filer of this petition would have viewed as a favorable outcome.

Sixth, the district court erred in granting summary judgment for Elysium on ChromaDex's false advertising claim where the record abounds with evidence that establishes, and at the very least creates triable issues of fact as to, the falsity of Elysium's advertising claims and the injury to ChromaDex caused thereby.

Seventh, the district court committed legal error by allowing Elysium's false advertising claim to survive in part despite Elysium's admission that it has no evidence of materiality and no evidence of injury caused by ChromaDex's alleged false advertising.

Eighth, the district court abused its discretion in excluding expert reports and testimony offered by ChromaDex.

STANDARDS OF REVIEW

A. The Settlement Order

ChromaDex agrees with Elysium that on appellate review of an order enforcing a settlement agreement, the Court reviews a district court's findings of law under a *de novo* standard, and its factual conclusions under a clearly erroneous standard of review. However, ChromaDex disagrees with Elysium's application of

the *de novo* standard of review. Specifically, Elysium couches several of its arguments/issues as a misapplication of law by the district court, when in reality Elysium takes issue with the district court's findings of *fact*. *See Ciaramella v. Reader's Dig. Ass'n, Inc*., 131 F.3d 320, 322 (2d Cir. 1997). Thus, all of Elysium's arguments regarding the at-issue settlement order should be governed by the clearly erroneous standard of review.

Moreover, ChromaDex disagrees with Elysium that there is a separate "inherent powers" test subject to *de novo* review when determining whether a district court had authority to enforce a settlement agreement. Rather, as discussed *supra,* the standard of review regarding a district court's authority to enforce a settlement agreement is articulated in *Ciaramella*–it is a *de novo* review regarding the district court's findings of law and a clearly erroneous standard regarding its factual determinations. Here, as articulated above, Elysium only takes issue with factual determinations the district court made and thus the clearly erroneous standard is applicable.

B. The Citizen Petition Order

The standard of review applicable to whether a lawsuit is "objectively baseless" for purposes of the sham litigation inquiry under the *Noerr-Pennington* doctrine is clearly erroneous when reviewing the district court's findings of fact and *de novo* when reviewing the district court's conclusions of law or mixed

questions of fact and law. *See Hirschfeld v. Spanakos,* 104 F.3d 16, 19 (2d Cir. 1997).

C. The Conditional Cross-Appeal

"On appeal from a grant of summary judgment [this Court] review[s] the record de novo to determine whether genuine issues of material fact exist requiring a trial." *Morales v. Quintel Entm't, Inc.*, 249 F.3d 115, 121 (2d Cir. 2001). Summary judgment will be affirmed only if "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FRCP 56(a). A dispute of material fact is genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

The exclusion of expert testimony is reviewed for abuse of discretion. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 138-39 (1997).

APPEAL ARGUMENT

I. The Court Correctly Granted ChromaDex's Motion to Enforce the Parties' Settlement Agreement

A. The district court did not clearly err in finding that there was mutual assent between the parties.

In determining mutual assent, courts look "to determine whether there is a sufficiently definite offer such that its unequivocal acceptance will give rise to an enforceable contract." *Express Indus. & Terminal Corp. v. N.Y.S. Dep't of Transp.*,

93 N.Y.2d 584, 590 (1999). The court's analysis in *Forcelli v. Gelco Corp*., 109 A.D.3d 244 (2d Dep't 2013) is illustrative. There, one party had sent an email confirmation of an oral agreement that set forth the material terms, contained an expression of mutual assent, did not condition the settlement on any further occurrence, and contained the author's name typed at the bottom. The court found the parties had formed a valid contract. *Id*. at 251. No post-acceptance communication is needed for a contract.

Elysium argues in its opening brief that the district court disregarded contrary evidence in the record that supported Elysium's position that there was no settlement agreement between the parties, and that the district court was clearly erroneous in finding that "Mr. Carter declares, without contradiction, that he stated on the February 2 Call that if Elysium agreed to the terms he laid out then the parties would have a deal and that neither he nor Mr. Wilhelm stated that the settlement agreement (should Elysium accept the offer) would be contingent on a signed document." Br. 31. Elysium is incorrect.

In his declaration, Mr. Carter states that he told Mr. Wilhelm during the February 2 Call that if Elysium agreed to all the material terms, the parties "would have a deal." Appendix for Appellant ("A") 1293. Elysium and Mr. Wilhelm did not dispute the contents of this call. In the Acceptance Email, Mr. Wilhelm reiterates all the material terms, and that Elysium would accept even though it was

a "tough sell." A-1301. Mr. Wilhelm concludes the Acceptance Email with: "I understand that *now that we have an agreement* you will get started on documentation" and types his name in the signature block. *Id.* (emphasis added). Now, grasping at straws, Elysium attempts to manufacture a contradiction between the accounts of Mr. Carter and Mr. Wilhelm.

First, Elysium argues that while Mr. Carter "claimed that he conveyed each and every single term constituting the settlement offer," Mr. Wilhelm contrastingly stated that Mr. Carter "only *discussed* additional 'guarantees' or conditions with respect to Elysium's second installment payment." Br. 31-32 (emphasis added). Elysium's argument is disingenuous and is an attempt at obfuscation. Whether or not each of the Material Terms were "discussed," Mr. Carter certainly "conveyed" the Material Terms, and Mr. Wilhelm never denied this in his declaration. *See* A-1303-05. Indeed, Mr. Wilhelm clearly understood the Material Terms that constituted the Offer because he re-stated them verbatim in the Acceptance Email. A-1301. There is no contradiction. The focus of the February 2 Call was to discuss the additional guarantees because the other terms had already been discussed in depth. The additional guarantees were the remaining hold-up. A-1291. So, for Elysium to latch onto the term "discussion" is a smokescreen—the distinction here is immaterial, particularly in light of the fact that the Material Terms were subsequently memorialized in the Acceptance Email.

Second, Elysium contorts itself further by arguing that the Material Terms (excluding the guarantees) contained in the Acceptance Email were "additional terms" that "may not be considered more than an unaccepted counteroffer in the first place." Br. 32. This is not a serious argument. As an initial matter, as discussed *supra*, Mr. Carter declared he conveyed the Material Terms to Mr. Wilhelm during the February 2 Call, and Mr. Wilhelm never disputed this—and indeed reiterated the Material Terms in the Acceptance Email. A-1292-93, -1301. Moreover, if the Acceptance Email was really an unaccepted counteroffer, as Elysium contends, then why did Mr. Wilhelm state therein that Elysium would accept the Offer even though it was a "tough sell" and conclude the email by stating "I understand that now that we have an agreement you will get started on documentation"? *See* A-1301. If Mr. Wilhelm was presenting a counteroffer, should not he have waited for ChromaDex to accept before declaring that the parties "have an agreement"? For this reason, Elysium's argument is easily refuted. Notably, Mr. Wilhelm does not state anywhere in his declaration that he intended the Acceptance Email to be a counteroffer, nor does he state anywhere in his declaration that he did not mean it when he stated that the parties now had an agreement. *See* A-1303-05. Mr. Wilhelm has offered no alternative meaning to this statement, which can be only construed one way—that the parties now had an agreement.

Third, Elysium attempts to get around the fact that Mr. Wilhelm did not dispute that Mr. Carter informed him on the February 2 Call that "if his clients agreed to the Material Terms, then the parties would have a deal" by pointing to two statements by Mr. Wilhelm that Elysium argues contradict Mr. Carter's statement. Specifically, in order to manufacture a contradiction, Elysium homes in on Mr. Wilhelm's assertions in his declaration that "Mr. Carter never expressed to me that ChromaDex was withdrawing its repeated reservation that it required a formal, written agreement to be bound," and "Mr. Carter also did not state that ChromaDex's Board of Directors had provided a final approval of settlement". Elysium's efforts are once again unavailing. Br. 32. ChromaDex agrees that on the February 2 Call Mr. Carter did not state that (1) a formal writing was required; or (2) Board approval was required, because *they were not conditions of the Offer*, as made clear in Mr. Carter's declarations. Indeed, Mr. Carter confirmed in his Supplemental Declaration that when he made the Offer, he had full authority to do so. A-1397-98. So, when Mr. Carter told Mr. Wilhelm that the parties would have a deal if the Offer was accepted—which Mr. Wilhelm does not dispute—it obviously follows that Board approval was not required, nor was a formal writing required.[2]

[2] Interestingly, Elysium's argument that Board approval and a signed writing were both required is based on its contention that these were required by ChromaDex,

B. The district court did not clearly err in finding that there was no express reservation.

Elysium's assertion that the parties repeatedly expressed that settlement was contingent on a formal writing is based on three inapposite communications: (1) an August 2021 email from Mr. Carter summarizing high-level settlement discussion points for the first time; (2) a September 2021 draft term sheet emailed to Elysium; and (3) an email from Mr. Carter during this time period to schedule a call to discuss the term sheet. Br. 38; A-1307-11, -1313-16, -1318-19, 1333-40. Elysium, however, conflates prior, unsuccessful settlement communications with the exchange on February 2-3, 2022, which was an entirely different—and substantially narrower—deal to end certain litigation.

As an initial matter, Elysium attempts to couch its issue with the district court's finding regarding the lack of an express reservation as a misinterpretation and misapplication of the *Winston* factors, but really the issue is factual not legal. Thus, the clearly erroneous standard of review should be applied. Here, contrary to Elysium's assertions, the district court evaluated the entire context and history of the parties' various negotiations and came to the correct conclusion after reviewing the evidence that there was no express reservation applicable to the at-issue settlement. The district court did not clearly err in its determination.

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not Elysium. But Mr. Carter submitted two declarations confirming that these were not requirements and he had full authority to make the Offer when he did so.

First, Elysium cites months-old, failed settlement communications, but omits the context of those discussions. Before trial in the California Action, the parties discussed a complex, global resolution that would have resolved all claims between the parties, including Delaware patent litigation (and any other intellectual property claim). A-1395-96. That deal would have required—among other things—execution of several agreements memorializing a comprehensive, multi-faceted, ongoing business arrangement: a supply agreement between the parties and third-party W.R. Grace ("Grace") (with pricing and royalty terms to be negotiated); R&D and other intellectual property coordination; ChromaDex's assistance in helping Elysium resolve separate patent litigation with Grace; a global resolution of all litigation between the parties; and jointly-authored public statements. *Id.* Obviously, establishing a complex ongoing business relationship and resolving a third-party's claims would require further discussions and separate written agreements. However, those discussions were ultimately unsuccessful, and the parties went to trial in California. A-1397

In contrast, starting in December 2021, the parties initiated new settlement discussions that contemplated a far narrower and simpler resolution: only mutual dismissal of this action and claims tried to the jury in California, and a payment by Elysium to ChromaDex. *Id.* Notably, these discussions did not include any ongoing business relationship, resolution of the parties' Delaware patent litigation,

or any commitment with respect to the Grace-Elysium litigation. *Id.* Based on the foregoing facts, the district court correctly found, *inter alia,* that "[t]he offer reflected in the February 2 Call and accepted by the February 3 Email was fundamentally different and far simpler [than the 2021 settlement negotiations]." A-1411. The district court also correctly found that the at-issue settlement "did not contemplate any continuing relationship between the parties, and there would have been no need for extensive documentation between the parties." *Id.* Finally, the district court correctly found that the Offer "did not contain any express or implicit reservations" and "[a]ll that was necessary was to prepare the documentation to effect what had already been agreed." *Id.*

The authorities on which Elysium relies offer it no support. In *Ciaramella*, the court found that the parties did not intend to bind themselves until the settlement had been signed because several paragraphs in the yet-to-be-signed settlement agreement itself "contemplated the moment of signing as the point when the settlement would become binding." 131 F.3d at 324-25. Similarly, in *Davidson Pipe Co. v. Laventhol & Horwath*, 1986 WL 2201, at *4 (S.D.N.Y. Feb. 11, 1986), the court found that the language in a settlement agreement that emphasized the execution date evinced an intent not to create a binding settlement until formal execution. *See also R.G. Group, Inc. v. Horn & Hardart Co*., 751, F.2d 69, 75 (2d Cir. 1984) (draft included integration and stated rights established "when duly

executed"). In contrast, the Acceptance Email includes no such caveat. Mr. Wilhelm confirms the February 2 Call, details all material settlement terms, states the parties "have an agreement," and asks ChromaDex to prepare the "documentation."[3] A-1301. As the district court found, "[n]either the contents of the February 2 Call nor those of the February 3 Email are conditional in any respect; neither reflect an intent not to be bound absent a written agreement signed by both sides." A-1409.

Elysium also relies for the first time on additional authorities that are equally inapposite. For example, in *Stockalert, Inc. v. The Nasdaq Stock Mkt, Inc*., 95-cv-9335, 1998 WL 556036 (S.D.N.Y. 1998), the court dealt with a situation where "[the] purported statement [that the parties had a deal] came after two months of negotiating language and provisions, exchanges of written drafts that contained merger and no modification clauses as well as execution pages for the parties' signatures, and memos indicating that legal review of drafts was necessary prior to the execution of an agreement." *Id.* at *11; *see also Reprosystem, B.V. v. SCM Corp.,* 727 F.2d 257, 262 (2d Cir. 1984) (finding a signed writing was required where, among other things, drafts of the at-issue agreement that were exchanged

[3] The Acceptance Email distinguishes between an "agreement" (which Mr. Wilhelm states the parties now have) and "documentation" to perform the agreement—the stipulated judgment and dismissals that need to be filed with courts. Elysium had never informed ChromaDex that settlement was contingent on yet another writing.

contained numerous requirements that there be a signed formal writing). Here, again, there were no written drafts of the at-issue settlement exchanged with execution pages or merger/no-modification clauses and no memos either – indeed, there were no written drafts exchanged at all. To the extent Elysium wants to try and conflate the 2021 negotiations with the 2022 negotiations, the district court correctly found that they were distinct and dealt with fundamentally different settlement terms, as discussed *supra*.

Additionally, Elysium relies on *ABC Trading Co., Ltd. v. Westinghouse Elec. Supply Co*., 382 F. Supp. 600 (E.D.N.Y. 1974) where the court found no intent to be bound absent an executed settlement agreement because defendant's counsel sent eight letters to plaintiff's counsel apprising him that the proposed settlement depended on a substantial contribution from a non-party supplier, as well as letter that expressly stated that his client's settlement offer was contingent on a formal written agreement. *Id.* at 602. Here, again, there were no such expressions in the negotiations relevant to and leading up to the at-issue settlement agreement. Moreover, in contrast to the 2021 negotiations, which involved non-party Grace, there were no non-party issues involved in the at-issue settlement agreement reached in 2022.

Second, Elysium's reference to ChromaDex's requirement of Board approval is a red herring. *See* Br. 38. On the February 2 Call, Mr. Carter informed

Mr. Wilhelm that if Elysium accepted the offer, the parties would have a deal (which Elysium and Mr. Wilhelm do not dispute). A-1293. Mr. Carter—on behalf of ChromaDex—identified no further precondition or suggested in any way that he lacked settlement authority. A-1293. Mr. Wilhelm has never stated that it was his understanding that the February settlement required further approval from ChromaDex. *See* A-1303-05; A-1297-1302. Nor did his February 3 email include any such understanding. A-1346-47. To the extent relevant, Mr. Carter had full settlement authority prior to the call. A-1397-98.

Third, Elysium relies on an email its outside counsel sent on January 5, 2022, to suggest that the parties contemplated a formal signed writing. A-1333. However, in that email, Elysium merely stated that if ChromaDex agreed to Elysium's proposed terms, the parties "can attempt to notify the New York court that they have reached an agreement in principle and request a continuance of the January 10 hearing date (or possibly a conditional dismissal of the case)." *Id.* Nowhere in this email did Elysium's counsel require (or even mention) a formal signed agreement to effectuate settlement. *See id.* Given the upcoming summary judgment hearing in this action, it would have been routine for the parties to notify the court of a settlement and request additional time to file a dismissal. Indeed, none of the emails leading up to the at-issue settlement—from either Elysium or ChromaDex—even mentions such a condition, nor was it mentioned in the

Acceptance Email. Regardless, courts routinely enforce "in principle" settlement agreements. *See RES Exhibit Servs., LLC v. Genesis Vision, Inc*., 155 A.D.3d 1515, 1518 (4th Dep't 2017) (non-material terms left for future negotiations does not render agreement ineffective); *Bed Bath & Beyond Inc. v. IBEX Constr., LLC*, 52 A.D.3d 413, 414 (1st Dep't 2008) ("[U]se of the language 'subject to' in the LOI, and reference to the execution of a construction agreement as a 'qualification,' do not amount to an express reservation of the right not to be bound . . . ."); *Conopco, Inc. v. Wathne*, 190 A.D.2d 587, 588 (1st Dep't 1993) ("The Letter Agreement contains all of the essential terms of the contract, and the fact that the parties intended to negotiate a 'fuller agreement' does not negate its legal effect."); *Vari-O-Matic Mach. Corp. v. N.Y. Sewing Mach. Attachment Corp*., 629 F. Supp. 257, 259 (S.D.N.Y. 1986) (enforcing agreement "reached in principle"); *Hostcentric Techs., Inc. v. Republic Thunderbolt, LLC*, 2005 WL 1377853, at *5 (S.D.N.Y. June 9, 2005) ("[T]he mere fact that the parties contemplate memorializing their agreement in a formal document does not prevent their informal agreement from taking effect prior to that event."); *see V'Soske v. Barwick*, 404 F.2d 495, 499 (2d Cir. 1968) ("To overcome the reasonable inference we draw from the language of the correspondence that the parties did indeed intend thereby to create a binding contract, appellees must do more than merely point to the circumstance that a formal document was contemplated."); *Westwide Winery, Inc. v. SMT Acquisitions,*

LLC, 511 F. Supp. 3d 256, 261-62 (E.D.N.Y. 2021) (email stating that the parties "will have to paper this and of course confirm the details with our clients" did "not 'expressly' reserve the right not to be bound"); *Brannon*, 2015 WL 13746664, at *5 ("intention to memorialize the agreement in writing does not vitiate the binding power of the e-mail exchange").

C. The district court did not clearly err in finding that all the material terms had been agreed upon.

Elysium argues that the district court "improperly altered" the third *Winston* factor into a "material terms standard" that was rejected by the Second Circuit in *Winston*. Br. 40. Elysium misapprehends the law. In *Winston*, it is true that the court stated that outstanding terms that may be characterized as "minor or technical" may negate a binding contract, but the court was focused on what was important to the parties (*i.e.*, material). *Winston v. Mediafare Entm't Corp.*, 777 F.2d 78, 82 (2d Cir. 1985). Specifically, the *Winston* court focused on the fact that counsel for the parties had "continually redraft[ed] the specific terms of [the] proposed agreement" and that the evidence indicated that these terms were "important enough to the parties to have delayed final execution and consummation of the agreement." *Id*. at 82-83. Indeed, the court emphasized that what matters is what is material to the parties so as to not "deprive the parties of their right to enter into only the exact contract they desired." *Id*. at 83. Similarly, in *R.G. Group*, which Elysium cites for the same proposition, the court found that

the plaintiff's chief operating officer "admitted in a deposition that the territory issue was an important one." *R.G. Group*, 751 F.2d at 76. Moreover, in *Ciaramella*, a case Elysium cites in the same section of its brief for a different proposition, the Second Circuit focused on whether the parties "had agreed on all *material* terms." *Ciaramella*, 131 F.3d at 326 (emphasis added). Therefore, contrary to Elysium's characterization of the law, the courts look to whether the parties agreed to all the material terms (*i.e.*, what was important to the parties themselves) in order to determine whether a binding agreement was entered into.

With respect to the district court's finding that all material terms had been agreed upon, Elysium first argues that the settlement "[could not] be consummated without the documentation of the stipulated judgment in the California Litigation." Br. 39-40. Elysium misses the mark. As the district court found, the "documentation" (*i.e.*, the Stipulated Judgment and notice of dismissal) were "necessary only to effectuate [the settlement agreement] but "[were] not necessary to have a settlement." A-1417. Settlement agreements are routinely entered into without the form of the effectuating documentation attached. It ultimately comes down to what is material to the parties. Elysium points to *Ciaramella*, *supra*, 131 F.3d at 325, but that case only reinforces why Elysium's argument is flawed. In that case, one of the drafts of the at-issue settlement agreement contained a copy of a letter of reference that was required by the agreement, and the parties went back-

and-forth on the wording of that letter. In *Ciaramella*, the exact wording of the letter was important to the parties in that case. Here, there were no such drafts exchanged or any indication whatsoever that settlement required agreement on the exact wording of the stipulated judgment or the notice of dismissal. All that mattered with respect to the documentation was that the New York Action would be dismissed in its entirety with prejudice, and the parties would request a stipulated judgment in the California Action in the amount of $2.5 million to ChromaDex on all issues tried to the jury in the California Action. A-1301.

Elysium next argues that there were outstanding key terms that the parties still needed to agree on, including the dates of the payments, the applicable interest rate, confidentiality, enforcement provisions and choice of venue and law provisions. Br. 40. Not true. As an initial matter, the Acceptance Email did not mention any of these terms. *See* A-1301. To the contrary, Mr. Wilhelm went out of his way to explain that Elysium would not accept any further conditions. *Id.* Nor does Mr. Wilhelm declare that Elysium contemplated these additional terms. *See* A-1303-05. Moreover, in Mr. Wilhelm's subsequent correspondence attempting to renege on the Acceptance Email, he did not list any of these terms as a basis for why a settlement agreement had not been reached.[4] A-1297-1302. Mr. Wilhelm

[4] Indeed, in Mr. Wilhelm's subsequent correspondence to Mr. Carter attempting to renege on the agreement after the orders were published, he also did not reference Mr. Morris still having to assent as a reason for why there was no agreement, nor

should be bound to his contemporaneous emails as opposed to *ex post facto* arguments as to why there was no agreement devised by his lawyers.

As for the terms Elysium now raises, not every agreement is confidential. Moreover, the stipulated judgment and the dismissal would, as a matter of law, be public non-confidential documents, so confidentiality would not have made any sense anyways. As for venue, the settlement agreement contemplates a stipulated judgment; the FRCP governs enforcement of a federal judgment. *See* FRCP 69, *see also* Wright & Miller, 12 Fed. Prac. & Proc. Civ. § 3013 (3d ed.) Issuance of Execution or Other Process ("Execution normally issues from the [judgment-rendering] court"); *see also Scheinmann v. Dykstra*, No. 16 Civ. 5446, 2017 WL 1422972, at *3 (S.D.N.Y. Apr. 21, 2017) ("[A] judgment would effectuate all the agreed-upon terms . . . ."). Moreover, not every settlement agreement has to have a choice-of-law provision. *See Scheinmann*, 2017 WL 1422972, at *3 ("That a mutual release is, as Smith argued, a 'standard item' in many—but not all—settlements does not make it material or render the agreement ambiguous where the intent to include such a term was not expressed."). As for the payment dates, Elysium never raised this argument below and it is thus waived. Regardless, the

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did he state that he understood his Acceptance Email to be a counteroffer, or that he understood that ChromaDex still required Board approval. Notably, Elysium never indicated, throughout its settlement discussions with ChromaDex, that Mr. Morris would need to separately approve any resolution. A-1398.

difference between February 1 or February 28 is hardly material and certainly was not material to the parties, otherwise it would have been set forth in the Offer and/or Mr. Wilhelm's February 3 email. Finally, Elysium spins its wheels regarding the amount of interest—again, if the amount of interest was material, the Offer would have set forth that amount and/or Mr. Wilhelm's would have responded that further negotiations were required regarding the precise amount of interest. That the Offer and Acceptance Email were silent on this (as well as the other boiler plate terms that Elysium now raises) illustrates that they were not material to the parties.

Finally, Elysium argues that because Mr. Wilhelm stated Elysium would not accept additional guarantees or conditions and that he was not trying to "gain leverage going forward" that somehow means there was no agreement. Br. 42. However, as the district court found, these statements only reinforce that a settlement agreement was reached. A-1414 ("[Elysium's] argument [that many terms remained to be discussed] is belied by the language of the parties. In accepting the offer, Elysium made clear that it would not accept any 'conditions beyond the two" ChromaDex had described in its offer . . . ."). Moreover, Elysium makes no effort to square its assertion with the fact that Mr. Wilhelm stated that he understood that the parties now "have an agreement." A-1301. Further, even assuming *arguendo*, that Elysium is correct that Mr. Wilhelm, contrary to his own

words declaring an agreement had been reached, believed he could renege on his agreement, his subjective misunderstanding of the legal effect of his acceptance of the Offer is irrelevant. *Hostcentric*, 2005 WL 1377853, at *6 ("In determining the parties' intent, a court must look, not to their after-the-fact professed subjective intent, but their objective intent as manifested by their expressed words and deeds at the time."); *see Brannon*, 2015 WL 13746664, at *5 (parties "should be held to their promises and courts should not be 'pedantic or meticulous' in interpreting contract expressions"). And even if it was relevant, which it is not, Mr. Wilhelm should have in his sworn declaration explained his subjective mindset when he chose to write these words or the words that the parties "have an agreement," but he did not.

D. The district court did not clearly err in finding that the fourth *Winston* factor weighed in favor of ChromaDex.

Elysium attempts to argue that the district court erred as a matter of law in finding that the at-issue agreement was not the type of contract that is usually committed to writing because the settlement amount was $2.5 million. However, as the district court articulated, the case law is clear that "there is no rigid cutoff that settlements that exceed a million dollars must always be in the form of a document executed by both sides." A-1417. Indeed, in determining this factor, courts must look to the specific circumstances of each case. *Grgurev v. Licul*, 2016 WL 6652741, at *7 (S.D.N.Y. Oct. 21, 2022). The district court engaged in a

comprehensive analysis of the specific elements of the at-issue settlement agreement and correctly found that the fourth *Winston* factor favored ChromaDex. A-1416-17.

Here, the parties agreed to a settlement amount of $2.5 million to be made in two equal installments (with interest accruing on the second $1.25 million payment unless payment is made on time), to file a request for partial judgment in the California Action, and to dismiss this action in its entirety with prejudice. Far from carrying into perpetuity, the agreement will last only until payment of the settlement amount. Moreover, as found by the district court, "[t]he magnitude of the settlement here was relatively small given the nature of the two commercial litigations it would resolve." A-1417. In sum, the agreement is not complex. *Compare Hostcentric*, 2005 WL 1377853 at *9 (finding the fourth factor to weigh in favor of enforcement where emails memorialized all the terms and "the agreement would last only the short time necessary for payment and removal of property, not for a lengthy time into the future") *with Adjustrite Sys., Inc. v. GAB Bus. Servs., Inc*., 145 F.3d 543, 551 (2d Cir. 1998) (finding the fourth factor to weigh against enforcement "[i]n view of the size of the transaction, the nature of the assets being purchased [intellectual property rights], and the length of the contemplated employment contracts [five-year periods]").

Moreover, Elysium's argument is moot because, as found by the district court, once Elysium agreed to the Material Terms in writing, "[t]he parties 'were not dealing with an oral agreement' but rather one that had been accepted and confirmed in writing by Elysium." *See, e.g., Scheinmann*, 2017 WL 1422972, at *5 ("In this case, moreover, there was a writing—Smith's counter-offer email that Bierman accepted by email. Those emails memorialized the agreement's only terms, and settled this lawsuit."); *Hostcentric*, 2005 WL 1377853 at *9-10 ("Moreover, in this case there was a writing-Republic's email (and Hostcentric's email accepting Republic's proposal without change). Those emails memorialized all the terms [of the agreement]."). Thus, as in *Hostcentric*, "even if one were to find that this type of agreement should be in writing, it was—the parties were not dealing with an oral agreement but one written in an email . . . ." *Hostcentric*, 2005 WL 1377853 at *10. Notably, Elysium does not provide any argument or case authority on this point in its opening brief and thus should be deemed to have abandoned any challenge to this finding by the district court. *See Int'l Tech. Mktg., Inc. Verint Sys., Ltd.*, 850 Fed. Appx. 38, 40 n.1 (holding that an argument that is not raised and developed in appellant's brief is deemed abandoned).

E. The district court had authority to enforce the at-issue settlement agreement.

Elysium argues, without citing to any authority, that the district court was not permitted to enforce a settlement agreement that resolved two cases in different jurisdictions. Br. 28. Elysium is incorrect.

"A district court has the power to enforce summarily, on motion, a settlement agreement reached in a case that was pending before it." *Velazquez v. Yoh Serv., LLC*, 2017 WL 4404470, at *2 (S.D.N.Y. Sept 25, 2017). Here, the district court was presiding over a case where both ChromaDex and Elysium were parties. The notion that the district court could not enforce a settlement agreement as to Elysium just because the settlement resolved two different cases is completely unsupported. Indeed, as the district court noted, if Elysium's position were to be adopted, "it would mean that any settlement that resolves disputes spanning multiple jurisdictions and that lacks a forum selection clause is categorically unenforceable." A-1415.

Elysium attempts to create a side-show by referencing Mark Morris, an Elysium executive who is a party to the California Action but not the New York Action. But this is a red herring. Elysium presents no argument for why the district court could not enforce the settlement agreement *as to Elysium* – which is precisely what the Court did. Elysium does not and cannot dispute that the district court had jurisdiction over Elysium and had the authority to enforce the settlement

agreement as to Elysium based on the evidence in the record. Any discussion or argument regarding the *effect* of the at-issue settlement order on Mr. Morris, based on a *res judicata* theory or any other theory, is not relevant to the analysis here regarding whether the district court clearly erred when it enforced the settlement agreement as to Elysium.

Finally, Elysium misstates the effect of the district court's ruling. Elysium claims that if the Court were to enforce the contract, it would contradict the jury verdict and the amount that Judge Carney ordered when denying ChromaDex prejudgment interest. Br. 29. Not so. The at-issue settlement resolved relevant claims in California and New York, including appellate and post-judgment rights. Notably, the $2.5 million amount appears nowhere in the jury verdict. A-1321-31. Parties resolve claims for a negotiated amount to avoid further litigation. Moreover, the at-issue settlement was reached before Judge Carney ruled on the prejudgment interest issue. A-1412. The fact that the issue was ruled on at all was due to no fault of ChromaDex, as the district court found when it addressed the partial performance factor (which Elysium has abandoned on appeal). A-1412-1413.

F. Elysium has waived arguments it now raises but did not raise below.

Elysium improperly raises a number of arguments for the first time in the instant appeal. *See Jacobson v. Fireman's Fund Ins. Co.*, 111 F.3d 261, 266 (2d

Cir. 1997) (We have "repeatedly held that if an argument has not been raised before the district court, we will not consider it," but "[t]his general rule may be disregarded . . . where the issue is purely legal and there is no need for additional fact-finding"); *Readco, Inc. v. Marine Midland Bank*, 81 F.3d 295, 302 (2d Cir. 1996). Because these newly raised arguments are not "purely legal," they should be deemed waived and not considered.

First, Elysium argues, without citing any authority, that the district court should have held an evidentiary hearing. Br. 29. But Elysium never requested an evidentiary hearing below. Thus, this argument should not be considered.

Second, Elysium argues there are contradictions between Mr. Carter's declaration and Mr. Wilhelm's declaration, and that the two cannot be reconciled, but it never made this purely factual argument below. Br. 31-32. It is thus also waived.

Third, Elysium argues for the first time that the Acceptance Email was really a counteroffer. Br. 32. Elysium did not raise this argument to the district court, and it is thus waived.

G. Public policy considerations favor ChromaDex.

Elysium argues that "important policy considerations mandate against a forcible settlement." Br. 45. As an initial matter, "public policy" is not a *Winston* factor and is not relevant to the instant appeal. Regardless, such considerations

strongly favor ChromaDex's position. Courts in this Circuit adhere to a strong public policy in favor of enforcing out-of-court settlements. Indeed, "voluntary out-of-court settlements are highly favored and will be upheld whenever possible." *Allen v. Colgate Palmolive Co*., No. 79 Civ. 1076, 1986 WL 8218, at *1 (S.D.N.Y. Feb. 20, 1986). Settlements alleviate overburdened court calendars, save judicial resources, and spare parties from the time and expense of further litigation. *See id*. Elysium's conduct here exemplifies the importance of enforcing settlement agreements.

II. The Citizen Petition Claims Are Not Ripe for Appeal

Elysium argues that if this Court affirms the Settlement Order, Elysium's appeal of the Citizen Petition would be ripe for adjudication. Br. 47. Elysium's argument is baseless. The at-issue settlement agreement dismissed "*all* claims and counterclaims *raised* in the New York action . . . ." A-1301 (emphasis added). Thus, any and all claims ever raised in the New York Action (including the Citizen Petition Claims) were clearly covered by the parties' settlement agreement. Moreover, the district court read the settlement agreement as dismissing the entire New York Action. A-1403, 1415. There was never any carve out of the Citizen Petition Claims argued by Elysium anywhere in its briefs nor was any carve out ever found by the district court. Indeed, when the parties wrote to the district court regarding the form of the dismissal of the New York Action, Elysium did not state

that the Citizen Petition Claims should be excluded from the scope of the dismissal with prejudice. *See* A-1419-25. It is true that in its order, the district court dismissed "all remaining claims and counterclaims" with prejudice, but that is because the Citizen Petition Claims had already been dismissed. *See* Appellant's Special Appendix 1. Elysium's argument that somehow the Citizen Petition Claims were excluded is not a serious argument and defies the plain terms of the at-issue settlement agreement.

III. The District Court Properly Dismissed Elysium's Citizen Petition Claims

Elysium falsely argues that the district court created a "new test" applying the *Noerr-Pennington* doctrine. The district court simply interpreted and applied controlling case authority and applied it to its findings of fact to determine that the "sham exception" did not apply. A-1254.

The "sham exception" to the *Noerr-Pennington* doctrine is a two-part test: First, the action must be "objectively baseless in the sense that no reasonable litigant[5] could realistically expect success on the merits[,]" which, in turn, is defined as being "reasonably calculated to elicit a favorable outcome." *Prof'l Real*

[5] Elysium attempts to argue that the district court should have analyzed whether "a reasonable nutraceuticals ingredient manufacturer realistically could have expected the FDA to grant the relief sought . . . in the Citizen Petition." Br. 49. But the standard is a "reasonable litigant." The end result is the same but Elysium misstates the standard.

Estate Investors, Inc. v. Columbia Pictures Indus., Inc. ("PRE"), 508 U.S. 49, 60 (1993). Second, "[o]nly if challenged litigation is objectively meritless may a court examine the litigant's subjective motivation." *Id.* at 61. "The sham exception should be construed narrowly so as to avoid intrusion upon, or a chilling of, one's right to petition under the First Amendment." *Id.* at 56. Moreover, "[t]he burden of proving the exception rests with the party attempting to invoke it." *Id.* at 60.

Regarding the first part of the test, "[a] winning lawsuit is by definition a reasonable effort at petitioning for redress and therefore not a sham." *Id.* at 60 n.5. The district court cited to numerous authorities that stand for the proposition that a "favorable outcome" is not limited to government action, and even a private settlement between the parties would constitute a "favorable outcome." A-1267 (citing numerous cases, including *In re. Fresh Del Monte Pineapple*, No. 04-Md.-1628 (RMB)(MHD), 2007 WL 64189, at *19 (S.D.N.Y. Jan. 4, 2007)). Moreover, a favorable outcome does not require a court judgment or a settlement if something of value is attained. *In re Terazosin Hydrochloride Antitrust Litig*., 335 F. Supp. 2d 1336, 1357 n.13 (S.D. Fla. 2004) (holding that it "cannot agree with Plaintiffs that a plaintiff who has filed suit and receives the relief sought (e.g., Monetary compensation, a change in conduct, etc.) could only have been deemed to have

'won' under *PRE* if it continued to litigate the case and received a favorable judgment from the court").

Here, the district court correctly found that "[p]rompting Elysium to remove toluene from Basis is, by definition, a favorable outcome" and that the at-issue Citizen Petition "expressly stated that [ChromaDex] hoped to cause the removal of Basis from the market so long as it 'contain[ed] a deleterious substance that render[ed] it injurious to health." A-1265. Moreover, the district court found that Elysium conceded that it chose to remove toluene from its product because it posed potential harm to consumers. *Id.* The district court ultimately concluded "[e]ither way, whether [ChromaDex] achieved the very outcome that motivated it to file the Citizen Petition," ChromaDex under *PRE* and its progeny "obtained an outcome that any objective filer of this particular petition would have to view as 'favorable' . . . ." *Id.*

Elysium argues that a "winning lawsuit" is not always dispositive and cites to *T.F.T.F. Capital Corp. v. Marcus Dairy, Inc.,* 312 F.3d 90, 94 (2002) for the proposition that a default judgment does not *ipso facto* constitute a favorable result for purposes of the "sham" exception. But Elysium conveniently leaves out that in *T.F.T.F.* there was a claim by the plaintiff that the default judgment was obtained through deceit (and by implication was not a valid judgment). *Id.* So, Elysium's

attempt here to create uncertainty in the standards utilized by the district court falls flat.

Elysium also argues that the FDA itself did not grant any relief and there was no settlement of the Citizen Petition Claims at that time between the parties, so there was no favorable result. However, as discussed *supra,* action by the regulatory agency itself or a settlement between the parties is not required in order to achieve a favorable result. Moreover, Elysium misstates the facts in *In re Terazosin* by claiming that the favorable results were part of a "settlement"—not so, there were numerous *voluntary* dismissals filed after Abbott received the information or results it was seeking. *Terazosin,* 335 F. Supp. 2d at 1357.

Elysium next argues that "alteration of Elysium's manufacturing process to remove any traces of toluene was *not* the relief sought under the Citizen Petition." Br. 51 (emphasis in original). However, Elysium provides no evidence or analysis for this conclusion. Notably, Elysium completely disregards the district court's finding that the at-issue Citizen Petition expressly stated that ChromaDex "hoped to cause the removal of Basis from the market so long as it 'contain[ed] a deleterious substance that render[ed] it injurious to health." A-1265. Moreover, the subjective intent of ChromaDex is not relevant to the first prong of the "objectively baseless" test—rather, this prong is based on what an objectively reasonable litigant would hope to achieve (not what ChromaDex actually hoped to

achieve). *See PRE,* 508 U.S. at 57 ("We left unresolved the question presented by this case—whether litigation may be sham merely because a subjective expectation of success does not motivate the litigant. We now answer this question in the negative and hold that an objectively reasonable effort to litigate cannot be sham regardless of subjective intent."). In any event, the district court found that Elysium had presented no evidence that ChromaDex had an improper subjective intent. A-1270 ("Since Elysium has not identified a genuine of [*sic*] issue of material fact to suggest that [ChromaDex] acted solely to damage Elysium and without a genuine interest in the removal of toluene from Basis, the sham exception is inapplicable."). Elysium has not challenged this finding by the district court in its opening brief.

Finally, Elysium attempts to make a public policy argument that the district court's "new rule" incentives abusive litigation practices. Br. 51. Again, the district court did *not* create a new rule – it accurately applied existing jurisprudence as discussed *supra.* This existing jurisprudence attempts to seek a balance between First Amendment protection and deterrence of "sham" litigation. A purely subjective analysis as Elysium proposes would be nearly impossible to apply in any consistent matter and would chill free speech and petitioning activity. Moreover, Elysium's claimed concern with abusive litigation tactics is not relevant

here as the district court found there was no evidence of any improper subjective intent by ChromaDex. A-1270.

CONDITIONAL CROSS-APPEAL ARGUMENT

If this Court affirms the district court's grant of ChromaDex's motion to enforce the parties' settlement agreement, it need not address ChromaDex's conditional cross-appeal. *See, e.g.*, *Tr. for Certificate Holders of Merrill Lynch Mortg. Investors v. Love Funding Corp.*, 496 F.3d 171, 173-74 (2d Cir. 2007) (per curiam). However, if the Court reverses the district court's Settlement Order, it should also reverse the district court's decisions granting Elysium's motion for summary judgment, allowing Elysium's claims to survive in part, and excluding certain expert testimony and reports.

IV. The District Court Erred in Granting Elysium's Motion for Summary Judgment and Dismissing ChromaDex's False Advertising Claim

A. Genuine disputes of material fact as to the falsity of Elysium's advertising claims require submitting ChromaDex's claim to a jury

The Court incorrectly granted in part Elysium's summary judgment motion as to the falsity element of the Lanham Act with respect to the following at-issue advertising statements.

1. Statements relating to the safety of Basis

ChromaDex presented abundant record evidence that Elysium falsely represented that the Dellinger Study confirmed the safety of Basis. As the district court correctly stated, Elysium's claim is what is often referred to as a "test prove claim" or "establishment claim." SA-3757. When challenging a tests prove claim, a plaintiff is not required to prove the falsity of the underlying proposition (here, that Basis is safe) by affirmative evidence; rather, a plaintiff's burden is only to show that the cited test or study did not establish the proposition for which it was cited (here, that that the Dellinger Study established that Basis is safe). As articulated by the Second Circuit, the Plaintiff must show that the underlying studies upon which the representations are based are "not sufficiently reliable to permit one to conclude with reasonable certainty that they established the claim made." *McNeil-P.C.C, Inc. v. Bristol-Myers Squibb Co.*, 938 F.2d 1544, 1549 (2d Cir. 1991) (internal quotation omitted). Plaintiff can carry this burden either by successfully attacking the validity of the underlying study directly or by showing that the study results are undermined or unsupported by other scientific studies. *Id.*; *see Castrol, Inc. v. Quaker State Corp.*, 977 F.2d 57, 62-63 (2d Cir. 1992) (distinguishing claim not based on testing, which must be proven false by affirmative evidence, from claim explicitly or implicitly based on tests or studies which may be proven false by showing that the tests did not establish the

proposition for which they were cited). Moreover, if the plaintiff can show that the tests, even if reliable, do not establish the proposition asserted by the defendant, the plaintiff has met its burden of demonstrating literal falsity. *Quaker State*, 977 F.2d at 63 ("The . . . 'sufficiently reliable' standard of course assumes that the tests in question, if reliable, would prove the proposition for which they are cited. If the plaintiff can show that the tests, even if reliable, do not establish the proposition asserted by the defendant, the plaintiff has obviously met its burden. In such a case, tests which may or may not be 'sufficiently reliable,' are simply irrelevant.").

As an initial matter, the district court erroneously placed on ChromaDex the burden of proving that Basis is not safe. As noted above, ChromaDex's burden is much narrower; it need only show that the Dellinger Study did not confirm that Basis is safe (and at the summary judgment stage, ChromaDex need only create a triable issue of fact).

The Dellinger Study results were published in an article that itself contradicts the claim that the study confirmed the safety of Basis. SA-3004-13. The study results revealed a "statistically significant" increase in LDL cholesterol levels when subjects were administered Basis and the study authors (including Elysium's founders and top scientists) conceded that "further studies are needed" to examine the impact oof Basis on LDL, "with increased number of subjects." SA-3009. As the study itself demonstrates that it does not confirm the safety of

Basis, ChromaDex has "obviously met its burden" on that ground alone. *See Quaker State*, 977 F.2d at 63.

Furthermore, ChromaDex has presented abundant additional evidence sufficient to create a triable issue of fact as to the reliability of the Dellinger Study's safety conclusion. The district court stated that ChromaDex:

> identifies no evidence regarding . . . the existence and feasibility of superior procedures, the objectivity and skill of the persons conducting the tests, the accuracy of the reports, or the results of other pertinent tests that would call into question the reliability of the Dellinger Study's conclusions.

SA-35. To the contrary, there is substantial evidence concerning those very categories. With respect to superior procedures, the Dellinger Study itself provides an example, namely a study that has an increased number of subjects. SA-3009. With respect to evidence calling into question the reliability of the Dellinger Study's conclusion that the study confirms the safety of Basis, ChromaDex identified, *inter alia*, a study of PT published in 2014 (the "Riche Study") that showed rises in LDL levels consistent with those seen in the Dellinger Study. SA-333-42.

The record also includes a letter published in a scientific journal, entitled "Pterostilbene raises low density lipoprotein cholesterol in people," which states that the Riche Study data are "wholly consistent with the [Dellinger S]tudy's finding of what is clearly a clinically meaningful increase in LDL-C." Dkt. 287-9.

In addition, ChromaDex identified a series of internal emails and meeting minutes showing Elysium executives and scientific advisory board members expressing their concern about the results of the Dellinger Study in light of the LDL data. *See* SA-7294-7345. These emails include, *inter alia*, an email from Dr. Sudhof, a Stanford medical doctor, expressing his concern to the board and ChromaDex executives that the LDL cholesterol increase seen in the Dellinger Study was "not trivial" and was of such magnitude that in the absence of further study, Elysium should remove the PT from Basis for safety purposes. *See* SA-7294. In another email, Elysium scientist Ryan Dellinger states that Basis consumers "need to be aware" of the potential for changes to their LDL levels if they increase their dose. *See* SA-7296-97. Also included are a series of emails showing Elysium's frantic efforts to minimize the LDL results through post-study manipulation of the data, but being unable to avoid the conclusion that the data shows a statistically significant increase in study participants' LDL levels. *See* SA-7296-7304. Finally, the emails show that Elysium internally concluded that further study of the impact of Basis on LDL was needed, going so far as to design such studies, but then abandoning them. SA-7295, -7309-7337, -7341.

Finally, the record includes consumer communications to Elysium expressing their concern regarding the risk of Basis increasing their LDL levels, as well as consumers who have notified Elysium that they have seen an actual

increase in their LDL levels after they began taking Basis. *See* SA-7213-92. Elysium tells these consumers there is no need to be worried, despite its concern behind-the-scenes. *Id.*

2. Statements relating to Basis being clinically proven to raise NAD+ levels based on the Dellinger Study, and being the only such supplement

In its operative complaint, ChromaDex alleges that "Elysium claims to be . . . the only supplement clinically proven effective." SA-3 ¶ 12; *see* SA-14 ¶ 63(a); SA-31 ¶¶ 120-121. ChromaDex attached an example of one iteration of this advertising claim to its complaint, Dkt 139-4, and obtained others during discovery, one of which it submitted as an exhibit to the summary judgment briefing, SA-3616. However, the district court inappropriately refused to consider ChromaDex's claim as pled and supported in summary judgment. *See* SA-3770 n.9. Instead, the district court limited its analysis to only the exact advertisement attached *as an example* to the complaint. *Id.* Because that iteration included additional language that the Court determined transformed the advertisement into being true, the district court granted summary judgment as to that advertising in favor of Elysium. SA-3770-73. The district court erred in excluding ChromaDex's false advertising claim based on Elysium's "only supplement

clinically proven effective" advertising, which was specifically pled and pursued by ChromaDex throughout the litigation.

3. Statements regarding FDA regulation of Basis

ChromaDex has alleged that Elysium makes advertising claims conveying to consumers that Elysium made a New Dietary Ingredient ("NDI") to the FDA that it, in fact, never made. Elysium attached a screenshot of Elysium's website to its complaint as an example of such advertising. ECF No. 139-11 (Ex. K). Under the heading "Our R&D Process," the website states:

> Our process for all products begins with a comprehensive evaluation of all available scientific literature and culminates in a product becoming available for purchase. In between, there are many important steps. The steps below help us discover and commercialize new products. They don't all necessarily happen in this order.

Id. Under this module, the website explains the "FDA NDI Submission" stage:

> We conduct rigorous safety studies for new dietary ingredient (NDI) submissions to the FDA. The Federal Food, Drug, & Cosmetic Act (FD&C) requires that we submit studies to demonstrate the safety of 'new dietary ingredients.

Id.

The above advertising regarding FDA NDI submissions was tested as part of the consumer survey conducted by Dr. Bruce Isaacson which was submitted by ChromaDex. SA-2219. Of survey respondents shown the above advertising, a net

percentage of 21.9% of them answered that the materials communicate or imply that Elysium submitted an NDI to the FDA. SA-2225-26.[6]

When considering the falsity of an implied message, extrinsic evidence is required. Yet, the district court engaged in its own interpretation of the message, without any reference to the on-point survey. SA-3776-78.

unilaterally construing the at-issue advertising as not communicating that Elysium submitted an NDI to the FDA (only that it was conducting studies for an NDI notification). The district court in fact states that "no reasonable reader could come away with that conclusion" despite the fact that the survey showed over 20% of respondents did. Given that the district court's decision makes no mention whatsoever of the survey evidence regarding this advertising claim, it is possible that the court overlooked that this was one of the tested advertising claims. Regardless, there is no proper basis for the court to substitute its own unilateral interpretation of the message conveyed by this advertising when there is survey evidence directly on point.

B. Elysium's false advertisements caused ChromaDex injury

To establish the existence of injury, the Lanham Act "demands only proof providing a reasonable basis for the belief that the plaintiff is likely to be damaged as a result of the false advertising." *Johnson & Johnson v. Carter-Wallace, Inc.*,

[6] This finding was not challenged by Elysium in its *Daubert* motion.

631 F.2d 186, 190 (2d Cir. 1980). There is no requirement for a plaintiff to "come forward with specific evidence that [the defendant's] ads actually resulted in some definite loss of sale." *Id.* Moreover, the Second Circuit instructs that where, as here, in the context a "nearly binary" market in which the parties were "obvious competitors," a presumption of injury applies.

Here, there is no dispute that Elysium and ChromaDex are in direct competition. Furthermore, during the relevant period, ChromaDex's TRU NIAGEN and Elysium's Basis products have been the top two NR capsule supplements in the market space, based on NR volume sold." This supports a finding of a "nearly binary" market. Indeed, because the only other companies selling NR during the relevant period were supplied by ChromaDex, there is ample support for finding a two-player market. In light of the foregoing, ChromaDex is entitled to a presumption of injury.

Moreover, even without a presumption, ChromaDex has presented evidence sufficient to show a likelihood of injury caused by Elysium's false advertising. Specifically, the record evidence shows a pronounced and substantial reduction in ChromaDex's market share during the damages period. At the liability (as opposed to damages) stage, this readily satisfies the required showing of injury and causation. *See, e.g.*, *Johnson & Johnson*, 631 F.2d at 91.

V. The District Court's Denial of ChromaDex's Motion for Summary Judgment Rested on Legal Error

A. Under clear Second Circuit precedent, Elysium's admission that it has no evidence of materiality is fatal to its claim

The district court committed legal error in concluding that Elysium can show materiality without any extrinsic evidence. In reaching its conclusion, the Court misread Second Circuit precedent.

As the district court correctly states, "[f]alsity alone does not make a false advertising claim viable." SA-3741 (quoting *Apotex Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51, 63 (2d Cir. 2016)). The plaintiff must also demonstrate that the misrepresentation was material, which "[t]he Second Circuit 'has defined [] as likely to influence purchasing decision.'" *Id.* (citing *Apotex*, 823 F.3d at 63); s*ee Church & Dwight Co., Inc. v. SPD Swiss Precision Diagnostics, GmBH*, 843 F.3d 48, 70 n.11 (2d Cir. 2016) (noting that *Apotex* "recently settled the materiality standard in this Circuit, explaining that the standard is whether the deception is 'likely to influence purchasing decisions'").

In *Apotex*, the defendant used a brochure in connection with its marketing of an anti-spasm medication that contained a graphic about drug concentration in the body and drowsiness side-effects. The district court in *Apotex* concluded—and the Second Circuit agreed—that the graphic conflated two measures of concentration of the medication's central ingredient leading to an overstatement of the

ingredient's mean concentration, and was therefore literally false. Nevertheless, the district court granted summary judgment for defendant—and the Second Circuit affirmed. As to the materiality prong, the *Apotex* plaintiff's claim failed because the plaintiff did not produce any evidence that the specific misrepresentation in the graphic was likely to influence consumers' purchasing decisions. *See Apotex Inc. v. Acorda Therapeutics, Inc.*, No. 11 Civ. 8803 (AT), 2014 WL 5462547, at *9 (S.D.N.Y. Oct 23, 2014). The court found that the plaintiff "offered no evidence that misstating the extent to which food affects mean tizanidine plasma concentration was likely to influence consumers' purchasing decisions." *Id.* Because the plaintiff had failed to make a sufficient showing of materiality, the district court found that its claim regarding the concentration graph could not survive a motion for summary judgment. *Id.*

On appeal, Apotex challenged the district court's materiality ruling, contending that it was not required to show that the relevant misrepresentation would have an effect on consumers' purchasing decisions. The Second Circuit rejected this argument, stating that it "ignores precedent from this Court which endorsed that definition of materiality—in line with the vast majority of our sister circuits." *Apotex*, 823 F.3d 51, 67 (2d Cir. 2016). The Second Circuit found that the district court made a sound decision in concluding that at most, Apotex's evidence showed that defendant's advertising overstated the plasma concentration

(i.e., that the evidence went to the truth or falsity of the advertising), "but that this evidence ultimately does not reveal anything about the impact on consumers' purchasing decision." *Id.* at 67. The Second Circuit agreed that "there is no record evidence that this inaccuracy would dissuade consumers from purchasing Zanaflex capsules. Certainly, Apotex has provided none." *Id.* The court noted that Apotex's showing consisted of generalized evidence that Acorda's increased sales of Zanaflex Capsules stemmed from its advertisement efforts, but that Apotex "fails to make the necessary showing that *the specific misrepresentation in the graphic*—in any of Acorda's advertisements—was likely to influence consumers' purchasing decisions." *Id.* (emphasis added).

Shortly after the *Apotex* decision, the Second Circuit issued its decision in *Church & Dwight* confirming that the materiality standard set forth in *Apotex* resolved any prior ambiguity. *Church & Dwight*, 843 F.3d at 70 n.11 (*Apotex* "settled the materiality standard in this Circuit, explaining that the standard is whether the deception is 'likely to influence purchasing decisions.'"). In its appeal, the defendant in *Church & Dwight* argued that "the district court failed to make findings necessary to support the court's conclusion that Defendant's misrepresentations were material to Plaintiff's claim." *Id.* at 70. The court found that the evidence "amply supported the conclusion that the falsity of Defendant's advertising was . . . material." *Id.* at 71.

In sum, the Second Circuit has made expressly clear that the materiality standard requires evidence that the alleged inaccuracy in the statements at issue would influence the purchasing decisions of consumers. Here, Elysium was required to present evidence that the specific alleged inaccuracies in the at-issue statements were likely to influence consumers' purchasing decision. Yet, Elysium readily conceded to the district court that it had none. *See* SA-3826 ("Elysium does not dispute that it has adduced no extrinsic evidence of the impact of ChromaDex's challenged advertising on consumer purchasing decision."). Rather, as the Court explained, Elysium asserted "that since the statements relate to an inherent quality of Basis they are material by definition." *Id.* Second Circuit precedent dictates that this conceded absence of materiality evidence is fatal to Elysium's claim and required the district court to grant summary judgment in favor of ChromaDex.

B. ChromaDex raised a triable issue as to injury

In denying ChromaDex's motion for summary judgment on Elysium's Lanham Act false advertising claims, the district Court held:

> To be entitled to any form of relief, Elysium will have to demonstrate injury and causation; however, since ChromaDex makes no arguments regarding Elysium's ability or inability to do so on this motion, and instead focuses on quantification of damages, the Court does not consider whether the evidence in the record is sufficient to create a triable issue as to causation and injury on Elysium's Counterclaim.

SA-3836. The district court stated that "ChromaDex makes no arguments regarding Elysium's ability or inability [to demonstrate injury and causation] in this motion." *Id.* ChromaDex, in fact, did very clearly make those arguments. ChromaDex argued in its memorandum of law that "Elysium has no evidence or quantification of harm." SA-2773. The memorandum of law further contained an entire section under the heading, "Elysium Cannot Prove Harm Or Entitlement To Relief." SA-2800-01. Therein, ChromaDex argued, *inter alia*, that "[t]o establish false advertising under Section 43(a) of the Lanham Act, a plaintiff must demonstrate that it has been injured as a result of the advertising in question"; that "causation must initially be established" before damages analysis; that "Elysium has offered no affirmative theory or quantification of damages"; that Elysium had failed "to articulate any theory underlying its supposed entitlement to recover damages, or even to quantify those damages in any way." SA-2800-01; *see also* SA-2802 ("[A]s discussed above, Elysium has no evidence to support a finding that the challenged advertising statements were misleading, material, or caused injury."). Thus, contrary to the district court's characterization, ChromaDex did not solely "focus[] on quantification of damages." To the extent the district court's misreading of ChromaDex's arguments was a result of its use of the term "harm," Black's Law Dictionary defines harm as "Injury, loss, damage; material or tangible detriment."

Notably, Elysium had no trouble understanding ChromaDex's argument. In its opposition brief to ChromaDex's motion for summary judgment, Elysium includes a section under the heading, "Elysium Has Demonstrated Causation and Injury," in which it correctly states that "ChromaDex argu[es] that Elysium failed to adduce evidence of causation." Dkt. 343 at 23. Further, ChromaDex's arguments were discussed with the Court at length as part of oral argument on the cross-motions for summary judgment. *See e.g.,* SA-3903 (delineating difference between materiality, injury, and damages).

C. The district court abused its discretion in excluding portions of the expert testimonies of Dr. Bruce Isaacson, Lance Gunderson, and Dr. Kurt Hong

1. Dr. Isaacson

Dr. Bruce Isaacson, a nationally recognized expert on survey research, conducted a survey to assess whether consumers were misled by the challenged advertising claims made by Elysium, and to assess whether the alleged misrepresentations and omissions were material to consumers' purchasing decisions. SA-2211-90. The survey measured four separate sets of test materials, representing marketplace communications from Elysium, and control materials. *Id.* Each of the groups surveyed was qualified in the same manner, saw one of four sets of test materials or four sets of control materials, and was asked the same questions about those materials. *Id.* ¶¶ 4, 6, 10. Dr. Isaacson's testing of 8

different stimuli generated more than 132 measures, which are found in Tables A through F of the Isaacson Report. Dr. Isaacson reviewed these measures as a whole as they pertained to each of the four Test and Control materials tested in arriving at his conclusions. *Id.* ¶¶ 121-30.

The proponent of expert opinion testimony must demonstrate admissibility by a preponderance of proof, and the district court serves as a gatekeeper to ensure that an expert is properly qualified and that his opinion testimony is relevant and reliable. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 592 n.10, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993); *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147-48 (1999); FRE 702 advisory committee's note to 2000 amendments. Expert opinion testimony must be both relevant—that is, it must tend to make the existence of any fact that is of consequence to the determination of the action more or less probable—and reliable. *Amorgianos v. Nat'l Railroad Passenger Corp.*, 303 F.3d 256, 265 (2d Cir. 2002). "[T]he Federal Rules of Evidence favor the admissibility of expert testimony, and [the court's] role as gatekeeper is not intended to serve as a replacement for the adversary system." *POM Wonderful LLC v. Organic Juice USA, Inc.*, 769 F. Supp. 2d 188, 197 (S.D.N.Y. 2011).

When evaluating survey evidence, errors in a survey's methodology usually go to the weight accorded to its conclusions rather than its admissibility. In *Daubert*, the Supreme Court explained that "[v]igorous cross-examination,

presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert*, 509 U.S. at 596.

In its *Daubert* motion, Elysium raised a scattershot series of technical challenges to Dr. Isaacson's survey. Dkt. 198 at 18-24. These challenges rely on misconstruing and mischaracterizing the Isaacson Survey, and find no support from case law or established survey methodology. Moreover, even if there were merit to Elysium's challenges, they are the type of challenges that go to the weight of survey as evidence, and do not come close to being grounds for complete exclusion of the materiality portion of the survey.

Elysium asserted that the Isaacson Survey was subject to a bias called "focalism" because Questions 4 and 5 in that survey asked each respondent about 5 or 6 statements, two of which (the "control statements") had not been asked about in Question 3. Dkt. 198 at 22-23. Elysium offered no evidence of the applicability of "focalism" to choices made in a false advertising survey and no examples of this concept ever having been applied to a false advertising survey. Elysium offers only unsupported concern that survey respondents answering Question 4 might have their attention drawn to a particular message conveyed by the challenged statement due to the sequence of questions. Elysium's concern is entirely speculative and fails to offer a plausible explanation, or evidence, that respondents

answering Question 4 would notice that two control statements were not part of Question 3, or if they did notice, whether they would give the control statements more or less importance. Notably, "[a]ll survey questions necessarily lead respondents to think in terms of the subject matter posed by the question—sometimes, regarding issues the respondent might not have considered without being stimulated by the question. That is the primary and necessary function of survey questions—to focus the respondent's thoughts on the issue of interest." Jacoby, Jacob, "Are Closed-Ended Questions Leading Questions?" *Trademark and Deceptive Advertising Surveys: Law, Science, and Design*, edited by Shari Seidman Diamond and Jerre B. Swann, ABA Publishing, 2012, pp. 272-73.

Likewise, Elysium's criticisms of the controls used by Dr. Isaacson, Dkt. 198 at 23, are speculative, illogical, and defy basic survey design principles. Elysium argues that the controls were flawed because they appeared for the first time only in the materiality portion of the survey. *Id.* Elysium again failed to provide a single relevant example of such a purported flaw being grounds for exclusion of a false advertising survey. The concerns raised by Elysium regarding vagueness are also without merit, and notably are raised as to only one of the four tested advertising statements.

As set forth above, none of the criticisms advanced by Elysium are well-founded, either individually or cumulatively. Moreover, even to the extent some or

all of the criticisms were valid, it was an abuse of discretion for the district court to exclude the entire materiality portion of the survey. Indeed, "[c]ourts in this district have routinely admitted flawed survey evidence where the evidence does not appear to be devoid of all probative value." *POM Wonderful LLC v. Organic Juice USA, Inc.*, 769 F.Supp.2d 188, 200 (S.D.N.Y. 2011) (citation omitted). So long as "there is sufficient indicia of reliability . . . '[v]igorous cross examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.'" *Rexall Sundown, Inc. v. Perrigo Co.*, 651 F.Supp.2d 9, 28 (E.D.N.Y. 2009) (quoting *Daubert*, 509 U.S. at 596). In sum, the district court overstepped its role as gatekeeper and improperly stepped into the role of the jury in evaluating expert evidence.

In addition to excluding the materiality portion of the survey, the district court excluded Dr. Isaacson's conclusions regarding the results of the confusion portion, finding that Dr. Isaacson inappropriately "added together" the results of his survey and that "his opinion was based on the cumulative results of the responses of respondents to all of the statements." SA-3676. However, the report itself provides measures for specific questions, and Dr. Isaacson's deposition testimony "disclaims" any theory that his survey measures apply to all of Elysium's advertising as a whole.

2. Mr. Gunderson

The district court abused its discretion in excluding the expert opinion of Lance Gunderson ("Gunderson"). Specifically, the district court found that Gunderson (1) "assumed but did not support that Elysium would have lost all of its sales but for the allegedly false and misleading advertisement"; and (2) "assumed, but did not support, that those sales would have gone to another supplier of Niagen or to Tru Niagen." SA-3699. In deciding to exclude Gunderson's opinion, the district court rejected application of the analysis set forth in *Church & Dwight Co., Inc. v. SPD Swiss, Precision Diagnostics GmbH*, No. 14-CV-585, 2018 WL 4253181 (S.D.N.Y. Sept. 5, 2018).[7]

To establish the existence of injury, the Lanham Act "demands only proof providing a reasonable basis for the belief that the plaintiff is likely to be damaged as a result of the false advertising." *Johnson & Johnson v. Carter-Wallace, Inc.*,

[7] The district court instead relied on *Dependable Sales * Serv., Inc. v. True Car, Inc.,* 311 F. Supp. 3d 653, 656 (S.D.N.Y. 2018). That case addressed neither a two-player market nor direct competition, and the court did not apply the doctrine articulated in *Merck.* Moreover, *Compania Embotelladora Del Pacifico, S.A. v. Pepsi Cola Co.*, 650 F. Supp. 2d 314 (S.D.N.Y. 2009), also cited by the district court, was a *breach of contract* action where the expert admitted he had no reliable data about the defendant's sales and conflated data from different geographies. *Id.* at 319-20. Finally, two other cases cited by the district court—*Verisign, Inc. v. XYZ.com LLC,* 848 F.3d 292 (4th Cir. 2017) and *Am. Home Prod. Corp. v. Johnson & Johnson,* 682 F. Supp. 769 (S.D.N.Y. 1988)—are also distinguishable. *Johnson & Johnson* predates *Merck* and does not discuss or address actions between direct competitors. And *Verisign,* involved messaging that was disseminated to "so small a group" that it was not commercial advertising.

631 F.2d 186, 190 (2d. Cir. 1980). There is no requirement for a plaintiff to "come forward with specific evidence that [the defendant's] ads actually resulted in some definite loss of sales." *Id.* Courts are permitted to account for "some degree of speculation" in determining the amount of damages. *Burndy Corp. v. Teledyne Industries, Inc.*, 748 F.2d 767, 771 (2d Cir. 1983). Moreover, in litigation between *direct competitors*, "it is appropriate to utilize a presumption of injury." *Merck Eprova AG v. Gnosis S.p.A.,* 760 F.3d 247, 260-61 (2d Cir. 2014).

In *Church & Dwight*, the at-issue advertising concerned the "product's key differentiating feature"—*i.e.*, the advertised ability of a pregnancy test to also provide a "Weeks Estimate." 2018 WL 4253181, at *5. The message was broadcast to relevant consumers. *Id.* at *6. As to be expected, neither the plaintiff nor the damages expert could prove conclusively that every consumer viewed the at-issue message or made a purchasing decision because of the advertising. *Id.* That said, given the pervasive nature of the advertising, the fact that the consuming public was "exposed to at least part of [the defendant's] marketing campaign," and the advertised message was concerning "the key distinguishing feature," it was "reasonable" for the damages expert to allocate 100% of the defendant's sales to remaining marketplace participants and calculate lost profits based on the plaintiff's share of the market. *Id.*

The district court incorrectly distinguished *Church & Dwight*, finding that it involved "a single advertisement that was used pervasively from the launch of the accused product to the present" and that "there was evidence that the advertisement pertained to the key distinguishing feature between the product and its competitors" while "[t]his case by contrast involves many advertisements with different themes, none of which ran throughout the launch of the product" and "there is no evidence that [the at-issue advertisements] pertained to the key distinguishing feature between the product . . . ." SA-3701.

As an initial matter, whether at-issue advertising is in fact a "key feature that differentiates" is an issue for trial. *Church & Dwight,* 2018 WL 4253181, at *6 (noting the court found the fact in the liability phase). A jury could reasonably conclude that a consumer would consider the features of Basis advertised by Elysium in the at-issue advertising are "key distinguishing feature[s]" of a dietary supplement.

Moreover, Gunderson explained that the at-issue messaging was broadcast on social media and Elysium's own website. SA-8273-74 (Tr. 222:22-25, 223:1-6). It is not controverted that Elysium spends almost all of its marketing dollars on online and website marketing. SA-4110. Notably, key at-issue messages appear on Elysium's website, which is the only relevant channel of commerce and comprises 99% of Elysium's sales. SA-6493. As explained by ChromaDex's

counsel at oral argument, "a jury could conclude that if you only advertise on the internet, and if you only advertise through social media and your website, and if 100 percent of consumers are going to your website to buy the product, then there's a reasonable assumption that 100 percent of consumers are viewing your false advertising messages, most of which are on their website." SA-3924. "Experts routinely employ assumptions as part of their analysis, and any contentions that the assumptions are unfounded go to the weight of the testimony, not its admissibility." *MBIA Ins. Corp. v. Patriarch Partners VIII, LLC*, 2012 WL 2568972, at *16 (S.D.N.Y. July 2, 2012) (citing *BIC Corp. v. Far E. Source Corp.*, 23 F. App'x 36, 38 (2d Cir. 2001); *Boucher v. U.S. Suzuki Motor Corp.*, 73 F.3d 18, 21 (2d Cir. 1996)).

Next, contrary to the district court's analysis, ChromaDex and Elysium are in direct competition in essentially a two-player market. Both companies sell a dietary supplement containing NR, and Elysium admitted that products that compete with Elysium's Basis product are "other products that contain NR." SA-8206. ChromaDex likewise views companies that sell NR-containing dietary supplements as its competitors. SA-4024-05. Gunderson further explains based on record evidence that during the relevant damages period, Tru Niagen and Basis have been the top two NR capsule supplements in the market" and that the NR-supplement market is a *two-player market*. SA-4058. The only other companies

that sold NR-containing supplements in the U.S. during the relevant period sold ChromaDex's NIAGEN wholesale ingredient. SA-4096-97. As explained by ChromaDex's counsel at oral argument, "[Before 2017] any supplement that contained NR that was sold in the United States marketplace . . . contained Niagen sourced from ChromaDex, and that includes Basis [which at one point was sourcing its NR from ChromaDex]." SA-3916-17. Moreover "[w]hen we look at the marketplace today, and if someone were to buy an NR-containing supplement, they have essentially three choices—they could buy Elysium's Basis, they could buy ChromaDex's Tru Niagen, or they could buy a product from a third-party company . . . that, for the most part . . . have contained ChromaDex's wholesale Niagen." SA-3917. Thus, ChromaDex would lose the indirect benefit of any sales diverted by Elysium from those third-party companies. SA-3917-18. Based on the foregoing it was certainly reasonable for Gunderson to rely on these facts. *Merck,* 760 F.3d at 260-61 (holding that in a two-player market "it is appropriate to utilize a presumption of injury"). At minimum, there is a triable issue of fact as to whether ChromaDex and Elysium operated in essentially a two-player market.

As for the district court's conclusion that Gunderson did not conduct an analysis as to how other advertising by Elysium that is not at issue in the case affected Elysium's sales, Gunderson actually identified a dramatic and substantial reduction in ChromaDex's market share during the damages period, starting in

March 2017. SA-8271-72; SA-4096. Moreover, the fact that Gunderson stated in his deposition that one purpose of damages is to punish a defendant is not a reason to exclude his report. Indeed, Gunderson, who was never presented as an expert on the rationale behind the Lanham Act, also calculates Elysium's incremental profits because the Lanham Act permits the award of a defendant's profits under Section 1117(a).

Finally, the district court abused its discretion in excluding Gunderson's alternative disgorgement analysis, finding that it is only relevant to the extent that ChromaDex can independently demonstrate causation or injury. SA-3700. As discussed above, ChromaDex presented triable issues of fact regarding causation and injury.

3. Dr. Hong

Dr. Kurt Hong is a Harvard and UCLA educated physician with over 15 years of clinical experience. His area of "expertise is in macro and micronutrition in medical nutrition therapy and understanding the role of nutrition in aging." SA-2813-14. The subject of this case—advertising statements relating to dietary supplements—is well within Dr. Hong's expertise. SA-8310 (Tr. 12:13-22). Dr. Hong's has offered opinions and testimony regarding technical scientific matters that are relevant to the issues and will aid the jury's understanding of those matters.

In its *Daubert* order, the district court erroneously relied on inapposite case law, Elysium's mischaracterization of the nature and substance of Dr. Hong's report, and went beyond the court's gatekeeping role. First, the district court minimized Dr. Hong's testimony by characterizing it as merely a narrative of factual issues for which he only had second-hand knowledge. SA-3719. The district court quotes *LinkCo, Inc. v. Fuitsu Ltd.*, 2002 WL 1585551, at *2 (S.D.N.Y. July 16, 2002) in holding that Dr. Hong's 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." SA-3719 (citing *LinkCo*, 2002 WL 1585551, at *2). In *LinkCo*, the expert's review was based on review of basic documents (*e.g.*, computer files and deposition transcripts) and did not "address technical questions that may be difficult for a jury to comprehend." *LinkCo*, 2002 WL 1585551, at *1-2. The full quote from *LinkCo* partially quoted above states that the expert there "does no more than counsel for [plaintiff] will do in argument, i.e., propound a particular interpretation of [defendant]'s conduct." *Id.* at *2.

Here, Dr. Hong offers his expert testimony regarding, *inter alia*, the results and import of clinical studies, the nature and import of scientific discovery relevant to the case, and concepts about the value and limitations of different types of studies. SA-2815-31. Thus, the nature and scope of Dr. Hong's testimony is not

remotely comparable to the disallowed testimony in *LinkCo* regarding basic documents and merely providing an interpretation of the defendant's conduct.

Expert testimony of the nature offered by Dr. Hong is regularly admitted in federal courts. *See, e.g.*, *In re Mirena IUD Prods. Lab. Litig.*, 169 F. Supp. 3d 396, 483 (S.D.N.Y. 2016) (considering expert qualifications of epidemiologist basing opinion on "a review of case reports, adverse event data, and relevant scientific and medical literature"); *In re Pfizer Inc. Secs. Litig.*, 2010 WL 1047618, at *7 (S.D.N.Y. 2010) (denying motion to preclude expert testimony of Ph.D. biostatistician regarding the meta-analysis of clinical trial data regarding the safety of a drug). In sum, the district court's exclusion of Dr. Hong's testimony was an abuse of discretion.

CONCLUSION

ChromaDex respectfully requests that this Court affirm the district court's order enforcing the parties' settlement agreement. ChromaDex further respectfully requests that this Court reject Elysium's appeal of the district court's order dismissing Elysium's Citizen Petition claims for lack of appellate jurisdiction. Should the Court determine it has jurisdiction over that portion of Elysium's appeal, the district court's order should be affirmed. If this Court reverses the district court's order enforcing the parties' settlement agreement, the Court should

also reverse the portions of the district court's summary judgment and *Daubert* orders as discussed above.

DATED: November 22, 2022

LTL ATTORNEYS LLP

By: *s/ Joe H. Tuffaha*
Joedat H. Tuffaha
Kate Elizabeth Cassidy

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Second Circuit Local Rule 28.1.1 because this brief contains 16,385 words.

This brief is in 14-Point Times New Roman proportional font and thus is in compliance with the requirement set forth in Federal Rules of Appellate Procedure 32(a)(5) and 32(a)(6).

DATED: November 22, 2022
New York, New York

LTL ATTORNEYS LLP

By: *s/ Joe H. Tuffaha*
Joedat H. Tuffaha
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SPECIAL APPENDIX

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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") and Defendant Elysium Health ("Elysium") cross-move for summary judgment pursuant to Federal Rule of Civil Procedure 56. Elysium moves for summary judgment on ChromaDex's claims, and both parties move for summary judgment on Elysium's counterclaims.

For the following reasons, the motions for summary judgment are each granted in part and denied in part.

BACKGROUND

Familiarity with the Court's prior opinions denying in part ChromaDex's motion to dismiss and granting in part and denying in part Elysium's motion to dismiss ChromaDex's counterclaims, Dkt. No. 44, and granting ChromaDex's motion for summary judgment as to Elysium's claims regarding ChromaDex's citizen petition under the *Noerr-Pennington* doctrine, Dkt. No. 63, is assumed.

The following facts are undisputed for the purposes of summary judgment except where otherwise indicated.

I. The Parties

This case arises from a dispute over the sales of, and credit for, nutritional products claimed to improve cellular health and cellular aging.

ChromaDex, which was founded in 1999, is a publicly traded nutraceutical company which, until recently, manufactured and sold chemical compounds only as a wholesaler to companies which incorporated ChromaDex's ingredients into their products for retail consumption. Dkt. No. 230-32 ("Joint 56.1") ¶¶ 1–2. NIAGEN® ("Niagen") is one of ChromaDex's products. *Id.* ¶ 3. The active ingredient in Niagen is ChromaDex's synthetically-produced isolated nicotinamide riboside ("NR"). *Id.* ¶ 4. NR is a naturally occurring form of Vitamin B_3 that increases nicotinamide adenine dinucleotide or NAD+, an essential coenzyme required for life and cellular functions. Joint 56.1 ¶¶ 7–8, 10; *see also* Dkt. No. 210 at 3; Dkt. No. 222 at 4. NAD+ is linked to cellular health and cellular aging. In 2000, Dr. Leonard Guarente—who is a co-founder and the Chief Scientific Advisor of Elysium—co-authored a paper on sirtuins, a family of proteins that regulate cellular health and cellular homeostasis. Guarente describes the paper as showing that Sir2, a sirtuin in yeast, controls aging in yeast cells and that NAD+ is necessary for Sir2 activity. Dkt. No. 221 ("Elysium's 56.1") ¶ 9. By increasing NAD+, NR is believed to improve cellular health and slow cellular aging.

Scientists have known about NAD+ since it was first discovered in 1906. *Id.* ¶ 10. NR has been in the scientific literature since the 1940s "as a growth factor for haemophilus influenzae." Joint 56.1 ¶ 7; *see also* Elysium's 56.1 ¶ 12; Dkt. No. 210 at 3; Dkt. No. 222 at 4. In 2007, ChromaDex's Chief Scientific Advisor, Dr. Charles Brenner, co-authored a study showing that NR increases NAD+ and Sir2 function. Dkt. No. 217, Ex. B. Six years later, ChromaDex launched Niagen, its synthetic isolated form of NR. When ChromaDex launched Niagen, it operated as a wholesaler and supplied the ingredient to other companies. Joint 56.1 ¶

24. It did the same with other ingredients it manufactured, including pTeroPure, its synthetic pterostilbene ("PT").

ChromaDex's co-founder and executive chairman is Frank Jaksch. Dkt. No. 257, Ex. 6 at 12. He was ChromaDex's CEO until approximately 2018; ChromaDex's current CEO is Rob Freed. *Id.* From December 2013 to August 2016, Dr. Ryan Dellinger was employed by ChromaDex as Director of Scientific Affairs. Dkt. No. 229 ¶ 7.

Elysium was until recently one of ChromaDex's customers. It is a dietary supplement company that sells directly to customers. Elysium was founded in 2013; its founders included Guarente, Dan Alminana, and Eric Marcotulli. The idea behind Elysium was to start a dietary supplement company grounded in science, serving consumers in between the nutraceutical space and the pharmaceutical space. Elysium's 56.1 ¶¶ 48–49.

Elysium's primary product is a dietary supplement called Basis, a direct-to-consumer product which combines NR with PT. *Id.* ¶¶ 22–23. Elysium launched Basis in February 2015. Until approximately August 2016, Elysium obtained its NR and PT from ChromaDex. Elysium entered into a supply agreement with ChromaDex on February 3, 2014, in which ChromaDex agreed to supply Elysium with Niagen. Joint 56.1 ¶ 20. ChromaDex supplied Elysium with NR in the form of Niagen from February 2015 until August 2016. *Id.* ¶ 24. Elysium also entered into a supply agreement with ChromaDex on June 26, 2014, in which ChromaDex agreed to supply Elysium with PT. *Id.* ¶ 21. After Elysium entered into the supply agreements with ChromaDex but before it launched Basis, in about September 2016, Dellinger, who previously had been employed as ChromaDex's Director of Scientific Affairs, left ChromaDex and joined Elysium as Director of Scientific Affairs. In approximately April 2020, Dellinger became Elysium's Vice President of Scientific Affairs. Dkt. No. 229 ¶ 8. Elysium's Chief Product

Officer is Mark Morris. Dkt. No. 227 ¶ 1. Morris was also previously employed by ChromaDex, from June 2007 to August 2009 and from January 2011 to July 2016. *Id.* ¶ 2. He joined Elysium in around July 2017 as Vice President of Research and Development, and in 2020 became Elysium's Chief Product Officer. *Id.* ¶ 3.

In approximately November 2016, ChromaDex sent Elysium a notice of non-renewal and terminated its agreements to supply Elysium with NR and PT. Elysium's 56.1 ¶¶ 74, 78. In March 2017, ChromaDex began selling a direct-to-consumer dietary supplement called TRU NIAGEN® ("Tru Niagen"), in which the only active ingredient is 300 mg of Niagen. Joint 56.1 ¶¶ 5–6.

After ChromaDex ceased to supply Elysium with NR and PT, in late 2016, Elysium began to develop its own method for manufacturing NR. Elysium's 56.1 ¶ 80. Elysium continued to produce and sell Basis and had other companies manufacture NR on its behalf and supply it with PT. Joint 56.1 ¶¶ 27–34.

II. FDA Regulation of Niagen, Tru Niagen, and Basis

The FDA regulates dietary supplements, and the ingredients they use, through various regulatory mechanisms. First, under the 1958 Food Additives Amendment to the federal Food, Drugs, and Cosmetic Act, any "food additive"—meaning a substance intentionally added to food—must undergo premarket approval by the FDA, subject to certain exemptions. Dkt. No. 209-3 ("Weisman Report") at 1 (citing 21 U.S.C. § 321(s)). One such exemption is for food ingredients that are found by qualified experts to be "generally recognized as safe" ("GRAS") for their intended use. To obtain GRAS status, companies must submit a dossier of historical and scientific evidence of safety to an independent panel of experts, who then 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)). Once the GRAS expert panel issues a finding, that finding can either be

voluntarily submitted to the FDA, or the company can choose not to submit the GRAS finding to the FDA. In the former case, 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's review is managed by a consumer safety officer who determines exactly what kinds of expertise is needed to review a particular GRAS submission. Dkt. No. 230-31 ("ChromaDex's 56.1") ¶ 7; Dkt. No. 249 ¶ 7. The FDA's review includes a consumer safety officer, a chemist, a toxicologist, sometimes a microbiologist, sometimes a food scientist, and sometimes a nutritionist. ChromaDex's 56.1 ¶ 8; Dkt. No. 249 ¶ 8. 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 GRAS status "should be of the same scientific rigor as a GRAS notification submitted to the FDA." Weisman Report at 7. 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.*

On December 21, 2015, Niagen was generally recognized as safe by an independent panel of expert toxicologists for the intended use of Niagen "as an ingredient in vitamin waters, protein shakes, nutrition bars, gum and chews." ChromaDex's 56.1 ¶ 4 (citing Dkt. No. 230, Ex. 10); Dkt. No. 230, Ex. 10 at 1. On March 8, 2016, ChromaDex submitted its GRAS dossier and the expert panel statement to the FDA and received the response: "Based on the information provided by ChromaDex, as well as other information available to the FDA, the agency has no questions at this time regarding ChromaDex's conclusion that NR is GRAS under the intended

conditions of use. The agency has not, however, made its own determination regarding the GRAS status of the subject use of NR." ChromaDex's 56.1 ¶ 5; Dkt. No. 249 ¶ 5.

Elysium prepared a "GRAS Notification of Nicotinamide Riboside Chloride," dated October 27, 2021, and a "Comprehensive GRAS Assessment of Pterostilbene," dated February 2, 2018. Joint 56.1 ¶¶ 39–40. Elysium did not notify the FDA of its GRAS self-affirmation for NR or PT. *Id.* ¶ 41. The panel reviewing Elysium's GRAS assessment for NR concluded that "Elysium's NR, when produced in accordance with FDA Good Manufacturing Practices requirements and when meeting those specifications presented by Elysium in Table 2, is Generally Recognized as Safe when consumed at the proposed levels [250mg/day] in conventional food and dietary supplements." Dkt. No. 227, Ex. C at 39. Elysium's GRAS assessment for PT was not reviewed by an independent panel. Dkt. No. 257, Ex. 18 at 125.

The FDA also regulates new dietary ingredients ("NDIs"). An NDI is "a dietary ingredient that was not marketed in the United States before October 15, 1994." 21 U.S.C. § 350b(d). Under the Federal Food, Drug and Cosmetic Act, "a dietary supplement which contains a new dietary ingredient shall be deemed adulterated" unless it "contains only dietary ingredients which 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" or the manufacturer or distributor of the dietary ingredient or dietary supplement submits a notification (an "NDI notification" or "NDIN") to the FDA with information regarding the history of use or other evidence of safety of the dietary ingredient based on which "the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe" at least seventy-five days before introducing the product to market. *Id.* § 350b(a).

On or about August 20, 2015, ChromaDex submitted an NDIN to the FDA for Niagen; it submitted a second NDIN for Niagen on December 27, 2017. Joint 56 ¶¶ 17–18. Elysium has never submitted an NDIN to the FDA for Basis, NR, or PT. *Id.* ¶ 38. Elysium asserts that it initially intended to submit an NDIN for Basis, but confirming the GRAS status of Elysium's NR and PT was Elysium's business priority because GRAS has a broader application than NDIN. Elysium's 56.1 ¶ 87 (citing Dkt. No. 227 ¶ 16).

Under an alternate regulatory pathway for new drugs, a sponsor may submit an investigational new drug application (an "IND") to the FDA. 21 C.F.R. § 312.20(a). INDs are reviewed by the FDA and include a safety determination component. Elysium's 56.1 ¶ 93; Dkt. No. 257, Ex. 34 at 32. The regulatory processes for an NDI and an IND are different, but they are similar in terms of the scientific rigor around safety. Elysium's 56.1 ¶ 96; Dkt. No. 257, Ex. 34 at 33. In 2019, the FDA accepted Elysium's IND application to evaluate the efficacy of Basis for the prevention of acute kidney injury in surgical cardiac patients. Elysium's 56.1 ¶ 92.

III. The Relevant Studies

The parties have each conducted and rely upon—both in their marketing and before this Court—various studies related to the safety and efficacy of NR and their products.

The first published human clinical study of synthetic isolated NR was published on October 10, 2016 in the journal *Nature Communications*. It was titled "Nicotinamide riboside is uniquely and orally bioavailable in mice and humans" (the "Trammell Study"). Joint 56.1 ¶ 9. The Trammell Study used ChromaDex's Niagen and reported that a single dose of NR increased NAD+ level in blood over a twenty-four-hour period. *Id.* ¶¶ 10, 16. The co-authors of the Trammell Study included, among others, Jaksch, Dellinger, and Brenner, all of whom were then working at or during the period of the study had worked at ChromaDex. In the study's clinical trial, "[t]welve healthy, non-pregnant subjects (six male and six female) were recruited and

randomized to one of three treatment sequences." Dkt. No. 229, Ex. A at 12. After fasting overnight, the subjects received a single morning dose of either 100 mg, 300 mg, or 1,000 mg of NR. *Id.* This was done on three test days, separated by seven-day periods with no supplement given. *Id.* The study reported dose-dependent increases in NAD+ levels following administration of 100 mg, 300 mg, and 1000 mg single doses of NR in adults. Joint 56.1 ¶ 11. There were no serious adverse effects in participants in the Trammell Study. *Id.* ¶ 12.

In 2017, Elysium published a study titled "Repeat Dose NRPT (nicotinamide riboside and pterostilbene) increases NAD+ levels in humans safely and sustainably: a randomized, double-blind, placebo-controlled study" (the "Dellinger Study"). *Id.* ¶ 42. The Dellinger Study examined Basis; the NR and PT ingredients used in the Dellinger Study were ChromaDex-supplied Niagen and pTeroPure. *Id.* ¶ 43. The study contained three groups: (1) approximately forty participants received a placebo for eight weeks; (2) approximately forty participants received a single dose of Basis for eight weeks (the "NRPT 1X group"); and (3) approximately forty participants received a double dose of Basis for eight weeks (the "NRPT 2X group"). Dkt. No. 229 ¶ 12, Ex. C. The study showed a dose-dependent increase in NAD+ levels sustained over the course of the trial. *Id.*

A six-week randomized, double blind, controlled cross-over clinical study of thirty middle-aged and older healthy volunteers was published in *Nature Communications* in 2018, entitled "Chronic nicotinamide riboside supplementation is well-tolerated and elevates NAD(+) in healthy middle-aged and older adults" (the "Martens Study"). Joint 56.1 ¶ 15. The Martens Study tested ChromaDex's Niagen. *Id.* ¶ 16. In this study, thirty healthy male and female participants between the ages of fifty-five and seventy-nine were randomized into one of two groups: Group A received placebo capsules during the first six weeks of the study and then

crossed over to receive NR capsules for the remaining six weeks at a 1000 mg per day dosage, and Group B did the opposite, receiving NR capsules first and then placebo capsules. Dkt. No. 230, Ex. 14 at 3–4. The study found that "NR was well tolerated at the dose tested, and no serious adverse effects occurred." *Id.* at 4.

In an eight-week study published in 2019, researchers evaluated the kinetics and dose-dependence of synthetic isolated NR oral availability and safety in overweight but otherwise healthy men and women (the "Conze Study"). Joint 56.1 ¶ 14. The Conze Study also tested ChromaDex's Niagen. *Id.* ¶ 16. In the ninety-day study, on which Charles Brenner was a co-author, 140 healthy male and female participants between ages forty and sixty were randomly assigned to different groups, and, during the eight-week interventional period of the study, received either 100 mg, 300 mg, or 1000 mg of NR per day, or a placebo. Dkt. No. 230, Ex. 15, at 2–3. The study also contained a two-week run-in period. *Id.* The participants were instructed to avoid foods containing high amounts of tryptophan and forms of vitamin B_3 during the run-in and NR supplementation periods. *Id.* at 2. The study concluded that NR produces dose-dependent increase in blood and urinary NAD+ metabolites, and that oral Niagen is safe and well-tolerated up to 1000 mg per day for eight weeks. *Id.* at 6, 8.

Elysium sponsored a clinical study published on August 3, 2020, entitled "Nicotinamide riboside with pterostilbene (NRPT) increases NAD+ in patients with acute kidney injury (AKI): a randomized, double-blind, placebo-controlled, stepwise safety study of escalating doses of NRPT in patients with AKI" (the "Simic Study"). Elysium's 56.1 ¶ 88. Elysium asserts that the Simic Study used Elysium's NR. *Id.* ¶ 89. The study was made up of four steps, in which NRPT was given to five subjects and a placebo was given to one subject twice a day for two days; the dosage was increased in each step. Dkt. No. 229, Ex. E at 1. The study showed that, "compared

to the baseline timepoint, NRPT at all doses increased whole blood NAD+ levels at 48 h, but only the increase with NRPT Step 2 (dose 500 mg/100 mg) reached statistical significance." *Id.* at 4. It further found that "NRPT was safe at all doses with only minor side effects reported that resolved without intervention." *Id.* at 7.

IV. Other Litigation Between ChromaDex and Elysium

Since Elysium's launch of Basis and ChromaDex's launch of Tru Niagen, the two companies have sued each other in several different federal courts.

In 2018, ChromaDex sued Elysium for patent infringement in the Delaware District Court. Joint 56.1 ¶ 51. ChromaDex's complaint alleged that Basis infringes various patents ChromaDex held related to the formulation of isolated NR for oral consumption. *See ChromaDex, Inc. et al v. Elysium Health, Inc.*, Case No. 1:18-cv-1434-CFC-JLH, ECF No. 1 ¶¶ 23–28. On September 21, 2021, Judge Connolly granted Elysium's motion for summary judgment in that action, holding that the allegedly-infringed patent claims "are invalid under 35 U.S.C. § 101 for claiming patent-ineligible subject matter." *See ChromaDex, Inc. v. Elysium Health, Inc.*, --- F. Supp. 3d ---, 2021 WL 4286527, at *5 (D. Del. Sept. 21, 2021).

The two companies are also adversaries in a lawsuit filed in the Central District of California, in which ChromaDex alleges claims for breach of contract, breach of fiduciary duty, and misappropriation of trade secrets and Elysium alleges counterclaims for breach of contract, fraudulent inducement, patent misuse, and unjust enrichment. *See* Dkt. No. 171 at 1. A jury trial was held in that action from September 21, 2021 to September 27, 2021; the jury returned a verdict for ChromaDex on its breach of contract claim, for Elysium on ChromaDex's misappropriation of trade secrets claims, for Elysium on ChromaDex's aiding and abetting breach of fiduciary duty claim, for Elysium on its breach of contract counterclaim, and for Elysium on its fraudulent inducement counterclaim, and found that ChromaDex acted with

malice, oppression, or fraud, and returned an award for punitive damages accordingly. *See* Case No. 8:16-cv-02277-CJCC-DFM, Dkt. Nos. 554–573.

PROCEDURAL HISTORY

This case has had a long and tortuous procedural history, which is set out in detail in the Court's Opinion and Order at Dkt. No. 171. For purposes of this motion for summary judgment, the relevant procedural history is as follows.

ChromaDex first filed its complaint in this action on September 27, 2017. Dkt. No. 1. ChromaDex's operative complaint is the second amended complaint, Dkt. No. 139 ("SAC" or "Complaint"), which was filed on February 27, 2020. The Complaint alleges claims for false advertising under the Lanham Act, 15 U.S.C. § 1125(a), federal unfair competition under the Lanham Act, and deceptive practices under New York General Business Law § 349.

Elysium's operative counterclaim is the fourth amended counterclaim, Dkt. No. 192 ("Counterclaim"), which was filed on April 21, 2021. The Counterclaim alleges claims under the same statutes as those alleged in the Complaint—false advertising under the Lanham Act, federal unfair competition under the Lanham Act, and deceptive practices under New York General Business Law § 349.

On June 4, 2021, Elysium filed its motion for summary judgment on ChromaDex's claims against it, and for partial summary judgment on its counterclaims, Dkt. No. 203, and ChromaDex filed its motion for summary judgment on Elysium's counterclaims, Dkt. No. 204. On June 25, 2021, ChromaDex filed its opposition to Elysium's motion, and Elysium filed its opposition to ChromaDex's motion. Dkt. Nos. 242, 250. The parties filed replies in further support of their respective motions on July 9, 2021 and July 10, 2021. Dkt. Nos. 262, 273.

LEGAL STANDARD

I. Summary Judgment

Under Federal Rule of Civil Procedure 56, a court "shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "When the burden of proof at trial would fall on the nonmoving party, it ordinarily is sufficient for the movant to point to a lack of evidence to go to the trier of fact on an essential element of the non-movant's claim." *Jaramillo v. Weyerhaeuser Co.*, 536 F.3d 140, 145 (2d Cir. 2008). If the movant meets its burden, "the nonmoving party must come forward with admissible evidence sufficient to raise a genuine issue of fact for trial in order to avoid summary judgment." *Id.* "An issue of fact is 'material' for these purposes if it 'might affect the outcome of the suit under the governing law,'" while "[a]n issue of fact is 'genuine' if 'the evidence is such that a reasonable jury could return a verdict for the nonmoving party.'" *Konikoff v. Prudential Ins. Co. of Am.*, 234 F.3d 92, 97 (2d Cir. 2000) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). In determining whether there are any genuine issues of material fact, the Court must view all facts "in the light most favorable to the non-moving party," *Holtz v. Rockefeller & Co., Inc.*, 258 F.3d 62, 69 (2d Cir. 2001), and the movant bears the burden of demonstrating that "no genuine issue of material fact exists," *Marvel Characters, Inc. v. Simon*, 310 F.3d 280, 286 (2d Cir. 2002) (citations omitted).

"[A] party may not rely on mere speculation or conjecture as to the true nature of the facts to overcome a motion for summary judgment." *Hicks v. Baines*, 593 F.3d 159, 166 (2d Cir. 2010) (quoting *Fletcher v. Atex, Inc.*, 68 F.3d 1451, 1456 (2d Cir. 1995)). Nor may the non-moving party "rely on conclusory allegations or unsubstantiated speculation." *F.D.I.C. v. Great Am. Ins. Co.*, 607 F.3d 288, 292 (2d Cir. 2010) (quoting *Scotto v. Almenas*, 143 F.3d 105,

114 (2d Cir. 1998)). Rather, to survive a summary judgment motion, the opposing party must establish a genuine issue of fact by "citing to particular parts of materials in the record." Fed. R. Civ. P. 56(c)(1)(A); *see also Wright v. Goord*, 554 F.3d 255, 266 (2d Cir. 2009). To defeat a motion for summary judgment, the non-moving party must demonstrate more than "some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). The non-moving party "cannot defeat the motion by relying on the allegations in [its] pleading, or on conclusory statements, or on mere assertions that affidavits supporting the motion are not credible." *Gottlieb v. Cnty. of Orange*, 84 F.3d 511, 518 (2d Cir. 1996) (internal citation omitted).

"[W]hen multiple parties cross-move for summary judgment, . . . 'each party's motion must be examined on its own merits and in each case all reasonable inferences must be drawn against the party whose motion is under consideration.'" *Century Sur. Co. v. Franchise Contractors, LLC*, 2016 WL 1030134, at *3 (S.D.N.Y. Mar. 10, 2016) (quoting *Morales v. Quintel Ent., Inc.*, 249 F.3d 115, 121 (2d Cir. 2001)).

The Southern District's Local Civil Rule 56.1 sets forth specific requirements about how the facts relied upon by the moving party and disputed by the opposing party are to be presented. Any party moving for summary judgment must "annex[] to the notice of motion a separate, short and concise statement, in numbered paragraphs, of the material facts as to which the moving party contends there is no genuine issue to be tried." L.R. 56.1(a). Local Rule 56.1(b), in turn, requires the party opposing the motion to "include a correspondingly numbered paragraph responding to each numbered paragraph in the statement of the moving party, and if necessary, additional paragraphs containing a separate, short and concise statement of additional material facts as to which it is contended that there exists a genuine issue to be tried." L.R. 56.1(b). All

statements in a Local Rule 56.1 submission "must be followed by citation to evidence which would be admissible." L.R. 56.1(d). "Each numbered paragraph in the statement of material facts set forth in the statement required to be served by the moving party will be deemed to be admitted for purposes of the motion unless specifically controverted by a correspondingly numbered paragraph in the statement required to be served by the opposing party." L.R. 56.1(c).

II. False Advertising Under the Lanham Act

Section 43(a) of the Lanham Act, codified at 15 U.S.C. § 1125(a), provides in relevant part that:

> (1) Any person who, on or in connection with any goods or services, . . . uses in commerce . . . any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which—
>
> . . .
>
> (B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities,
>
> shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

15 U.S.C. § 1125(a). A false advertising claim under 15 U.S.C. § 1125(a)(1)(B) thus applies only to "commercial advertising or promotion." *Id.*; *see also Fashion Boutique of Short Hills, Inc. v. Fendi USA, Inc.*, 314 F.3d 48, 57 (2d Cir. 2002).

"To prevail on a Lanham Act false advertising claim, a plaintiff must establish that the challenged message is (1) either literally or impliedly false, (2) material, (3) placed in interstate commerce, and (4) the cause of actual or likely injury to the plaintiff." *Church & Dwight Co. v. SPD Swiss Precision Diagnostics, GmBH*, 843 F.3d 48, 65 (2d Cir. 2016) (citing *Merck Eprova AG v. Gnosis S.p.A.*, 760 F.3d 247, 255–56 (2d Cir. 2014)).

A. Falsity

Falsity can be established in two ways. First, "[t]o establish literal falsity, a plaintiff must show that the advertisement either makes an express statement that is false or a statement that is 'false by necessary implication,' meaning that the advertisement's 'words or images, considered in context, necessarily and unambiguously imply a false message.'" *Id.* (quoting *Time Warner Cable, Inc. v. DIRECTV, Inc.*, 497 F.3d 144, 158 (2d Cir. 2007)). "A message can only be literally false if it is unambiguous." *Id.*

Second, "[i]f a message is not literally false, a plaintiff may nonetheless demonstrate that it is impliedly false if the message leaves 'an impression on the listener or viewer that conflicts with reality.'" *Id.* (quoting *Time Warner Cable*, 497 F.3d at 153). "'Where the statement at issue is not literally false,' a plaintiff alleging a Lanham Act violation 'must demonstrate, by extrinsic evidence, that the challenged content tends to mislead or confuse consumers, and must demonstrate that a statistically significant part of the commercial audience holds the false belief allegedly communicated by the challenged advertisement.'" *Board-Tech Electronic Co., Ltd. v. Eaton Corp.*, 737 F. App'x 556, 560 (2d Cir. 2018) (summary order) (internal alterations omitted) (quoting *Tiffany (NJ) Inc. v. eBay Inc.*, 600 F.3d 93, 112–13 (2d Cir. 2010)); *see also Time Warner Cable*, 497 F.3d at 153 ("[A] district court *must* rely on extrinsic evidence to support a finding of an implicitly false message." (internal alterations and citations omitted)); *Board-Tech*, 737 F. App'x at 560–61 (citing *Time Warner Cable* for the same proposition). As will be seen, the parties offer only limited extrinsic evidence with regard to implied falsity; as such, most of the challenged statements rise or fall on the question whether they are literally false.

B. Materiality

"Falsity alone does not make a false advertising claim viable; 'under either theory, the plaintiff must also demonstrate that the false or misleading representation involved an inherent or material quality of the product.'" *Apotex Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51, 63 (2d Cir. 2016) (quoting *Time Warner Cable*, 497 F.3d at 153 n.3). "Such a 'requirement is essentially one of materiality, a term explicitly used in other circuits.'" *Id.* (quoting *S.C. Johnson & Son, Inc. v. Clorox Co.*, 241 F.3d 232, 238 (2d Cir. 2001)). The Second Circuit "has defined materiality as 'likely to influence purchasing decisions,' a definition in harmony with other Circuits' use of the term." *Id.* (quoting *Nat'l Basketball Ass'n v. Motorola, Inc.*, 105 F.3d 841, 855 (2d Cir. 1997)); *see also Church & Dwight*, 843 F.3d at 70 n.11 (noting that *Apotex* "recently settled the materiality standard in this Circuit, explaining that the standard is whether the deception is 'likely to influence purchasing decisions'" (quoting *Apotex*, 823 F.3d at 63)).

Thus, to establish a Lanham Act claim, the plaintiff must demonstrate that the statement at issue involved an inherent or material quality of the product and that the deception is likely to influence purchasing decisions.

C. Injury

A Section 43(a) false advertising plaintiff must also establish "that 'the plaintiff . . . has been injured as a result of the misrepresentation, either by direct diversion of sales or by a lessening of goodwill associated with its products.'" *Merck Eprova*, 760 F.3d at 255 (quoting *Cashmere & Camel Hair Mfrs. Inst. v. Saks Fifth Ave.*, 284 F.3d 302, 311 (1st Cir. 2002)). "A plaintiff must show that its injury was 'caused by or attributable to' the false advertisements, as opposed to a lawful factor, like a defendant's lower prices." *Dependable Sales & Serv., Inc. v. TrueCar, Inc.*, 311 F. Supp. 3d 653, 659 (S.D.N.Y. 2018) (quoting *Burndy Corp. v. Teledyne Indus., Inc.*, 748 F.2d 767, 773 (2d Cir. 1984)).

A presumption of injury arises where the false or misleading advertising makes reference "to a specific competing product," which "necessarily diminishes that product's value in the minds of the consumer," *McNeilab, Inc. v. American Home Prods Corp.*, 848 F.2d 34, 38 (1988), and where "even though [the challenged advertising] does not identify [the competitor] by name, consumers . . . undoubtedly understand [the] derogatory statement . . . as referring to [the competitor]," *Time Warner Cable*, 497 F.3d at 162. A presumption of injury also arises "where . . . a plaintiff has met its burden of proving deliberate deception in the context of a two-player market, . . . even if it is not a classic instance of comparative advertising where one company's advertisement mentions a competitor's product by name." *Merck Eprova*, 760 F.3d at 260–61.

"[A] plaintiff who establishes false advertising in violation of § 43(a) of the Lanham Act will be entitled only to such damages as were caused by the violation." *Burndy*, 748 F.2d at 771. "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). "It is the plaintiff's burden to demonstrate that false advertisements resulted in lost sales." *Dependable Sales*, 311 F. Supp. 3d at 659. A plaintiff seeking injunctive relief, however, does not need to quantify actual damages. "The statute demands only proof providing a reasonable basis for the belief that the plaintiff is likely to be damaged as a result of the false advertising." *Johnson & Johnson v. Carter-Wallace, Inc.*, 631 F.2d 186, 190 (2d Cir. 1980). "The correct standard is whether it is likely that [the defendant's] advertising has caused or will cause a loss of [the plaintiff's] sales, not whether [plaintiff] has come forward with specific evidence that [the defendant's] ads actually resulted in some definite loss of sales." *Id.* As a general matter,

however—except in cases in which a presumption of injury and causation applies—"the likelihood of injury and causation will not be presumed, but must be demonstrated." *Id.*[1]

DISCUSSION

Elysium moves for summary judgment on ChromaDex's claims against it. ChromaDex, in turn, moves for summary judgment on Elysium's counterclaims against it, and Elysium moves for partial summary judgment in its favor on the counterclaims. The Court addresses both parties' motions as to the Lanham Act false advertising claims first, and then turns to the remaining claims.

I. The Parties' Lanham Act False Advertising Claims

A. Advertising or Promotion

Only one category of claims is challenged as not constituting advertising or promotion. Elysium's Counterclaim asserts a Lanham Act false advertising claim based on statements that appeared on a blog called Right of Assembly. ChromaDex moves for summary judgment on this counterclaim. It argues that it has no liability for these statements that appeared on a third-party blog, regardless whether they were false, material, or caused injury, because the statements are not covered by the Lanham Act at all because they do not constitute "advertising or promotion." It further argues that even if the statements are actionable under the Lanham Act, they were not made by ChromaDex. Both arguments are well-taken.

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[1] ChromaDex recites the *Johnson & Johnson* standard as if it applied to all claims at the summary judgment stage and not just those seeking injunctive relief. However, *Johnson & Johnson* itself clearly distinguishes between a claim for money damages and a claim for injunctive relief and holds that the standard applies only to plaintiffs seeking injunctive relief. 631 F.2d at 190 ("If such a showing is made, the plaintiff will have established a reasonable belief that he is likely to be damaged within the meaning of § 43(a) and will be entitled to injunctive relief, as distinguished from damages, which would require more proof.").

Section 43(a)(1)(B) of the Lanham Act does not cover all speech that is damaging to a competitor; rather, it applies only to misrepresentations made in "commercial advertising or promotion." 15 U.S.C. § 1125(a)(1)(B); *see also Fashion Boutique*, 314 F.3d at 57. The "touchstone of whether a defendant's actions may be considered 'commercial advertising or promotion' under the Lanham Act is that the contested representations are part of an organized campaign to penetrate the relevant market." *Fashion Boutique*, 314 F.3d at 57. Although "Section 43(a) of the Lanham Act has been characterized as a remedial statute that should be broadly construed," *Gordon & Breach Science Publishers v. AIP*, 859 F. Supp. 1521, 1532 (S.D.N.Y. 1994), "Congress, in extending the Lanham Act to product disparagement, made clear that this extension should not be interpreted so as to infringe on free speech protected by the First Amendment," *id.* at 1533. As Judge Sand explained after reviewing the relevant legislative history in *Gordon & Breach*, the reach of Section 43(a) "specifically extends only to false and misleading speech that is encompassed within the 'commercial speech' doctrine developed by the United States Supreme Court." *Id.* at 1533–34, 1536. Commercial speech "is entitled to a lesser degree of protection than other forms of constitutionally guaranteed expression. Accordingly, the government may regulate commercial speech in ways that it may not regulate other speech." *Id.* at 1536 (internal citations omitted).

The Second Circuit has established a three-factor test to determine whether statements constitute "commercial advertising or promotion" under Section 43(a) of the Lanham Act: The statement "must be (1) commercial speech, (2) made for the purpose of influencing consumers to buy defendant's goods or services, and (3) although representations less formal than those made as part of a classic advertising campaign may suffice, they must be disseminated sufficiently to

the relevant purchasing public."[2] *Gmurzynska v. Hutton*, 355 F.3d 206, 210 (2d Cir. 2004) (internal quotation marks and citations omitted) (collecting cases); *see also Enigma Software Group USA, LLC v. Bleeping Computer LLC*, 194 F. Supp. 3d 263, 293 (S.D.N.Y. 2016) (quoting and applying this *Gmurzynska* standard).

Pure "commercial speech" is "speech which does no more than propose a commercial transaction." *Gmurzynska*, 355 F.3d at 210; *see also Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 66 (1983) (noting that the "core notion of commercial speech" is "speech which does no more than propose a commercial transaction" (internal quotation marks omitted) (quoting *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 762 (1976))). A "'hybrid' communication, *i.e.*, one that combines commercial and non-commercial elements, may also be considered 'commercial' where (1) it is an advertisement; (2) it refers to a specific product or service; and (3) the speaker has an economic motivation for the speech." *Bleeping Computer*, 194 F. Supp. at 294 (citing *Bolger*, 463 U.S. at 66–67). In *Bolger*, the Supreme Court held that informational pamphlets "discussing the desirability and availability of prophylactics in general or [the defendant's] products in particular" were commercial speech because they were "conceded to be advertisements," contained "reference to a specific product," and the defendant "ha[d] an economic motivation for mailing the pamphlets. *Bolger*, 463 U.S. at 66–67. Even though no one of those factors was

[2] This test "adopts three of the four prongs first described by the Honorable Leonard B. Sand in *Gordon & Breach Science Publishers S.A. v. Am. Inst. of Physics*, 859 F. Supp. 1521, 1535–36 (S.D.N.Y. 1994)." *Boule v. Hutton*, 328 F.3d 84, 91 (2d Cir. 2003). The Second Circuit has repeatedly declined to reach the question whether "the fourth prong from *Gordon & Breach*—that the defendant and the plaintiff be competitors—is necessary to find commercial advertising and promotion." *Id.*; *see also Fashion Boutique*, 314 F.3d at 58; *Gmurzynska*, 355 F.3d at 210. Even if the fourth requirement is necessary, it is not at issue here; there is no debate that ChromaDex and Elysium are competitors.

independently sufficient to place the pamphlets in the category "commercial speech," the combination of the three made them commercial speech "notwithstanding the fact that they contain discussions of important public issues." *Id.*

Elysium's Counterclaim challenges a specific statement on the Right of Assembly blog, a blog located at the website address right-of-assembly.org. Joint 56.1 ¶ 49. The challenged statement is:

> ChromaDex isn't allowed to say that NR treats any disease, because the FDA has not approved that. But the FDA doesn't regulate me, so I am free to tell you that the scientific evidence is growing that NR supplements replenish cellular NAD, which can protect against MANY ailments, including Alzheimer's, Heart Disease, Parkinson's Disease, Breast Cancer, alcohol induced liver poisoning, chemotherapy induced peripheral neuropathy, organ injury from sepsis and in my own experience, Restless Legs Syndrome (RLS). You can find out more here: AboutNAD.com.

Id. Elysium alleges that the statement appears "on upwards of 20 blog posts—posts that were flooded with advertisements for Tru Niagen, and with direct links to purchase the product." Counterclaim ¶ 144. Elysium further asserts that Right of Assembly is "a marketing website for Tru Niagen for which ChromaDex pays commissions to Shelly Albaum for Tru Niagen customers referred through the website." Dkt. No. 249 ¶¶ 19–20, 23.

The challenged statement is not pure commercial speech, i.e., "speech that does no more than propose a commercial transaction." It does not propose a commercial transaction at all, but merely purports to convey information about NR and NR supplements. As ChromaDex points out, the challenged statement is "about the 'scientific evidence' surrounding NR [and] does not refer to Tru Niagen, ChromaDex, or link to any website where Tru Niagen may be purchased." Dkt. No. 262 at 4. The challenged statement, viewed in isolation, also would not constitute "hybrid" commercial speech under the *Bolger* analysis. Even accepting, as the Court must on summary judgment, that the evidence construed favorably to Elysium establishes that the speaker

had an economic motivation for the speech,[3] the challenged statement on its face is not an advertisement and does not refer to any specific product or service. It is a comment on a molecule and on a category of products no different than a comment which one might see made in the public interest with respect to any category of products claimed to have health benefits.

Elysium argues that the Court should analyze the website as a whole to determine whether it is commercial speech, rather than analyzing the challenged statement in isolation. It characterizes Right of Assembly not as a "third-party, noncommercial blog," but rather "as a referral website for Tru Niagen" that "advertises Tru Niagen at the top of every page of its website." Dkt. No. 250 at 18–19.

The law supports the proposition that whether a statement constitutes commercial speech in the first instance and a promotion or advertisement in the second is not to be judged solely by looking at the challenged statement alone and in isolation but also by examining the entire communication in which the statement appears. With respect to commercial speech, *Bolger* itself is illustrative. The Court did not limit its analysis to each sentence in the pamphlets being regulated but addressed the pamphlet as a whole. In the Lanham Act context, as well, courts do not end the analysis with the language that is alleged to be false and misleading but also consider the larger communication in which the statement is located. *See, e.g.*, *Apotex*, 823 F.3d at 66 (examining brochures as a whole); *Gmurzynska*, 355 F.3d at 210–11 (considering whether alleged misrepresentations were actionable under the Lanham Act, and analyzing both the statements themselves and the broader context in which the statements were made—in a museum exhibition catalogue and in a magazine article). A statement that a product has health or other

[3] This remains true regardless whether the speaker is properly viewed as Albaum on his own behalf, or Albaum as ChromaDex's agent.

benefits may be considered a public service announcement if it is located in a copy of Consumer Reports. *See Gordon & Breach*, 859 F. Supp. at 1534. It would take on quite a different flavor and the communication as a whole would be regulated by the Lanham Act if it was issued by a person with an economic motive and at the end of the commercial or advertisement touting health benefits, a banner appeared "Buy This Product." *See id.*; *cf. Donini Intern., S.p.A. v. Satec (U.S.A.) LLC*, 2004 WL 1574645, at *7 (S.D.N.Y. July 13, 2004) (rejecting Lanham Act claim based on allegedly false and defamatory statements appearing in articles in a trade magazine in part because the magazine "is not in the business of selling any goods or services that could have been promoted by statements contained in the articles in question").

Elysium's argument, however, runs afoul of the federal and the local rules regarding summary judgment. A party with the burden of proof may not rely on mere assertion alone when its claim is properly challenged by the movant. Under Federal Rule of Civil Procedure 56(c), it must either cite to "particular parts of materials in the record" including depositions and documents that would create a genuine issue of fact or show that the materials cited do not establish the absence of a genuine dispute. Fed. R. Civ. P. 56(c); *see also Jaramillo*, 536 F.3d at 145; *Wright*, 554 F.3d at 266. Under Local Rule 56.1(d), a statement by an opponent to summary judgment "must be followed by citation to evidence which would be admissible, set forth as required by Fed. R. Civ. P. 56(c)." L.R. 56.1(d); *see also Holtz*, 258 F.3d at 74. Although Elysium states in its Rule 56.1 statement of additional facts that the blog "has Tru Niagen advertisements at the top of *each page* that are live links to purchase Tru Niagen" the only evidence to which it points is a screenshot of one page of the Right of Assembly blog that does not contain the challenged statement. *See* Dkt. No. 245, Ex. UU. Rather, it shows advertisements for Tru Niagen on what appears to be the homepage of the blog, with links to

blog posts in order of recency. *Id.* The single page does not demonstrate that the challenged statement is accompanied by an advertisement for Tru Niagen. ChromaDex pointed out the absence of evidence that the blog statement was commercial speech in its Rule 56.1 statement. ChromaDex 56.1 ¶¶ 19–20. The burden thus fell to Elysium to support its claim. *See Jaramillo*, 536 F.3d at 145 (stating that, if the moving party meets its burden, "the nonmoving party must come forward with admissible evidence sufficient to raise a genuine issue of fact for trial in order to avoid summary judgment"); *Gottlieb*, 84 F.3d at 518 (stating that the nonmoving party "cannot defeat the motion by relying on the allegations in [its] pleading, or on conclusory statements, or on mere assertions that affidavits supporting the motion are not credible" (internal citation omitted)). It did not meet that burden. As ChromaDex notes, "Elysium does not provide links to or screenshots of the posts where the above language appeared." Dkt. No. 210 at 7 n.3. Nor does the evidence support Elysium's assertion that there is a reference to Tru Niagen on the top of every page of the website. That assertion is pure *ipse dixit*. Elysium had the opportunity to take discovery. It could have deposed the blogger or presented evidence of what was on the blog as a whole if that evidence supported its claim. In the absence of any such evidence, Elysium cannot withstand ChromaDex's motion for summary judgment on this claim.

Elysium's claim cannot withstand summary judgment for another reason. Elysium has identified no admissible evidence to support the claim that ChromaDex made the challenged statement. The Lanham Act is directed to the "person who . . . uses in commerce" a false or misleading statement in commercial advertising or promotion. 15 U.S.C. § 1125. The language connotes being an active user, not a passive beneficiary. The law ordinarily applies where the challenged statement is made by the defendant and attributed to it; that is the clearest use in commerce. It has been applied in a handful of cases where, even though a statement is not

attributed to the defendant, it is made by an agent of the defendant. *See, e.g.*, *Bleeping Computer*, 194 F. Supp. 3d at 269. The theory presumably is that the statutory language carries with it the common law concept that a principal is typically liable for tortious acts committed by its agent within the scope of the agent's authority. *See* Restatement (Third) of Agency 2, *Introductory Note* ("This Chapter states . . . the three distinct bases on which the common law of agency attributes the legal consequences of one person's action to another person."). There are no reported cases where Lanham Act liability is extended to a company that merely benefits from the statement and compensates the author for the statement in the absence of an agency relationship or evidence that it has exercised control over or caused the statement.

In its Rule 56.1 statement, ChromaDex points to the absence of evidence that it made the challenged statement on the Right of Assembly blog. ChromaDex asserts the blog is "the personal blog of an individual named Shelly Albaum." ChromaDex's 56.1 ¶ 19 (citing www.right-of-assembly.org); *see also* Dkt. No. 245, Ex. UU ("Right of Assembly is my personal blog. All opinions are my own."). ChromaDex states that "[t]here is no evidence in the record that ChromaDex controls editorial content, including any at-issue language, on Right of Assembly." ChromaDex's 56.1 ¶ 20. Elysium responds that "Mr. Albaum is acting as ChromaDex's advertising agent," Dkt. No. 250 at 19, and that the Right of Assembly is "a marketing website for Tru Niagen for which ChromaDex pays commissions to Shelly Albaum for Tru Niagen customers referred through the website," Dkt. No. 249 ¶¶ 19–20, 23.

The evidence that Elysium cites fails to create a genuine issue of material fact. An agency relationship exists "when one person (a "principal") manifests assent to another person (an "agent") that the agent shall act on the principal's behalf and subject to the principal's control, and the agent manifests assent or otherwise consents so to act." Restatement (Third) of

Agency § 1.01. Thus, "[a]n essential characteristic of an agency relationship is that the agent acts subject to the principal's direction and control." *In re Shulman Transport Enterprises, Inc.*, 744 F.2d 293, 295 (2d Cir. 1984). If the principal is able to control the actions of the agent, it is not unfair to impose liability on the principal for injury caused to a third party.

The evidence Elysium does not create a genuine issue of fact that Albaum acts under ChromaDex's direction and control. Elysium cites an undated slide deck on ChromaDex's affiliate program which includes Albaum as one of ChromaDex's affiliates, Dkt. No. 251, Ex. SS,[4] but the deck does not support the proposition that ChromaDex enjoyed any agency relationship with Albaum. It indicates only that at some point in time (either before or after the challenged statement) a marketing consultant—not Albaum—was asking "[w]hat placements can be optimized" and "[w]ill she [sic] work with you to ad [sic] content regularly." Rather than support Elysium, the deck supports the inference that Right of Assembly did not report to ChromaDex and that it did not even regularly work with the company in creating content. Dkt. No. 263 ¶ 23. Elysium also cites to evidence that the Right of Assembly blog holds Albaum out as a ChromaDex marketing affiliate. Dkt. No. 245, Exs. VV–WW (screenshots from the Right

[4] ChromaDex argues that this slide deck is unauthenticated and inadmissible. Under Federal Rule of Evidence 901(a), the requirement that documents be authenticated "is satisfied by evidence sufficient to support a finding that the matter in question is what the proponent claims." F. R. Evid. 901(a). "[T]estimony of a witness with knowledge provides appropriate authentication." *Commercial Data Servers, Inc. v. IBM Corp.*, 262 F. Supp. 2d 50, 58 (S.D.N.Y. 2003). Elysium offers this slide deck along with a declaration from its attorney that it "is a true and correct copy of ChromaDex's "TRU NIAGEN Affiliate Program Audit" produced by ChromaDex in this action bearing the Bates numbers CDX_00077392-410." Dkt. No. 251 ¶ 11. This declaration "constitutes testimony by a witness with knowledge of what the firm received from its opponent in response to legitimate discovery requests" and therefore properly authenticates the document. *IBM*, 262 F. Supp. at 58–58; *cf. Wahhab v. City of New York*, 386 F. Supp. 2d 277, 291 (S.D.N.Y. 2005) (holding that where "[t]he documents in question are not sworn, they do not contain an affirmation indicating the truth of their contents, nor do they assert a basis in personal knowledge," they "do not qualify as evidentiary proof in admissible form" and thus "will not be considered by this court in this summary judgment ruling").

of Assembly website indicating that it is a ChromaDex marketing affiliate). But that Right of Assembly calls Albaum a marketing affiliate, without more, does not support the notion that ChromaDex holds him out publicly as a marketing affiliate or that ChromaDex exercises any authority over the speech that Albaum makes or does not make.

Finally, Elysium cites to deposition testimony of then–ChromaDex CEO Frank Jaksch that Albaum is a ChromaDex shareholder and that characterizes an affiliate relationship as one where "somebody else would post a small ad or whatever you want to call it, something on the website that if somebody clicked on it would drive them to our website if they bought that product. Where that traffic came from or who had that ad posted would be paid some form of a commission." Dkt. No. 251, Ex. TT at 141–46. Elysium also cites to two emails between Albaum and Jaksch in one of which Albaum reaches out to Jaksch with a blog article (albeit not one with the challenged statement) that he states he chose not to post but will post the article if "Jaksch wants me to" and requests that Jaksch "consider these ideas seriously," and in another of which Jaksch reaches out to Albaum to flag the filing of ChromaDex's citizen petition. *Id.* ¶ 24 (citing Dkt. No. 251, Ex. XX–YY).

That evidence does not establish that ChromaDex had a relationship with Albaum or with Right of Assembly where it was able to exercise direction or control over Albaum's communications. That Albaum was a shareholder of ChromaDex gave him an independent economic incentive to tout its products no different than the economic incentive that any investor, whether an activist institutional investor or a retail investor, might have to promote the products of a company in which it has a financial interest. That interest does not give the company whose shares are owned the ability to exercise direction and control over its shareholder nor does it make the company responsible for every one of the shareholder's

statements. Likewise, the fact that ChromaDex might reward Albaum or any other third party for steering business ChromaDex's way does not establish that ChromaDex has the ability to exercise any control or direction over the statements that Albaum might make. A whole industry exists of social media influencers, who create their own content touting products and receive commission on sales of those products that stem from their advertising. A claim might lie directly against such persons whether under federal law or the state law of trade defamation if they make a false and misleading statement. But in the absence of evidence that an influencer is making the statement on behalf of the defendant or at the defendant's direction or under its control rather than simply for its own benefit, the company cannot be held liable on a principal–agent theory. *See In re Fyre Festival Litigation*, 399 F. Supp. 3d 203, 213 (S.D.N.Y. 2019) (holding that "[c]ertain allegations reference statements made by online influencers who are not defendants . . . cannot form the basis of a fraud claim" against the defendants because they are not "attributable to defendants").

The emails reflect that Albaum believed he had the authority to make his own independent decisions whether to post or not, even if he might—based on the exercise of his own discretion—choose to follow a request of Jaksch. They do not reflect that Jaksch made such a request as to any communication or that Albaum honored it. To the extent the emails show ChromaDex communicating with a shareholder who—in turn—was communicating with the public, companies not infrequently communicate with shareholders and other third parties who might write about the company or its products. Both the company and its shareholder have an interest in getting the communication right. *Cf. Elkind v. Liggett & Myers, Inc.*, 635 F.2d 156, 163 (2d Cir. 1980) (affirming lower court's finding that defendant did not "place its imprimatur, expressly or impliedly," on projections even though it "did examine and comment on a number

of reports" and "made suggestions as to factual and descriptive matters in a number of the reports it reviewed"), *superseded on other grounds as stated in Acticon AG v. China North East Petroleum Holdings Ltd.*, 692 F.3d 34 (2d Cir. 2012). But that the fact that the company might communicate with a person who later writes about the company or its product does not make the company liable under the Lanham Act. To so penalize the company or its executive officers based solely on a company's executives private communications with the company's shareholder would strain both the Lanham Act and the First Amendment.

The principal case cited by Elysium highlights the deficiency of Elysium's claim. In *Enigma Software Group USA, LLC v. Bleeping Computer LLC*, a computer software company asserted a Lanham Act false advertising claim, for statements made about it and its product on a computer support website owned and operated by the defendant.[5] 194 F. Supp. 3d at 269. The court concluded that the allegations regarding a moderator on the site, Quietman7, "plausibly support the conclusion that Quietman7 was acting, at a minimum, as [defendant's] implied agent when he posted the allegedly offending content." *Id.* at 274–75 (internal quotation marks, citations, and alterations omitted). Quietman7 was publicly designated by the defendant as a "Global Moderator" and "Advisor," which are "the second and third highest 'staff member' positions within the [defendant] member group hierarchy"; publicly accepted those appointments and held himself out on the website as a member of the staff; was, as a staff member of the defendant, "authorized and expected to post in [defendant's] forums," and "directed to recommend and promote certain products for which [the defendant] receives commissions and to discourage use of other products from which it does not receive commission"; and as an

[5] The court thus did not consider whether the same claim could be asserted against the plaintiff's direct competitor with whom the defendant had an affiliate relationship, a much closer parallel to this case. *See id.* at 271.

"Advisor" was "touted as [an] expert[] who can be trusted to give correct and understandable answers to [defendant's] member's questions," and as a "Global Moderator" was "authorized to enforce the rules of [the defendant's website], to answer questions (or help people with problems), and to suspend forum posting privileges of members who violate forum rules." *Id.* In those circumstances, it was fair to believe that a principal–agent relationship existed.

There are no similar facts here that could support a finding of an agency relationship between ChromaDex and Albaum. No evidence suggests that ChromaDex controls or even monitors any of the content on the Right of Assembly webpage, let alone the challenged statements themselves. No evidence suggests that ChromaDex publicly held out Albaum to be a member of its staff, endorsed to make statements on his blog that ChromaDex attested were "correct." No evidence suggests that Albaum publicly held himself out to represent ChromaDex; in fact, his blog explicitly disclaims any such representation.

Rather, the record reflects only that Albaum is a ChromaDex shareholder and a successful member of ChromaDex's marketing affiliate program who receives a commission for sales of Tru Niagen through his webpage. As in *Bleeping Computer*, if Elysium has a claim based on alleged false advertising on the blog, that claim would lie against Right of Assembly or Albaum, not against ChromaDex.

B. Falsity

Both parties' motions for summary judgment focus heavily on the falsity element of the Lanham Act. Elysium moves for summary judgment, asking this Court to dismiss ChromaDex's "claims in its Second Amended Complaint . . . in their entirety" because "ChromaDex cannot show that any of Elysium's alleged misstatements are false or misleading." Dkt. No. 222 at 1, 11. ChromaDex, in turn, moves for summary judgment on Elysium's counterclaims because "Elysium cannot meet its burden of showing that any of ChromaDex's purported advertising

claims are literally false." Dkt. No. 210 at 1. Elysium also moves for summary judgment on the portion of its Counterclaim that relates to what it terms the "Counterfeit Page," arguing that "the statements in the Counterfeit Page . . . are literally false or false by necessary implication . . . ." Dkt. No. 222 at 25. The Court addresses the arguments as to falsity in these two motions in turn.

1. ChromaDex's Complaint

Elysium's motion for summary judgment on ChromaDex's claims as to the falsity element of the Lanham Act is granted in part and denied in part. Elysium's motion is granted with regard to ChromaDex's claims about statements regarding the safety and purity of Basis, statements that Basis is clinically proven to raise NAD+ levels based on the Dellinger Study, statements that Basis is the "first" such supplement, statements regarding the expected synergistic effects of combining NR and PT, statements regarding FDA regulation of Basis, statements regarding Elysium's role in the research behind Basis, statements that Elysium is the exclusive licensee of an NR patent, statements regarding the amount of NR in Basis, and statements about Elysium's Scientific Advisory Board and client testimonials. Elysium's motion is denied with regard to the statement that Basis is the "only" supplement proven to increase and sustain NAD+ levels in humans.

a. Statements Relating to Safety and Purity of Basis

i. Statements Regarding the Dellinger Study

As it has been limited through the briefing, ChromaDex's allegations that Elysium made false statements that Basis is "safe" and "pure," Dkt. No. 222 at 11, have been reduced to one statement. On its website, Elysium made the following claim:

- "Basis Increases NAD+ Levels, Safely and Sustainably," and the Dellinger Study "confirmed the safety of Basis, demonstrating that participants experienced no serious adverse effects and that Basis continues to be safe for daily use as determined by standard safety measures." Dkt. No. 255 at 16 (quoting SAC, Exs. G, N).

ChromaDex alleges that the statement is literally false; it alleges that Basis did not increase NAD+ levels safely and the Dellinger Study did not confirm the safety of Basis. Dkt. No. 255 at 16.

"One kind of literally false claim is a claim of test-proven superiority. The premise is that the 'defendant's advertisement explicitly or implicitly represents that tests or studies prove its product superior' . . . ." *Apotex*, 823 F.3d at 63 (internal alterations omitted) (quoting *Castrol, Inc. v. Quaker State Corp.*, 977 F.2d 57, 63 (2d Cir. 1992)). The claim challenges whether a cited test supports the underlying proposition, not the truth or falsity of the underlying proposition itself. Accordingly, to succeed on a claim of false advertising for statements based on clinical studies, the plaintiff must demonstrate that the relevant study is "not sufficiently reliable to permit one to conclude with reasonable certainty that [it] established the claim made." *McNeil-P.C.C., Inc. v. Bristol-Myers Squibb Co.*, 938 F.2d 1544, 1549 (2d Cir. 1991); *McNeil-PPC, Inc. v. Pfizer Inc.*, 351 F. Supp. 2d 226, 248–49 (S.D.N.Y. 2005). "The fact-finder's judgment should consider all relevant circumstances, including the state of the testing art, the existence and feasibility of superior procedures, the objectivity and skill of the persons conducting the tests, the accuracy of their reports, and the results of other pertinent tests." *Proctor & Gamble Co. v. Chesebrough-Pond's Inc.*, 747 F.2d 114, 119 (2d Cir. 1984). If the test is not sufficiently reliable to permit one to conclude with reasonable certainty that the test established the claim made, then the advertising assertion that the test proved or established the proposition is false.

On its face, the Dellinger Study says what Elysium claims it said. As noted above, the study showed a dose-dependent increase in NAD+ levels sustained over the course of the trial. Dkt. No. 229 ¶ 12, Ex. C ("Dellinger Study"). In the group receiving a single dose of Basis for

eight weeks ("NRPT 1X"), NAD+ levels increased by approximately 40% as compared to the placebo baseline, and in the group receiving a double dose of Basis for eight weeks ("NPRT 2X"), NAD+ levels increased by approximately 90%, as compared to the placebo baseline. Dellinger Study at 1. In both groups, the increased NAD+ levels were sustained throughout the eight-week study. *Id.* Moreover, the study reported "no serious adverse events," and concluded that "a repeat dose of NRPT is a safe and effective way to increase NAD+ levels sustainably." *Id.* The study thus supports Elysium's claim—that "Basis Increases NAD+ Levels, Safely and Sustainably," and that the Dellinger Study "confirmed the safety of Basis."

The burden is on ChromaDex at summary judgment to adduce evidence from which a factfinder could determine that the Dellinger Study was not sufficiently reliable to "establish the proposition for which [it was] cited." *Apotex*, 823 F.3d at 63 (quoting *Castrol*, 977 F.2d at 63). ChromaDex has identified no evidence to support that the Dellinger Study is not sufficiently reliable to permit one to conclude with reasonable certainty that it establishes the proposition for which it was cited—that Basis safely and sustainably raises NAD+ levels. It identifies no evidence regarding the state of the testing art, the existence and feasibility of superior procedures, the objectivity and skill of the persons conducting the tests, the accuracy of the reports, or the results of other pertinent tests that would call into question the reliability of the Dellinger Study's conclusions.

ChromaDex relies exclusively on the fact that the Dellinger Study found that the groups taking Basis experienced increases in LDL-cholesterol and that the study concluded that further research was needed to fully understand whether these changes were attributable to Basis. The study stated:

> Total cholesterol and LDL-cholesterol showed within-group increases at day 30 (NRPT 2X) and day 60 (NRPT 1X and NRPT 2X) compared to baseline. The

> increase in total cholesterol in the NRPT 1X group compared to the placebo group was not significant at day 30 or day 60. The increase in LDL cholesterol in the NRPT 1X group compared to the placebo group was approximately 3% at day 30 and 3.5% at day 60. Larger increases in total cholesterol and LDL cholesterol were observed in the NRPT 2X group. However, there were significant across group differences in total and LDL cholesterol at baseline mainly due to lower levels in the placebo group, confounding the interpretation of the study data.
>
> Thus, we stratified the three treatment groups by BMI and reanalyzed the data. Subjects in the NRPT 1X group with normal BMI[6] (18–25) showed no significant increases in LDL cholesterol at day 30 or day 60. Subjects in the NRPT 2X group with normal BMI did show increases in LDL cholesterol at day 30 and day 60. Subjects in the overweight category (BMI 25–32) showed increases in LDL cholesterol at day 30 and day 60 in both the NRPT 1X and NRPT 2X groups. However, overweight subjects in the placebo group also showed a significant increase at day 60. Overall, these findings suggest a small but significant increase in cholesterol may occur at the normal dose of NRPT, at least for people with a higher than normal BMI. Further studies are needed with increased number of subjects to determine if the small changes observed are real or due to chance.

Dellinger Study at 5.

The evidence that the Dellinger Study itself found a 3.5% increase in LDL cholesterol in the group taking Basis does not call into question the reliability of the conclusion reached by the authors of that same study that Basis is safe. In particular, ChromaDex identifies no evidence either from fact or expert witnesses that would support the conclusion that Basis caused the increase in cholesterol. From the evidence before the Court, it would require an unfounded leap to infer that Basis is unsafe simply because in the study there was a correlation between taking Basis and a slight increase in LDL cholesterol. *Cf. In re Mirena IUS Levonorgestrel-Related Products Liab. Litig.*, 387 F. Supp. 3d 323, 337-38 (S.D.N.Y. 2019) (requiring expert evidence of general and specific causation in products liability case). To conclude otherwise is to fall prey to the "post hoc, ergo propter hoc" fallacy—that simply because one event follows another one can conclude that the first event caused the second.

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[6] Body mass index, *see* Dellinger Study at 7.

More importantly, ChromaDex identifies no evidence that the increase in cholesterol reported in the Dellinger Study says anything about the safety of Basis. To the contrary, Elysium points to various pieces of evidence that show both that Basis did not necessarily lead to the increase in LDL and that the increase in LDL did not make Basis unsafe. That evidence includes the declaration of Marguerite Brackley, an independent medical consultant retained by Elysium, stating both that "[n]umerous factors unrelated to Basis could explain the LDL results, including the very small sample sizes, differences in baseline characteristics of the patients in the different trial arms, and normal variations in LDL levels," and that "there was no indication that any increase in LDL was *clinically* significant, i.e., that it had any health consequences for the patients in the study." Dkt. No. 226 ¶ 4. It also includes Brenner's testimony at deposition that LDL fluctuates day to day in a healthy person and "can fluctuate . . . 5 or 10 percent," Dkt. No. 223, Ex. 1 at 179, i.e., that the increase of 3.5% in the Dellinger Study is consistent with normal fluctuations and that a person could experience the increase in LDL reflected in the study while still remaining healthy. Elysium also points to the deposition testimony of Kurt Hong, who was retained by ChromaDex as an expert witness, that when he was evaluating the Dellinger Study, he was not able to determine how likely the participants were to have an adverse health effect based on the increase in their LDL levels. Dkt. No. 223, Ex. X at 157. Finally, Elysium points to testimony that it conducted a clinical study which is not yet published, but the details of which are available on clinicaltrials.gov, in which participants who took Basis for ninety days showed no statistically significant change in LDL levels. Dkt. No. 257, Ex. 4 at 168–71; Ex. 7 at 142–45.

ChromaDex's argument to the contrary relies on "unsubstantiated speculation." *F.D.I.C.*, 607 F.3d at 292. It fails to identify anything in the record inconsistent with that evidence or that

would create a genuine issue of fact as to whether the Dellinger Study was not sufficiently reliable to permit one to conclude with reasonable certainty that Basis was safe. It does not identify evidence from which a jury could conclude that Basis caused the increase in LDL levels or that even if it did, such increase rendered Basis unsafe. Thus, there is no evidence to dispute what the Dellinger Study authors themselves reported and what Elysium then relayed—that the Dellinger Study confirmed that Basis is safe.

ChromaDex points to "numerous customer communications with complaints about increased LDL cholesterol in customers taking Basis." Dkt. No. 355 at 11 (citing Dkt. No. 257, Ex. 23). In particular, Exhibit 23 contains forty-one "Zendesk tickets," ranging in dates from 2016 to 2020, each of which involves a customer communication referencing cholesterol or LDL. Dkt. No. 257, Ex. 23. In some cases, the consumers claim that Basis raised their cholesterol or that their LDL levels increased after taking Basis, regardless of causation, *see, e.g.*, *id.* at 2 ("affected hers and her husband's cholesterol and caused it to increase"); *id.* at 3 ("After taking basis for 6 months, my LDL levels in bloodwork came back much higher."); in others, the consumer simply raises a concern about the possibility of Basis affecting their cholesterol, *see, e.g.*, *id.* at 5 ("I am concerned about taking Elysium because it contains pterostilbene which has been shown to increase LDL."). The evidence is not surprising and not inconsistent with the Dellinger Study— it does not create an issue with respect to the reliability of the Dellinger Study. The Dellinger Study found that some persons on Basis experienced increases in LDL. It thus stands to reason that there would be some persons who experienced increases in LDL while on Basis who complained about that increase. But it does not follow from the complaints that the increase was caused by Basis or that it led to an unsafe condition. The complainants did not know the cause of the increase in their LDL. It is not disputed that that the forty-one tickets were

among the 525,037 customer messages received by Elysium during this four-year period. Dkt. No. 273 at 7 (citing Dkt. No. 270, Ex. RRR). ChromaDex provides no context for or any other information about these messages. It does not provide information regarding "the source, content, and context of the reports." *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 43 (2011). There is no information to support that the reports of an increase in LDL or cholesterol were accurate, that the increase was sufficient to create safety concerns, or that the increase was related in any way to Basis as opposed to some other health condition of the comment author. Even assuming that the reports were reliable and that the increase in cholesterol was significant and sustained, "the mere existence of reports of adverse events . . . says nothing about whether the drug is causing the adverse events." *Id.* at 44. Pointing to a few dozen customer complaints referencing cholesterol, in context of the hundreds of thousands of customer messages received during this time, is not sufficient to create a triable issue of fact regarding the reliability of the Dellinger Study.

ChromaDex also claims broadly that Elysium's scientific advisory board ("SAB") "recommended eliminating PT from Basis because 'a 10% increase in cholesterol is not trivial,'" and that "there was Board consensus that, at the very least, additional studies were needed" but that "Elysium has not published any follow-up studies on the effect or either PT or the NRPT combination on LDL levels." Dkt. No. 255 at 12 (citing Dkt. No. 257, Ex. 24). The opponent of summary judgment may not rely simply on assertion but most point to "particular parts of materials in the record" to support the assertion. *See Wright*, 554 F.3d at 266 ("When a motion for summary judgment is properly supported by documents or other evidentiary materials, the party opposing summary judgment may not merely rest on the allegations or denials of his pleading; rather, his response, by affidavits or otherwise as provided in the Rule, must set forth

'specific facts' demonstrating that there is 'a genuine issue for trial.'" (quoting Fed. R. Civ. P. 56(e))). The evidence that ChromaDex cites does not support its assertions. The only evidence ChromaDex cites is an email from one board member who did not attend the meeting where the results were discussed who, after stating that "a 10% increase in cholesterol is not trivial," adds "I may misunderstand some of the results or facts." Dkt. No. 257, Ex. 24 at 2. The Dellinger Study did not show a 10% increase in cholesterol in the recommended dosage; it showed that increase in the group taking twice the recommended dosage. *See* Dkt. No. 257, Ex. 4 at 159–60. There is no evidence that the SAB recommended eliminating PT from Basis. As to the supposed consensus that additional studies were needed, that was the view of the Dellinger Study itself. It is not inconsistent with its conclusion, nor does it call into question its methodology.[7]

ChromaDex points to no evidence suggesting that the study's conclusion—that, considering all the results including the increase in LDL levels, Basis safely and sustainably increased NAD+ levels—was false or unreliable, and therefore that Elysium's citation to that conclusion in its advertising was, by extension, false. As such, there is no triable issue of fact, and Elysium is entitled to summary judgment on this claim.

ii. Other Statements Regarding Safety and Purity

In its complaint, ChromaDex initially challenged other of Elysium's statements regarding safety and purity including:

- Elysium's statement in a *CEO/CFO Magazine* article published on or around December 11, 2017 that "[w]e also needed to develop the supply chain so that we have the highest quality material possible and in the purest form possible." Dkt. No. 222 at 11 n.1 (quoting SAC ¶ 98, Ex. P).

[7] Moreover, Elysium did conduct a follow-up study which tracked the effects of Basis on cholesterol levels over time, as recommended by the advisory board. *See* Dkt. No. 257, Ex. 4 at 168–71.

- Elysium's statement in a *Proof Wellness* article published on or around August 13, 2019 that "we wanted to set a new standard for quality and purity for consumer products by establishing a supply chain that exceeded guidelines set by the FDA and was validated by third-parties." *Id.* (quoting SAC ¶ 98, Ex. EE).

- Elysium's statement in a *Techcrunch* article published on or around August 29, 2019 that "[b]y and large [Basis] is one of the safest products we've ever seen." *Id.* (quoting SAC ¶ 114, Ex. GG).

- Elysium's statement first published on its website on or around February 23, 2019 that Basis is "Setting A New Standard o[f] Quality and Purity." *Id.* (quoting SAC ¶ 98, Ex. G).

ChromaDex initially alleged that Elysium's claims regarding the "quality" and "purity" of its ingredients were false because Elysium's methods of manufacturing "caused high levels of acetamide, a known carcinogen, to be present in Basis shipped to consumers." SAC ¶ 99. That allegation, however, did not survive discovery. As Elysium points out, the undisputed evidence establishes that it "eliminated all acetamide from its manufacturing process in or about August 2017," and that it "made its Safety and Purity Claims *after* acetamide was eliminated from the ingredient." Dkt. No. 222 at 12 (citing Dkt. No. 227 ("Morris Decl.") ¶ 7, Ex. A). There is no other basis ChromaDex has asserted for challenging the truth of the statements regarding quality and purity. Thus, Elysium is entitled to summary judgment.

In any event, ChromaDex does not defend against the argument by Elysium that the statements are either true or are not literally false and thus the claims are deemed abandoned. *See, e.g.*, *Shenk v. Karmazin*, 868 F. Supp. 2d 299, 311 n.12 (S.D.N.Y. 2012) ("While [the plaintiff] originally alleged in his complaint that the defendants breached their fiduciary duties . . . , he has not responded to defendant's arguments on summary judgment. Accordingly, he has conceded that defendants are entitled to summary judgment on this claim for breach." (citing *Taylor v. City of New York*, 269 F. Supp. 2d 68, 75 (E.D.N.Y. 2003) ("Federal courts may deem a claim abandoned when a party moves for summary judgment on one ground and the party

opposing summary judgment fails to address the argument in any way."))); *Douglas v. Victor Capital Group*, 21 F. Supp. 2d 379, 393 (S.D.N.Y. 1998) (deeming claims alleged in the complaint abandoned where "Defendants' summary judgment motion specifically addressed all of these claims," but the plaintiff's "opposition papers, however, addressed none of these claims," and collecting cases where other courts have similarly deemed claims abandoned for failure to defend them in opposition to summary judgment).

b. Statements Regarding Elysium's Clinical Studies

i. "Basis is clinically proven to raise NAD+ levels based on the Dellinger Study"

ChromaDex also alleges that a "key advertising claim . . . that Basis is clinically proven to raise NAD+ levels based on the Dellinger Study" is literally false because at the time it was made Elysium had ceased to use ChromaDex's Niagen and was using a different source of NR for Basis and "the Dellinger Study was conducted on ChromaDex's ingredients, not Elysium's." Dkt. No. 255 at 15. ChromaDex makes two related arguments: (1) because Elysium had started using a different source of NR and PT after the time of the Dellinger Study, its statements based on reports conducted on the earlier version of the product are necessarily false; and (2) the statements give consumers "the false impression that its clinical trials were conducted on the same ingredients in Basis today." SAC ¶ 63(d)(i).

As with ChromaDex's prior challenge to the Dellinger Study, to succeed in its claim, ChromaDex must demonstrate that the study is "not sufficiently reliable to permit one to conclude with reasonable certainty that [it] established the claim made." *McNeil-P.C.C., Inc. v. Bristol-Myers Squibb Co.*, 938 F.2d at 1549; *McNeil-PPC, Inc. v. Pfizer Inc.*, 351 F. Supp. 2d at 248–49. The burden, therefore, is on ChromaDex to present evidence sufficient to create a jury issue that the Dellinger Study is not sufficiently reliable to permit one to conclude with

reasonable certainty that it establishes that Basis, as formulated at the time of the statements at issue, raises NAD+ levels. ChromaDex has not identified any such evidence.

ChromaDex argues that because at the time the trial was conducted, Elysium was sourcing its NR and PT from ChromaDex, but later sourced those ingredients from other suppliers, the study no longer reliably demonstrates anything about Basis as currently sourced. However, there is no evidence to suggest that the NR Elysium used after ChromaDex was no longer its supplier was anything other than materially identical from a functioning, safety, and efficacy standpoint to the NR that it sourced from ChromaDex at the time of the study. Dkt. No. 273 at 8–9. To the contrary, Dr. Claire Kruger, the managing partner of Spherix Consulting Group, ChromaDex's regulatory consultant, *see* Dkt. No. 222 at 13 n.2, testified at deposition that the NR molecule is the same in nature and in ChromaDex's NR. Dkt. No. 223, Ex. W at 49–52. In addition, Morris, Elysium's Chief Product Officer, stated that the NR molecule in synthesized NR is the same as in nature. Morris Decl. ¶ 5. Robert Martin, a former head of the FDA's GRAS department, also testified that "[c]omparing the specifications listed for ChromaDex's NR and Elysium's NR and the certificates of analysis for both of them, one reaches the conclusion that the two products are essentially the same," and "pretty much are equivalent." Dkt. No. 274, Ex. TTT at 121–24.

In response to this evidence, ChromaDex makes the general assertion that "a finished product includes not just active ingredients (or the same 'molecules'), but impurities resulting from the manufacturing process." Dkt. No. 255 at 16. It points to the expert report of Dr. Steven M. Weisman, an expert retained by ChromaDex to provide opinions and testimony about FDA regulation of dietary supplements. Dkt. No. 230, Ex. 11. Weisman opines that Elysium could not rely on ChromaDex's GRAS status to support that Elysium's NR was GRAS, because

"properties may not match the information considered in a prior GRAS assessment, rendering the previous determination of GRAS status inapplicable. GRAS conclusions can only apply to ingredients from other companies if the ingredients are manufactured in a way that is consistent with the existing notification and they meet the listed specifications." *Id.* at 20. He notes that "in their GRAS assessment, Elysium included a chart comparing the specifications for Elysium's NR and ChromaDex's NR, which demonstrates important differences in the specifications, solvents, by-products (including acetamide), and impurity specifications," and includes the chart in his report. *Id.* at 21–22. He concludes 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 23.

For two reasons, Weisman's opinion fails to create a triable issue of fact as to whether the change from ChromaDex's NR to Elysium's NR renders the Dellinger Study insufficiently reliable to support claims about Basis as currently formulated. First, at deposition, Weisman was asked about these differences in specifications and ultimately admitted that he did not know whether they had any safety implications whatsoever. He stated: "I don't know if they're meaningful from a safety perspective, but those are clearly differences in the specifications that could infer differences – a difference in the product that could confer a difference in safety. I'm not rendering an opinion as to whether they do or they don't." Dkt. No. 257, Ex. 34 at 118. It thus would require a guess for the jury to determine the differences were safety related—a guess that Weisman himself was unwilling to hazard.

Second, Weisman's opinion was limited: He opined simply that for the purposes of a GRAS assessment, differences in manufacturing *may* create differences that could be relevant to safety, and thus one manufacturer cannot simply rely on a different manufacturer's GRAS

assessment. Weisman did not opine—nor was he asked to—that these changes in byproduct specifications mean anything about the efficacy or functioning of the ingredient. In other words, Weisman's opinion and testimony is simply that ChromaDex's NR and Elysium's NR had differences in their specifications due to their manufacturing; he does not opine as to whether those differences were actually material to safety—and Elysium points to evidence that they were not—nor does he opine even that they may have caused differences as to the efficacy or functioning of the ingredients. A party opposing summary judgment must demonstrate more than "some metaphysical doubt as to the material facts." *Matsushita Elec. Indus.*, 475 U.S. at 586. Weisman's testimony does not suggest that there was any *actual* difference between the products in terms of safety, efficacy, or functioning, just that there *may* have been a difference—and Elysium points to ample evidence that there was not.

ChromaDex also cites to two out-of-context statements by Elysium's CEO that speak to the dangers of selling products that have not been tested but those statements do not refer to (i) any flaws with the Dellinger Study, (ii) a view that Elysium's NR is any different from ChromaDex's NR, or (iii) concerns that results of a study conducted on Basis using ChromaDex's NR would not be equally applicable to Basis using Elysium's own NR:

- "In a lot of these established categories – take prenatal – there's great literature supporting the use of folic acid. There's [sic] companies that sell products around that. But they'll make unique claims or link to literature that's been done by other companies on other formulations or other delivery methodologies. Those can be dangerous. The data might appear to be good but in fact their own product hasn't been tested." SAC, Ex. GG at 9.
- "Often, in the rare case where a consumer-facing company cites clinical trial research, they are leveraging the work of others – and, almost always, the formulation, dosage, and delivery method are entirely different. While something like that would be obvious to any scientist or clinician, it's a practice that's clearly meant to mislead consumers into a false sense of security that we refused to perpetuate." SAC, Ex. EE at 10–11.

Neither of these statements provide any support for the proposition that Elysium's study, conducted on their own product, is no longer reliable to show the efficacy of that product when the only difference between the product as tested and the product as currently sold is the sourcing of the ingredients, but not their formulation, characteristics, functioning, or efficacy.[8]

Thus, ChromaDex is left only with the proposition that a company that has a study done of its product using an ingredient sourced from one company must as a matter of law cease referring to the results of that study when it starts sourcing, and using in identical quantities, a

[8] ChromaDex also cites several cases to support its proposition that "Elysium was required, at the very least, to confirm the results" of the Dellinger Study after it changed its suppliers; none of those cases suggests that a manufacturer of a product is required, any time it changes the sourcing of an ingredient in an otherwise-identical formulation, to either abandon any claims based on its previously-conducted studies or to conduct new studies to confirm that the change in sourcing did not change the results. In *Vidal Sassoon, Inc. v. Bristol-Myers Co.*, study participants who rated a shampoo were allowed "to use other brands while they were testing [the subject shampoo]," which meant that "the women's responses may not accurately reflect their reaction to [the subject shampoo] as distinct from other shampoos." 661 F.2d 272, 275, 277–78 (2d Cir. 1981). This potential methodological flaw in the way the study was conducted has no bearing on whether a properly-conducted study is rendered inapplicable if a company changes the sourcing of its ingredients. In *Upjohn Co. v. Riahom Corp.*, the challenged study was "conducted on the Italian version of [the product], which has a different concentration of [the active ingredient] than the [defendant's version of the product]." 641 F. Supp. 1209, 1244 (D. Del. 1986). As such, the court reasoned that "[t]he Italian tests therefore may be totally irrelevant as to the safety of the [defendant's] product." *Id.* Here, in contrast, there is no allegation that the formulation of Basis is any different now than it was when the Dellinger Study was conducted, or that it contains a different amount of any ingredient. It is merely the sourcing of the ingredients that has changed; *Upjohn* does not suggest that in such a situation the study becomes irrelevant. In *Burndy Corp. v. Teledyne Indus., Inc.*, the defendant marketed connectors it sold as compliant with certain agency standards; when it began marketing them as such, the components did result in connectors that were compliant with those standards, but subsequently the components were down-sized and as a result the connectors were no longer compliant. 584 F. Supp. 656, 660–61 (D. Conn. 1984). The court found that "[d]own-sized connectors did not comply with the . . . standard and thus they were not the product approved by the [agency]. Holding them out to be [agency] approved constituted a false representation." *Id.* at 662. Once again, the problem with the representation is not that the sourcing of the components had changed since the approval but rather that the specifications of the components had materially changed such that the product was no longer the same and no longer compliant with the standards; if the sourcing had changed but the specifications had not, the court's reasoning in finding that the representations were false would not have applied.

materially identical ingredient from a different company. Its motion necessarily rests on the proposition that such a change in ingredient is alone sufficient to support a jury verdict that the test is not reliable and that the sponsor's invocation of the report is false and misleading. It cites no law to support such a contention. The proposition—which would mean that a company which once uses a particular supplier must forevermore use that same supplier on pain (if it does not do so) of being in violation of the Lanham Act—finds no home within any of the case law under the Lanham Act. It would present every company that does not manufacture all of its source ingredients with the Hobson's Choice of being locked into its prior suppliers, no matter how extortionate the demands they make or whether they are able to sell, or being silent regarding the outcome of a study, the results of which would be of consumer interest. In the absence of anything more, it is not sufficient to create a genuine issue of fact. ChromaDex therefore presents no triable claim for relief.

ii. "Basis is the first and only supplement clinically proven to increase and sustain NAD+ levels"

ChromaDex also alleges that Elysium's statement that "Basis is the first and only supplement clinically proven to increase and sustain NAD+ levels" is literally false.[9] The statement appears on Elysium's website.

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[9] In its summary judgment papers, ChromaDex alleges that Elysium also stated that "Basis is the first and only supplement clinically proven to increase NAD+ levels," without the "and sustain" qualifier. Dkt. No. 255 at 18 (quoting Dkt. No. 257, Ex. 29). Basis disputes that it ever made the statement without the "and sustain" qualifier, but it does not dispute the authenticity of the Facebook advertisement to which ChromaDex cites that contains the statement. As Elysium pointed out at oral argument, however, ChromaDex's Complaint cites only the version of the statement with the "and sustain" qualifier. Oral Argument Tr. at 54; *see also* SAC ¶ 63(a)(i). The Court thus considers only the statement that was actually pled in ChromaDex's Complaint. ChromaDex is not entitled to a trial on a claim it did not plead. The complaint in a Lanham Act action is not a mere formality that opens the door to trial on any similar—but not identical—misstatements a party later discovers. If ChromaDex believed the statement without the "and sustain" qualifier was false and that it was injured by it and wished to assert a claim, it could have moved to amend its Complaint and thus given Elysium notice of the allegation and an

There is no genuine dispute that Basis was the "first" supplement clinically proven to increase NAD+ levels. It preceded Tru Niagen by two years. Joint 56.1 ¶¶ 5, 22. ChromaDex identifies no other supplement introduced earlier than Basis that was clinically proven to increase NAD+ levels.[10]

ChromaDex argues, however, that Elysium's claim that Basis is the "only" supplement proven to increase and sustain NAD+ levels in humans is false—and thus that Elysium is not entitled to summary judgment on this claim—because at the time the statement was made, Tru Niagen was clinically proven to increase NAD+ levels in humans.

ChromaDex bases its argument on two propositions. First, it points to the Trammell Study which studied Niagen and demonstrated that Niagen raised NAD+ levels and to the Dellinger Study of Basis (which used ChromaDex's Niagen) and also demonstrated efficacy. It argues "if the 'molecules are the same,' the Dellinger Study would apply equally to NIAGEN, rendering any 'first' or 'only' claim literally false." Dkt. No. 255 at 18–19. The existence of these two studies fails to create a genuine issue of fact. The Trammell Study does not support that Tru Niagen increases *and sustains* NAD+ levels. It demonstrated that the molecule Niagen administered at dosages of 100 mg, 300 mg, and 1000 mg on a one-time basis resulted in an increase in NAD+; it reported that Niagen administered at a dosage of 300 mg—the dosage in Tru Niagen—did not result in a statistically significant increase in NAD+ levels. Moreover, the

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opportunity to defend. It cannot simply assert it in opposition to the motion for summary judgment—to which its distinctions from the statements actually pled is significant—without having alleged it in an operative pleading. *See infra* note 19.

[10] The same applies to Elysium's other "first" claims, including that "Basis was the world's first cellular health product informed by genomics," and that Basis was the "first product out there, available now, that comes out of basic rigorous research on aging. *See* Dkt. No. 222 at 16 n.4; Dkt. No. 255 at 18 n.8. There is no genuine dispute that Basis was the first such consumer product. ChromaDex points to no evidence of such a product that predated the introduction of Basis to the direct-to-consumer supplement market.

study tested only a one-time administration of Niagen, and thus did not demonstrate anything about Tru Niagen's ability to sustain NAD+ levels. As to the Dellinger Study, it did not study Tru Niagen. It tested the efficacy of Basis, a supplement that combines 250 mg of NR with PT. Tru Niagen has a completely different formulation, and does not contain PT. The fact that the Dellinger Study shows the effectiveness of Basis does not support that Tru Niagen is clinically proven effective.

Second, ChromaDex argues that the statement is false because Elysium continued making it after "numerous other clinical studies of NIAGEN that were as long as—if not longer—than Elysium's study," including the Conze Study. Dkt. No. 255 at 18–19. This argument has greater merit. The Conze Study[11] tested Niagen at 300 mg and showed that it increased NAD+ levels within two weeks and that such increase was sustained throughout the remainder of the eight-week trial. As such, if the Conze Study is credible, it follows that Basis is not the "only" supplement clinically proven to increase and sustain NAD+ levels; the Conze Study proved the same of Tru Niagen. Elysium, however, argues that it is entitled to summary judgment because "the Conze Study is unreliable because ChromaDex artificially depleted NAD+ levels through a restrictive diet in advance of the study." Dkt. No. 273 at 9. The parties discuss the evidence demonstrating the reliability—or unreliability—of the Conze Study at length in context of ChromaDex's motion for summary judgment on Elysium's Counterclaim. For the reasons discussed *infra*, the Court finds that there is a genuine issue as to the reliability of the Conze Study. If the jury were to resolve that disputed issue in favor of ChromaDex, there would be

[11] The remainder of the studies ChromaDex points to tested Niagen at dosages significantly higher than the 300 mg dosage in Tru Niagen; the Martens Study tested Niagen at a 1000 mg per day dosage, and the Dollerup Study tested Niagen at a 2000 mg per day dosage. Dkt. No. 230, Ex. 5 at 9.

evidence from which it could find Elysium's statement to be false. As such, Elysium's motion for summary judgment as to this statement is denied.

c. Statements Regarding Synergistic Effects of Combining NR with PT

Elysium argues that it is entitled to summary judgment on ChromaDex's claim that Elysium falsely stated that the NR and PT in Basis have a synergistic effect. Dkt. No. 222 at 15 (citing SAC ¶¶ 88–94). The Complaint alleges that "Elysium has repeatedly misrepresented that Basis is more effective than its competitors because its active ingredients NR and PT combine to produce a synergistic effect that is greater than their sum." SAC ¶ 88. It identifies two specific statements by Elysium—one on the website and the other in the *MIT Technology Review*:

- "[O]n its website, Elysium states that '[t]he proprietary formulation of nicotinamide riboside and pterostilbene is designed to increase levels of the coenzyme NAD+ and to support a class of proteins called sirtuins. NAD+ and sirtuins work together in vital cellular processes including energy production.'" SAC ¶ 91 (quoting Ex. W).[12]
- "[I]n an interview with *MIT Technology Review*, published on February 3, 2015, Elysium co-founder Guarente discusses the presence of NR and PT in Basis and touts, '[w]e expect a synergistic effect [from] combining them.'" *Id.* ¶ 92 (quoting Ex. X).

Elysium argues that in fact it "never claimed that there is a proven synergistic effect between NR and PT." Dkt. No. 222 at 15. ChromaDex disputes this, arguing that "Elysium states that they have never advertised Basis as having an established synergistic effect, only an expected effect. This is not true." Dkt. No. 255 at 20 (citing Dkt. No. 257, Ex. 30).

Elysium is entitled to summary judgment. The statements on the Elysium website and to the *MIT Technology Review* do not claim that PT and NR have a synergistic effect. The website statement speaks to the "design" of Basis—that the formulation of NR and PT was designed to increase levels of NAD+. It does not speak to the effect of the combination of NR and PT or

[12] ChromaDex challenges only the portion of this statement claiming a synergistic effect between NR and PT, not the statement about how NAD+ and sirtuins work together.

whether the design was successful—a statement that could only be made after the product was designed and after there was a period for study of its results in operation which, as Elysium explained in one of the challenged communications, could take decades. *Cf. In re Axonyx Securities Litig.*, 2009 WL 812244, at *3 (S.D.N.Y. Mar. 27 2009) (holding that statements that trials were "*intended to* demonstrate the safety and efficacy" of a drug were "accurate on their face" despite allegations that the trials were in fact defective). A reasonable reader might take the implication from the fact that a retailer was advertising the design of its product that the retailer had determined such design was effective. But Elysium's communication does not necessarily or unambiguously convey that message. The more natural reading, and a reasonable reading, is that the combination of the two chemicals were "devise[d] for a specific function or end," *see* Merriam-Webster Online Dictionary, *available at* https://www.merriam-webster.com/dictionary/design (last updated Jan. 21, 2022), to operate in combination and that the scientists had a good-faith belief that they would do so. Because ChromaDex has not offered extrinsic evidence that a "statistically significant part of the commercial audience" took away the allegedly false belief, *see Board-Tech*, 737 F. App'x at 560, ChromaDex is not entitled to a jury trial on the issue.

ChromaDex's claim based on the statement to the *MIT Technology Review* suffers from the identical flaw. The statement, which was made before Basis was available at retail, reflected Elysium co-founder Guarente's expectation with respect to the combination of NR and PT. An expectation looks forward to a future event, *see* Merriam-Webster Online Dictionary, *available at* https://www.merriam-webster.com/dictionary/expecting (last updated Jan. 21, 2022); it is different than a current effect. The statement thus does not address the effect of the combination of the two ingredients. In fact, in the very same interview in which he stated that "[w]e expect a

synergistic effect from combining [NR and PT]," Guarante explained to the *MIT Technology Review* that "it's nearly impossible to prove, in any reasonable time frame, that drugs that extend the lifespan of animals can do the same in people; such an experiment could take decades." SAC, Ex. X. ChromaDex has not offered evidence that Guarante did not expect a synergistic effect. Guarante's statement in the interview that a synergistic effect between PT and NR was *expected* was neither literally false nor misleading; considered either in isolation or in context, it could not be reasonably interpreted to mean anything other than that Guarante believed the PT and NR would be synergistic. It did not convey that such an effect was proven or demonstrated. *See Time Warner Cable*, 497 F.3d at 158 ("[A] district court evaluating whether an advertisement is literally false 'must analyze the message conveyed in full context,' i.e., it 'must consider the advertisement in its entirety and not . . . engage in disputatious dissection.'" (first quoting *Castrol Inc. v. Pennzoil Co.*, 987 F.2d 939, 946 (3d Cir. 1993); and then quoting *Avis Rent A Car System, Inc. v. Hertz Corp.*, 782 F.2d 381, 385 (2d Cir. 1986))). Nor is there evidence that a statistically significant portion of the commercial audience took away a different understanding.

ChromaDex falls back on an internal Elysium email in which one Elysium employee states that in a communication with a news outlet Elysium should "harp on the fact that the synergistic effect of the combination is a huge benefit to consumers and a big differentiator," and another Elysium employee agrees. Dkt. No. 257, Ex. 30. The chain ends with the recommendation that Elysium put the message in one email to the news outlet. *Id.* ChromaDex offers no evidence that the message was ever delivered. As Elysium points out in its reply, Exhibit 30 contains "*draft* talking points in an *internal* e-mail," Dkt. No. 273 at 12. ChromaDex has not pointed to any evidence, in its briefing or its 56.1 statements, either that the talking points

were actually used or that Elysium ever claimed in any advertising or promotion that there is a proven or established synergistic effect between PT and NR; internal statements do not constitute "commercial advertising or promotion" and are not actionable under the Lanham Act. *See Fashion Boutique*, 314 F.3d at 57 ("[T]he touchstone of whether a defendant's actions may be considered 'commercial advertising or promotion' under the Lanham Act is that the contested representations are part of an organized campaign to penetrate the relevant market. Proof of widespread dissemination within the relevant industry is a normal concomitant of meeting this requirement."); *id.* at 58 (holding that evidence of "a total of twenty-seven oral statements regarding plaintiff's products in a marketplace of thousands of customers" is "insufficient to satisfy the requirement that representations be disseminated widely in order to constitute 'commercial advertising or promotion' under the Lanham Act").

d. Statements Regarding FDA Regulation of Basis

ChromaDex next challenges certain of Elysium's statements relating to compliance with FDA regulations. Elysium made the following statements on its website:

- "We conduct rigorous safety studies for new dietary ingredient (NDI) submissions to the FDA. The Federal Food, Drug, and Cosmetic Act (FD&C) requires that we submit studies to demonstrate the safety of 'new dietary ingredients.'" SAC ¶ 63(c)(iv), Ex. K.
- Basis complies with "regulations as stipulated by the FDA." SAC, Ex. K.
- Basis "Exceeds FDA Recommendations." Dkt. No. 257, Ex. 32.[13]

Elysium also included an "informational" article on its website that states: "If a supplement maker introduces a new ingredient to the market it's supposed to notify the FDA." Dkt. No. 255

[13] This statement is the heading for a paragraph that states: "The ingredients in Basis have been tested for safety and are produced in facilities that meet FDA requirements." Dkt. No. 257, Ex. 32.

at 19 (internal quotation marks omitted) (quoting SAC, Ex. J).[14] ChromaDex claims that the statements are literally false. It argues that the first sentence of the first statement is untrue because "Elysium admits that it has never made an NDI submission to the FDA." *Id.* at 19–20. It makes no other arguments.

Elysium argues that ChromaDex has failed to satisfy its burden to identify evidence that would support that any of these statements is untrue. Elysium identifies evidence that it did conduct rigorous safety studies for new dietary ingredient (NDI) submissions to the FDA. It notes that when it used NR supplied by ChromaDex for Basis, that ingredient did have NDI status. Dkt. No. 222 at 15 (citing Joint 56.1 at 17–18). It points to the declaration of its Chief Product Officer that after it "began manufacturing its own NR, it initially planned to submit an NDI notification," and that it only later transitioned to seek IND status in 2018. Dkt. No. 222 at 15 (citing Morris Decl., Dkt. No. 227 ¶¶ 14–21). An IND application seeks approval to conduct clinical trials on a drug to be used for a specific medical treatment while an NDI which is a general notification required for new dietary ingredients in supplements. *See* 21 C.F.R. § 312.20(a); 21 U.S.C. § 350b(d). There is no evidence that the transition was made as a result of any difficulty with the NDI application or concerns that the product would not pass the safety studies. NDIs and INDs require similar levels of scientific rigor in proving safety. Dkt. No. 222 at 16 (citing Dkt. No. 223, Ex. Z at 33–34 ("If you're asking about the rigor, I would say that the scientific rigor around safety is comparable between these two approaches.")). Rather, although "[i]nitially, Elysium intended to submit an NDI for Basis," after studies positively evaluated the safety of Basis in patients with acute kidney injury, the company submitted an Investigational

[14] ChromaDex's opposition cites Exhibit J; the challenged statement, however, appears in Exhibit L to the Second Amended Complaint.

New Drug (IND) application instead, which was accepted by the FDA, and subsequently decided not to pursue the NDI notification as well. Morris Decl. ¶¶ 16–21. Elysium further points out that its "reference to an NDI was removed after it decided to apply for IND status instead." Dkt. No. 273 at 11 (citing Dkt. No. 213, Ex. Y ¶¶ 10, 12).

ChromaDex does not point to any evidence that could support a finding that Elysium, at the time of the statements at issue, was *not* working on studies for an NDI notification. That fact is undisputed for purposes of this motion. Instead, it argues that Elysium failed to submit an NDI notification. But the statement at issue refers to the studies that Elysium was conducting and not to the applications it had made.[15] It does not necessarily or unambiguously convey that Elysium had submitted an NDI notification to the FDA. Indeed, no reasonable reader could come away with that conclusion. Accordingly, the evidence that Elysium later did not make an application to the FDA does not render the statement that Elysium did make literally false and creates no issue for trial. Elysium is entitled to summary judgment on this claim.

e. Statement Regarding Elysium's Role in NR Research

Next, ChromaDex alleges that Elysium made statements that falsely implied that it was significantly involved with the research behind the ingredients in Basis. ChromaDex challenges:

- Statements on Elysium's website that Basis is "[t]he culmination of more than 25 years of aging research," that "Elysium turns critical scientific advancements in aging research into health solutions you can access today," and the websites direction to consumers to "take a tour of the science and history that led to Basis." Dkt. No. 222 at 17 n.5 (quoting SAC ¶ 63(b)(ii), Exs. D, G).
- Elysium's statement in an *Allure* article published on October 18, 2017 that "[w]ith regard to Basis, the pill seems simple, but the amount of research behind it is quite extensive." *Id.* (quoting SAC ¶ 63(b)(iii), Ex. H).

[15] At oral argument, counsel for ChromaDex referenced an "advertisement that says [Elysium has] submitted an NDI," which they stated was "either Exhibit D to the complaint or Exhibit DD to the complaint." Oral Argument Tr. at 98–99. Neither Exhibit D nor Exhibit DD to the operative complaint include such a statement. Complaint, Exs. D, DD.

ChromaDex argues that "[t]he reality is that neither Elysium nor any of its employees had done any research into NR before launching Basis." Dkt. No. 255 at 17. These are the only statements for which ChromaDex offers evidence of implied falsity. It offers the report of Bruce Isaacson, ChromaDex's survey expert, who ChromaDex retained to test how consumers viewed several of Elysium's statements. Isaacson tested a statement made on Facebook that "[i]nside this bottle is 25 years of research," and found that of respondents who viewed that statement "82.7% answered that the materials communicate or imply that the company conducted 25 years of research on aging, compared with 43.8% for the control." Dkt. No. 213-37 at 12–13. The control statement tested was: "Inside this bottle is years of research, that was conducted by us and others." *Id.* at 10.

Elysium makes two arguments for judgment in its favor. First, it claims that the Isaacson report is not admissible and that, in the absence of the Isaacson report, there is no evidence of implied falsity. Second, it argues that the statements imply at most direct involvement by Elysium in the research behind Basis and in research into *aging* and not in the research behind NR per se. Thus, even if these statements implied direct involvement by Elysium in the research behind Basis or into aging, that implication would be true because "[o]ver the course of 30 years of research, Guarente demonstrated the connection between aging and sirtuins, and then demonstrated the connection between sirtuins and NAD+." Dkt. No. 222 at 17.

The material facts are not disputed—Guarante did substantial research into NAD+ and aging. He has been the director of The Paul F. Glenn Center for Biology of Aging Research at MIT since 2008, Dkt. No. 256 ¶ 4, and "[i]n the three decades that [he] has operated a laboratory at MIT, [his] research has been focused on the genetic and molecular basis of aging," Dkt. No.

217 ¶ 5.[16] Brenner testified at deposition that Guarente "has made seminal contributions to gene regulation and other aspects of molecular biology over the decades," and has done research on aging. Dkt. No. 223, Ex. 1 at 26–27. Guarente's research involved, among other things, research into the role of sirtuins in cellular aging, and the relationship between sirtuins and NAD+, which Basis is designed to boost—a study published by Guarente in 2000 demonstrated that NAD is necessary for yeast SIR2 activity. Dkt. No. 221 ¶¶ 7–9; Dkt. No. 256 ¶¶ 7–9. However, while he may have played an instrumental role in the research into NAD+ and how it affected aging, he was not involved in the research regarding the connection NAD+ and NR.

As an initial matter, the challenged statements do not either expressly or by necessary implication state that Elysium itself was involved with all of the research behind Basis, much less that it was involved in the research regarding NR; as such, they are not literally false. Fairly read, they make the point that Elysium's *product* is the result of more than twenty-five years of aging research and that Elysium's role is to convert or "turn" that research into a product not to conduct that research itself. They do not speak to the role of Elysium itself or its officers in the underlying research itself. It thus would be irrelevant to the truth or falsity of the statement, literally read, whether Elysium itself conducted any of the research either into aging or into NR. Elysium's statement would be literally true even if it piggybacked on the research done by others.

[16] ChromaDex challenges the validity of Guarente's declaration, Dkt. No. 256 ¶¶ 2–3, but fails to point to any evidence calling into question Guarente's history of research into aging. It cites Brenner's testimony that "Dr. Guarente has done very important work in yeast aging, which I believe is greatly overinterpreted." Dkt. No. 257, Ex. 1 at 29. Brenner agreed, however, that "research on aging and yeast can potentially tell us something about human aging," and that he has conducted experimentation on aging in yeast which has informed further experimentation in humans. *Id.* at 29–30. That testimony does not contradict Guarente's testimony that he did research into the role of sirtuins in the aging process, and the connection between NAD+ and sirtuins, both of which relate directly to the science behind Basis.

ChromaDex also has not identified any evidence to support a jury verdict that the statements were misleading or impliedly false. It relies on Isaacson's expert report, but, as stated, that report tested the statement "[i]nside this bottle is 25 years of research," and found that 82.7% of respondents thought the statement communicated or implied that "the company conducted 25 years of research on *aging*, compared with 43.8% for the control." Dkt. No. 213-37 at 12–13. The study thus supports the proposition that a net 38.9% of the commercial audience would understand Elysium's statement to imply that it had done the research—but only research on aging. ChromaDex has not identified any evidence to contradict the assertion that Elysium (or its founder) conducted twenty-five years of research on aging and that such research contributed to Basis. Thus, the evidence to which ChromaDex points that "neither Elysium nor any of its employees had done any research into *NR* before launching Basis," Dkt. No. 255 at 17, is insufficient to create a genuine issue of material fact whether the statement about research into aging is false. *See Anderson v. Hertz Corp.*, 507 F. Supp. 2d 320, 326 (S.D.N.Y. 2007) ("A fact is 'material' when it 'might affect the outcome of the suit under the governing law.'" (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986))).

ChromaDex also argues that another challenged statement by Elysium regarding Elysium's involvement in research was literally false:

- Elysium's statement on social media that "Basis is revolutionary because it's the first product to come out of really good aging research." *Id.* (quoting SAC ¶ 63(b)(iv), Ex. I).

ChromaDex argues that this statement is "demonstrably false," because (i) Basis combined two existing active ingredients, (ii) there were already multiple products on the market containing either NR or PT, and (iii) Elysium did not conduct its own research into either of these ingredients. Dkt. No. 255 at 18. Elysium responds that the statement that "Basis is revolutionary" is inactionable puffery, and ChromaDex does not proffer any evidence suggesting

that there were other products that combined NR and PT at the time the statement was made. Dkt. No. 273 at 10.[17]

The statement that "Basis is revolutionary" is inactionable puffery. At worst, it reflects "an exaggeration or overstatement expressed in broad, vague, and commendatory language." *Time Warner Cable*, 497 F.3d at 159 (quoting *Castrol*, 987 F.2d at 945); *see also Lipton v. Nature Co.*, 71 F. 3d 464 (2d Cir. 1995) (quoting *Groden v. Random House, Inc.*, 1994 WL 455555, at *5 (S.D.N.Y. Aug. 23, 1994), *aff'd*, 61 F.3d 1045 (2d Cir. 1995), for the statement that "[s]ubjective claims about products, which cannot be proven either true or false, are not actionable under the Lanham Act," and concluding accordingly that a party's "general assertion that the research he conducted was 'thorough[]' is mere 'puffing' and therefore, not actionable"). "Such sales talk, or puffing, as it is commonly called, is considered to be offered and understood as an expression of the seller's opinion only, which is to be discounted as such by the buyer. . . . The 'puffing' rule amounts to a seller's privilege to lie his head off, so long as he says nothing specific." *Time Warner Cable*, 497 F.3d at 159 (internal quotation marks omitted) (quoting *Castrol*, 987 F.2d at 945 (quoting W. Page Keeton et al., *Prosser and Keeton on the Law of Torts* § 109, at 756–57 (5th ed. 1984))).

[17] ChromaDex's complaint also alleged that "Elysium falsely claims to be the 'first' to market." SAC ¶ 12. Elysium's motion for summary judgment argues that it "never made that claim," and that even if it did, such a statement would not be false because "Elysium was the first to sell NR and PT in combination as a single product and ChromaDex did not enter the direct-to-consumer market until after Elysium." Dkt. No. 222 at 16. ChromaDex's opposition does not respond to these arguments or defend the allegations that Elysium claimed to be the 'first' to market and that this statement was false. Therefore, the Court deems this allegation abandoned, and examines only the specific "first" and "only" claims that ChromaDex defends in its memorandum. *See* Dkt. No. 255 at 18–19; *see also, e.g.*, *Shenk v. Karmazin*, 868 F. Supp. 2d 299, 311 n.12 (S.D.N.Y. 2012); *Taylor v. City of New York*, 269 F. Supp. 2d 68, 75 (E.D.N.Y. 2003); *Douglas v. Victor Capital Group*, 21 F. Supp. 2d 379, 393 (S.D.N.Y. 1998).

The claim that a product is "revolutionary" is broad and vague and cannot "be proven either true or false." *Lipton*, 71 F.3d at 474. It is not "specific and measurable." *Castrol*, 987 F.2d at 946. No one would understand it to be making a verifiable claim of fact regarding Elysium's "goods, services, or commercial activities" or those of another person. 15 U.S.C. § 1125(a)(1)(B). It therefore is not independently actionable.

Elysium's claim that Basis is "the first product to come out of really good aging research" is more concrete and measurable in the sense that it conveys that it was the "first" product to come out of the aging research and that there were not others that preceded it. However, ChromaDex has not pointed to evidence that would support a finding that Elysium's statement was false. Although ChromaDex claims that "there is no dispute that . . . there were already numerous NIAGEN-containing products and numerous pterostilbene-containing products on the market when Basis launched in 2015," Dkt. No. 255 at 18, it cites to no evidence supporting that claim or indicating what products it refers to. While ChromaDex manufactured Niagen and pTeroPure before Elysium launched Basis, those were wholesale ingredients and not consumer products. As such, the record does not reflect any genuine dispute of material fact as to whether Basis was the first product of its kind to come out of the aging research in question.

f. Statement that Elysium is the Exclusive Licensee of a NR Patent

ChromaDex's Complaint alleges that "Elysium falsely represents to consumers that it is the exclusive licensee of a patent for the use of NR for the slowing of aging." SAC ¶ 63(e). The challenged statement, contained in a press release issued on August 16, 2018, is:

> Elysium Health Inc.,™ a life sciences company developing clinically validated health products based on aging research, has entered into an exclusive license agreement with Mayo Clinic and Harvard University to use nicotinamide riboside for dietary supplement applications in the slowing of aging and age-related diseases. . . . "With this license . . . we are excited to build upon Elysium Health's intellectual property portfolio to support our leading research in the field of aging."

Id. ¶ 63(e)(ii) (quoting Ex. O). ChromaDex alleges that this announcement "is intended to make consumers believe that Elysium is the exclusive licensee of a patent obtained by Harvard and the Mayo Clinic and is now the only party that can sell NR supplements for use in connection with aging or age-related diseases." *Id.* It states "[i]n reality, Elysium has licensed a patent application—not an issued patent." *Id.* ¶ 63(e)(iii)–(iv).

The Court "must analyze the message conveyed in full context." *Time Warner Cable*, 497 F.3d at 158 (quoting *Castrol*, 987 F.2d at 946). In full context, the press release does not state or convey that Elysium is the exclusive licensee of an issued patent for NR. It states that Elysium has an exclusive license agreement with two institutions—Harvard and the Mayo Clinic—for the purpose of using NR for dietary supplement applications. The first reference to a patent is in the third paragraph and it refers to a "pending patent" for a specific pathway to increasing NAD+ (i.e., a patent application)—one involving a crucial enzymatic system, the CD38 pathway, was the main regulator of intracellular NAD+ levels and sirtuin 1 in living organisms. Dkt. No. 139, Ex. O. The statement, therefore, when "considered in context," does not "necessarily and unambiguously imply a false message," and as such is not literally false. *Church & Dwight*, 843 F.3d at 65 (quoting *Time Warner Cable*, 497 F.3d at 158).

Elysium further argues that there is no evidence that consumers took away a misleading message from the release. ChromaDex, in its opposition, does not address this claim at all, let alone point to extrinsic evidence suggesting that the press release is misleading.

g. Statements Regarding the Amount of NR in Basis

Next to last, ChromaDex alleges that Elysium made statements about the amount of NR in Basis, and that these statements were false. "Elysium advertises that a dose of Basis contains 250 mg of NR." SAC ¶ 95. In its complaint, ChromaDex alleged "testing of commercially

available Basis revealed that as many as a third of Basis doses sold to consumers contain materially less NR." *Id.* (internal citations omitted).

Elysium argues that it is entitled to summary judgment on this claim. The challenged statement is a response to one of a set of Common Questions on Elysium's website. Dkt. No. 139, Ex. G. The question is, "What are the ingredients in Basis?" The answer is, "Each serving of Basis (two capsules) contains 250mg of Elysium's crystalline nicotinamide riboside and 50mg of pterostilbene. See nutrition label for a full list of ingredients." *Id.* The Common Questions page goes on to state that Elysium "recommend[s] two capsules in the morning, with or without food." *Id.* The statement is literally true. Elysium has identified evidence from discovery that Basis "is tested by third parties that verify the dosage of ingredients meets or exceeds the dosage claimed by Elysium." Dkt. No. 222 at 18 (citing Morris Decl., Ex. B). Exhibit B to the Morris Declaration, the evidence to which Elysium cites, reflects that of all the tested batches, the amount of NR in a capsule exceeded the label claim of 125 mg of NR; results ranged from 126 mg to 149 mg. Dkt. No. 227-2. ChromaDex identifies no evidence that Elysium's statement is false. Elysium is entitled to summary judgment on this claim.

h. Statements Regarding the Scientific Advisory Board and Client Testimonials

Finally, ChromaDex claims that Elysium's statements regarding its Scientific Advisory Board and Client Testimonials are misleading to consumers. SAC ¶¶ 64–74.

i. Scientific Advisory Board

Elysium states that it "works in partnership with the world's leading scientists and research universities," and that their "board guides the scientific direction of Elysium." *Id.* (quoting Exs. P, Q).

ChromaDex's Complaint does not allege that any of the statements Elysium makes about the board are literally false. The SAB "holds formal quarterly meetings with Elysium's team, and members otherwise interact regularly and meet on an ad hoc basis with Elysium team members. During the quarterly meetings, Elysium's team presents on current and planned products, ongoing clinical trials and new data. SAB members ask questions, give input and generally advise Elysium on pursuing research, designing clinical studies and translating that work into accessible products. Certain members of the SAB have also conducted studies or testing using Basis." Dkt. No. 225 ¶ 6 (declaration of Dan Alminana, Elysium's Chief Operating Officer).

Rather, ChromaDex argues that even if it is true that Elysium has an active SAB, the statements leave the misleading impression that the SAB "guides the scientific direction of Elysium," SAC ¶ 65 (quoting Ex. Q), and "give[s] consumers the false impression that these scientists were involved in the science and discovery behind the Basis product, were active in research and development at Elysium, and can vouch for Basis' safety and efficacy," *id.* ¶ 64. ChromaDex says that such statements would be untrue because the SAB scientists were not involved in the science and discovery behind the Basis product, were not active in research and development, and could not vouch for Basis's safety and efficacy. According to ChromaDex, "Elysium largely ignored its scientific advisory board, using them for nothing more than the veneer of credibility." Dkt. No. 255 at 20 (citing Dkt. No. 255 at II.D.3.C).

Elysium's statements do not either expressly state or necessarily and unambiguously imply that its SAB—which is claimed to be an *advisory* board—was itself involved in the research and development or would vouch for Basis's safety and efficacy. It is plausible that a reader might take away that message from the statement. But it is equally plausible that

Elysium's scientists and executives use the SAB as an "advisory" board—to obtain advice and opinions from it without requiring of its members that they become active in research and development and without requiring of itself that it blindly accept any opinion of a member of the SAB, without making its own independent judgment regarding safety and efficacy. *See Apotex*, 823 F.3d at 67 (holding that "plausible" understanding of a statement does not make it literally false when it is not "unambiguous"). It is a positive thing for a company to appoint an advisory board or to obtain advisors and to inform the public that it has done so. Absent a false statement about what the advisory board has done or the capacity in which its members serve, a company is not required to convert every advisor to an officer or to follow each piece of advice it receives at the expense—if it does not do so—of inviting a Lanham Act lawsuit. Moreover, ChromaDex has not identified evidence that "a statistically significant part of the commercial audience holds the false belief allegedly communicated by the challenged advertisement.'" *See Board-Tech*, 737 F. App'x at 560 (internal alterations omitted) (quoting *Tiffany*, 600 F.3d at 112–13)); *Time Warner Cable*, 497 F.3d at 153 ("[A] district court *must* rely on extrinsic evidence to support a finding of an implicitly false message." (internal alterations and citations omitted)); *Board-Tech*, 737 F. App'x at 560–61 (citing *Time Warner Cable* for the same proposition). Isaacson's expert report, ChromaDex's only extrinsic evidence relating to consumer impressions from Elysium's advertising, did not test consumer impressions of any statements relating to Elysium's Scientific Advisory Board. *See* Dkt. No. 213-17.

In any event, ChromaDex fails to support its broad claim that Elysium largely ignored its scientific advisory board or used it as nothing more than a "veneer" and fails to raise a genuine issue of material fact for trial. ChromaDex claims that "Elysium's scientific advisory board recommended eliminating PT from Basis because 'a 10% increase in cholesterol is not trivial,'"

and that there "was Board consensus that, at the very least, additional studies were needed" but "Elysium has not published any follow-up studies on the effect of either PT or the NRPT combination on LDL levels." Dkt. No. 255 at 12 (citing Dkt. No. 257-24). The Court has addressed this claim earlier in its opinion. The evidence ChromaDex cites does not support its argument or create a triable issue. The statement that "a 10% increase in cholesterol is not trivial" was not a recommendation by the board; it was contained in an email from a board member who missed the meeting to other board members and included the caveats that he was expressing his "personal opinion[n]" and that "I may misunderstand some of the results or facts." Dkt. No. 257-24 at 2. The email adds: "I am really impressed by the effect of BASIS on NAD levels, blood pressure, and transaminases" and that it is "possible that the effect on LDL cholesterol is transient." Even construing the evidence favorably to ChromaDex, the study about which he was writing—the Dellinger Study—did not show a 10% increase in cholesterol in the recommended dosage. *See* Dkt. No. 257-4 at 159–60. It showed an increase in a dosage that was not recommended. The Scientific Advisory Board's recommendation was not that Elysium should eliminate PT from Basis, but rather that Elysium should conduct a follow-up study; Elysium did so. It conducted a follow-up study which tracked the effects of Basis on cholesterol levels over time, as recommended by the Scientific Advisory Board. *See* Dkt. No. 257, Ex. 4 at 168–71. Guarente testified that the study "did not show a significant effect of Basis on LDL cholesterol." *Id.* at 171. Thus, even if the statement that the Scientific Advisory Board "guides the scientific direction of Elysium" was concrete enough to be susceptible to a challenge of literal falsity and gave rise to the messages ChromaDex claims it conveyed, ChromaDex has not identified evidence that such message was false.

ii. Client Testimonials

Elysium showcases client testimonials on its website, including:

- A testimonial from customer Pamela Olin, who is quoted as saying, "I liked the fact that Elysium has scientists on staff. I liked the fact that there is data . . . . *It just seemed like two simple ingredients.* The fact that there are *so many knowledgeable people* involved in this, and that you were so responsive when I had questions. It left me feeling secure in the knowledge that I was given and made it worth a shot. I'm thoroughly enjoying it." SAC ¶ 72 (quoting Ex. R) (emphasis added by ChromaDex in the SAC).

- A testimonial from customer Suzy Oo, who is quoted as saying, "I was following Dr. Guarente's work actually. Scientists have their groupies—I guess I was one of his. He's kind of a rockstar in the scientific community . . . . I went through the original research papers. I looked at it as a hypothesis. Based on what's out there, is it likely to work and is it going to cause me any harm? Based on everything I read I didn't think it was going to cause me any harm, and based on the literature I thought Basis made sense." *Id.* ¶ 73 (quoting Ex. S).

- A testimonial from customer Tom Flynn, who is quoted as saying, "I came across an article about Elysium. I said, let me look at this because of the credibility of the founder and his work at MIT. I was buoyed by the idea that these people had confidence in the research and were promoting it." *Id.* ¶ 74 (quoting Ex. T).

ChromaDex does not allege in its Complaint that these testimonials are literally false. Rather, it alleges only that "Elysium compounds its deceptive information by including client testimonials, emphasizing their reliance on the alleged scientific foundation of Basis, and their comfort level afforded by Elysium's bevy of apparent sponsors from medical and scientific fields." *Id.* ¶ 71. ChromaDex proffers no evidence that these client testimonials were fabricated, mislead consumers, or conveyed an implied message to consumers that was false; this evidentiary defect is fatal to its claim. Moreover, "a collection of client reviews reflects subjective judgments. A reasonable reader would understand that each review is merely an opinion." *Davis v. Avvo, Inc.*, 345 F. Supp. 3d 534, 543 (S.D.N.Y. 2018) "Not only are the positive reviews opinions, but simply indicating that a particular consumer was satisfied with a service plainly does not constitute a false or misleading statement." *Id.* Finally, although Elysium makes this argument in its motion for summary judgment, ChromaDex does not defend its allegations in its opposition and does not address the client testimonials at all. As such, these allegations are deemed abandoned. *See, e.g.*, *Shenk v. Karmazin*, 868 F. Supp. 2d 299, 311 n.12

(S.D.N.Y. 2012); *Taylor v. City of New York*, 269 F. Supp. 2d 68, 75 (E.D.N.Y. 2003); *Douglas v. Victor Capital Group*, 21 F. Supp. 2d 379, 393 (S.D.N.Y. 1998).

2. Elysium's Counterclaims

ChromaDex's motion for summary judgment on Elysium's counterclaims as to the falsity element of the Lanham Act is granted in part and denied in part. ChromaDex's motion is granted with regard to Elysium's counterclaims about statements regarding ChromaDex's funding and scientific research, statements that Niagen increases NAD+ levels by 60%, statements about the safety and trustworthiness of Tru Niagen, and statements about FDA regulation of ChromaDex's products that make no explicit mention of efficacy. ChromaDex's motion is denied with regard to statements that Brenner discovered NR, statements that Tru Niagen increases NAD+ levels by 40–50%, statements about "other NAD-dependent clinical study results," statements about FDA regulation of ChromaDex's products that do explicitly mention efficacy, and statements that ChromaDex is the only seller of NR.

Elysium's motion for partial summary judgment on its own counterclaims is granted with regard to the statement on the Counterfeit Page that ChromaDex is the only seller of NR, but denied with regard to the messages on that page that Basis is inauthentic, unsafe, and ineffective.

a. Statements Regarding ChromaDex's Role in Research

Elysium's counterclaims challenge various categories of ChromaDex's statements about their role in the research and development of NR.

i. Brenner Discovered NR

First, Elysium alleges that ChromaDex's website "touts . . . [t]he false assertion that ChromaDex's lead scientist discovered NR in 2004, even though NR was discovered more than 50 years ago." Counterclaim ¶ 84. ChromaDex made the following challenged statements:

- On the "FAQ" page of the Tru Niagen website, it stated that "[i]n 2004, Charles Brenner PhD discovered a unique and overlooked form of vitamin B3 (nicotinamide riboside) that is a natural precursor to NAD." *Id.* ¶ 85 (quoting Ex. 4).

- On the "Our Product" page of the Tru Niagen website, addressing another FAQ how Tru Niagen is "different from other vitamin B3," ChromaDex answers that "Tru Niagen is a specialized form of vitamin B3 *discovered by our Chief Scientific Advisor Charles Brenner, PhD* and developed specifically to increase NAD more effectively than any other B3 before it." *Id.* ¶ 86 (emphasis in original) (quoting Ex. 5).

The first of these statements is on a page on the Tru Niagen website with several other FAQs. The second of these statements—which appears on the Product page of the Tru Niagen website—is in one of the two FAQs included on that page, underneath which there is a link to "SEE ALL FAQS." Counterclaim, Ex. 5 at 4. That link brings the viewer to the FAQ page, on which many FAQs appear—including the first of these statements.

ChromaDex does not dispute that if the statements asserted that Brenner discovered NR, they would be false. Brenner did not discover NR, which was identified in the 1940s. There is evidence he discovered a use for NR and a method to make synthetic NR. Rather, ChromaDex argues that the statements cannot be read to advertise that Brenner discovered NR. With regard to the first challenged statement—the statement on the FAQ page that Brenner "discovered a unique and overlooked form of vitamin B3 (nicotinamide riboside)"—it argues that "[s]tatements are to be read in context." Dkt. No. 210 at 11 (quoting *Reed Const. Data Inc. v. McGraw-Hill Companies, Inc.*, 49 F. Supp. 385, 411 (S.D.N.Y. 2014), *aff'd*, 638 F. App'x 43 (2d Cir. 2016)). It points to an additional statement on that same FAQ page that, it asserts, provides context to the challenged statement:

- The statement on the FAQ page, addressing "How Much Research Has Been Done On NIAGEN®?" that "[a] naturally-occurring, unique form of vitamin B3 known as nicotinamide riboside *was first identified in the 1940s*. This discovery came years after it was established that vitamin B3, in the common forms of niacin and niacinamide, could cure a disease caused by vitamin B3 deficiency known as pellagra. Since that time, the role of nicotinamide riboside as a precursor to an essential coenzyme called NAD has been widely studied in the scientific community and become better understood." Dkt. No. 210 at 11–12 (emphasis in original) (quoting Counterclaim, Ex. 4).

ChromaDex argues that "looking at the full context, the at-issue page clearly states that naturally-occurring nicotinamide riboside was first identified in the 1940s." *Id.* at 12. It reasons that, in context, the first statement that in 2004, Brenner discovered a "unique and overlooked form of vitamin B3 (nicotinamide riboside)" could not be read to refer to the earlier-discovered NR. *Id.*

It is true that "a district court evaluating whether an advertisement is literally false 'must analyze the message conveyed in full context,' i.e., it 'must consider the advertisement in its entirety and not . . . engage in disputatious dissection.'" *Time Warner Cable*, 497 F.3d at 158 (first quoting *Castrol*, 987 F.2d at 946; and then quoting *Avis Rent A Car*, 782 F.2d at 385). But the FAQs as a whole do not qualify or dispel the notion that Brenner was the one who discovered NR and that he did so in 2004.[18]

[18] Elysium makes a separate argument that is not meritorious. Relying on *Mantikas v. Kellogg Co.*, 910 F.3d 633, 637 (2d Cir. 2018), it argues that "a consumer should not be expected to go searching for the truth; it's up to the advertiser to make it clear in the context that's immediately available to the consumer," Oral Argument Tr. at 38–39; Dkt. No. 250 at 21 (same). The argument is based on the supposition that a reader of the first statement would have to expand the FAQs to view the purportedly clarifying statement. In *Kellogg*, the Second Circuit held that representations in the center of the front of a Cheez-It box that product was "WHOLE GRAIN" was not qualified by "Nutrition Facts" on the side of the box, which said in smaller print that the serving size was twenty-nine grams and that the first ingredient in the product was "enriched white flour," because "a reasonable consumer should not be expected to consult the Nutrition Facts panel on the side of the box to correct misleading information set forth in large bold type on the front of the box." 910 F.3d at 634–35. But the first challenged statement—the one at issue here—appears (on the record before the Court) only on the FAQ page, in the third paragraph of the answer to the sixth FAQ. Counterclaim, Ex. 4 at 2. The statement that ChromaDex asserts clarifies that NR was first identified in 1940 appears in the first paragraph of

The statement that "Charles Brenner PhD discovered a unique and overlooked form of vitamin B3 (nicotinamide riboside) that is a natural precursor to NAD" means, unambiguously and in plain English, that Brenner discovered *NR, which is a natural precursor to NAD*, not that he discovered *that NR is a natural precursor to NAD*. The "context" of the additional statement that "nicotinamide riboside was first identified in the 1940s" does not *clarify* what the earlier statement meant and thus render it in fact true as properly understood; it *contradicts* the earlier statement on its face and, if credited, reveals that the earlier statement is false. This claim thus survives summary judgment.

ChromaDex's argument with respect to the second statement is no more successful. Conceding again that Brenner was not the discoverer of NR, it argues that there is ambiguity in the statement that "Tru Niagen is a specialized form of vitamin B3 discovered by our Chief Scientific Advisor Charles Brenner, PhD," in that the statement can refer to the discovery of Niagen or Tru Niagen and not to the discovery of NR.[19] But for a statement to be ambiguous,

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the answer to the eighth FAQ on the same page. The protracted "investigation process," Oral Argument Tr. at 39, that Elysium describes simply does not exist.

[19] Elysium, in response, points to additional statements by ChromaDex that clearly states that Brenner discovered *NR*, including the statement on the "Science" page of the Tru Niagen website that "in 2014, Dr. Brenner discovered a naturally occurring vitamin in milk called nicotinamide riboside," Dkt. No. 250 at 21 (quoting Dkt. No. 245, Ex. AAA), and the headline of a Facebook advertisement for an interview with Brenner which says: "Listen: The Scientist Who Discovered Nicotinamide Riboside Talks about NAD & Staying Healthy As We Age," *id.* (quoting Dkt. No. 245, Ex. BBB). These statements are raised for the first time in Elysium's opposition to ChromaDex's motion for summary judgment; they are not referenced in Elysium's Counterclaim. The Court thus does not consider them here for the purposes of determining whether the challenged advertising is literally false. Although "false advertising causes of action under the Lanham Act are generally framed in terms of claims (i.e., messages or statements) that are embodied in advertising, rather than each specific piece of advertising containing that claim," *Church & Dwight Co., Inc. v. SPD Swiss Precision Diagnostics GmbH*, 2014 WL 5769236 (S.D.N.Y. Oct. 28, 2014), that principle means that a court can enjoin and a plaintiff can recover for advertising beyond what is listed in the complaint when it contains *the same defect* as the advertising in the complaint, *see id.* (citing *Am. Home Prods. Corp. v. Johnson & Johnson*, 577 F.2d 160, 160 (2d Cir. 1978), for its affirmance of an "injunction that prohibited 'any

requiring extrinsic evidence of meaning, there must be more than one reasonable reading of the statement. *See Time Warner Cable*, 497 F.3d at 158 ("[I]f the language or graphic is susceptible to more than one reasonable interpretation, the advertisement cannot be literally false."). There is not more than one reasonable interpretation here. The statement refers plainly and unambiguously to NR. It cannot be reasonably read to refer to synthetic NR or Niagen or to ChromaDex's product Tru Niagen. Neither is "a specialized form of vitamin B3"—they are products and not molecules; nor could any reader understand the statement to mean that Brenner discovered Niagen or Tru Niagen and not NR. Niagen and Tru Niagen are not things that can be "discovered"; they are a wholesale product and a dietary supplement created by ChromaDex.

Nor could Brenner have "discovered" synthetic NR. To "discover" means "to make known or visible," "to obtain sight or knowledge of for the first time," or to "find out." Merriam-Webster Online Dictionary, *available at* https://www.merriam-webster.com/dictionary/discover (last updated Jan. 23, 2022). It thus entails uncovering something that *already existed*. The parties spend a lot of time arguing about whether synthetic

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advertisement or promotional material which contains' *the false or misleading message* about that product" and *Santana Prods v. Bobrick Washroom Equip., Inc.*, 249 F. Supp. 2d 463, 522–23 (E.D. Pa. 2003), *rev'd on other grounds*, 401 F.3d 123 (3d Cir. 2005), for its rejection of an argument . . . that a false advertising plaintiff "cannot seek recovery for any advertisement beyond those listed in the complaint" because "all of [defendants] advertising materials suffer from *the same defect* raised in the original complaint" (emphasis added)). Here, considering these statements that were not raised in the Counterclaim to determine whether the challenged advertising is literally false would aid Elysium only if the statements alleged in its Counterclaim were not literally false but the newly raised statements were. In that case, the newly raised statements are not merely additional examples of the same, defective advertising claim raised in the Counterclaim; they are materially different statements that could be the basis of an actionable Lanham Act Claim while the claims raised in the Counterclaim are not. As such, these statements may be relevant to the scope of relief if judgment on liability is rendered in favor of ChromaDex, but the Court does not consider these statements at this stage.

NR differs from the NR that appears in nature[20]; ultimately, however, the answer is immaterial. Synthetic NR is either something that Brenner *created* for the first time and which did not exist prior to that—and therefore is not something that can be "discovered"—or synthetic NR is something that existed in nature—that is, NR itself, which Brenner did not discover and was in fact discovered in the 1940s. Because a reading of ChromaDex's statement as conveying that Brenner discovered synthetic NR is either an implausible reading, because synthetic NR differs from the NR in nature and did not exist prior to Brenner's development of it and therefore could not be "discovered," or is literally false, because synthetic NR is the same as the NR which exists in nature, which was discovered in the 1940s, the dispute over whether synthetic NR is the same as the NR in nature is not a genuine dispute as to a *material* fact.

The statement that "Tru Niagen is a specialized form of vitamin B3 discovered by our Chief Scientific Advisor Charles Brenner, PhD," thus necessarily implies that Brenner discovered "a specialized form of vitamin B3"—i.e., NR, the "specialized form" of B_3 at issue. *Cf.* Counterclaim, Ex. 4 (describing "[a] naturally-occurring, unique form of vitamin B3 known as nicotinamide riboside"). ChromaDex, as the summary judgment movant, fails to demonstrate

[20] Elysium argues that "synthetically produced nicotinamide riboside in Tru Niagen is identical to naturally occurring nicotinamide riboside in any event." Dkt. No. 250 at 21 (citing Dkt. No. 251, Ex. PP at 51–52 (Kruger deposition transcript, in which she agrees that the NR molecule is the same in Niagen and in nature, but some of the byproducts and the impurity profile may be different); Dkt. No. 251, Ex. TT at 83–86 (Jaksch deposition transcript, in which he confirms that the NR in Tru Niagen "is structurally and functionally identical to naturally-occurring NR"); Dkt. No. 245, Ex. CCC (screenshot of the Tru Niagen website stating that the NR in Tru Niagen is "nature-identical" because "[t]here is no structural or chemical difference between the two"). ChromaDex disputes this, arguing that "the record is clear that naturally occurring NR is not the same as synthetic, isolated NR." Dkt. No. 262 at 6. To support this, ChromaDex points only to the same portion of the Kruger deposition as Elysium does. Kruger's testimony is that there is no difference between natural NR and the NR in Niagen, but that the Niagen product contains byproducts and impurities that natural NR does not.

that the record is clear that such necessarily implication is true; in fact, the record supports that it is false.

ii. ChromaDex's Funding and Scientific Research

Elysium's Counterclaim also alleges that ChromaDex "proudly advertises that it 'pioneered NAD research by investing millions of dollars in safety and human clinical trials on its patent protected NR' and claims to have supplied NR to 'over 160 leading institutions for research.'" Counterclaim ¶ 149. It claims that the statements are false; they create "the misleading impression that ChromaDex has funded or is funding more than 160 studies relating to NR" when in fact it "admit[ed] on a November 10, 2016 earnings call that 'It's also important to note that ChromaDex is not paying for these studies . . . .'" *Id.*

Elysium relies for its claim of falsity on a January 2017 slide deck and an accompanying email chain from Jaksch. It claims that the documents demonstrate, or at least create a genuine fact issue, that ChromaDex's claim to have invested millions of dollars in research is false. For its part, ChromaDex offers evidence of the truth of the statement regarding the investment of millions of dollars. It points to its 2018 10-K filing which states that "[r]esearch and development costs for the fiscal years ended [sic] December 31, 2018, and December 30, 2017, were approximately $5.5 million and $4.0 million, respectively." ChromaDex, Annual Report (Form 10-K) (March 7, 2019) at 13.[21]

[21] The filing is not in the summary judgment record; ChromaDex references the publicly available document for the first time in its reply briefing. Dkt. No. 262 at 7. However, "[c]ourts resolving summary judgment motions regularly accept SEC filings for the truth of their contents." *Donoghue v. Astro Aerospace Ltd.*, 2021 WL 1964294, at *1 (S.D.N.Y. May 17, 2021); *see also Desclafani v. Pave-Mark Corp.*, 2008 WL 3914881, at *5 n.7 (S.D.N.Y. Aug. 22, 2008) ("Because courts may take judicial notice of the contents of filings with the [SEC], and 'any facts subject to judicial notice may properly be considered in a motion for summary judgment,' I take judicial notice of the contents of [a filed] Proxy Statement and consider it for the purposes of this motion." (internal citations omitted) (quoting *Fed. Election Comm'n v. Hall-Tyner Campaign Comm.*, 524 F. Supp. 955, 959 n.7 (S.D.N.Y. 1981))).

Because the burden at trial would be on Elysium at trial to demonstrate that the statements it challenges are literally true, once ChromaDex, as the moving party, has pointed to the absence of such evidence, Elysium must identify evidence to create a genuine issue of fact at the summary judgment stage. *Jaramillo*, 536 F.3d at 145; *Wright*, 554 F.3d at 266. It has failed to discharge that duty.

The statements to which Elysium points relate to specific projects and the investment ChromaDex made in those projects and not to ChromaDex's research investments as a whole. In a slide deck that Elysium points to entitled "Investor Presentation," ChromaDex states that it engaged in "[m]ore than 100 pre-clinical and clinical studies [that] represent over $50 million of non-paid research for ChromaDex." Dkt. No. 251, Ex. NN at 21. Elysium also points to an email chain in which Jaksch sends "a current copy of our investor deck," along with accompanying text providing additional information about the slides. Dkt. No. 251, Ex. OO at 13. The deck includes a slide detailing ChromaDex's collaborative agreements on Niagen with universities and research institutions that "either currently or will soon be conducting studies surrounding various specific possible health benefits related to NR," and the accompanying text flags that "[i]t's also important to note that ChromaDex is not paying for any of this research." *Id.* The antecedent for "this research" is the particular collaborative agreements. The comment states that ChromaDex is "not paying for any of *this* research," not that ChromaDex is not paying for *any* research at all.[22]

[22] Elysium also points to testimony of Dellinger that when he was employed by ChromaDex, he was told by Jaksch that "clinical research was not a company priority" and that "clinical studies don't mean anything," and that he was directed by Jaksch to "facilitate as many free pre-clinical and clinical studies with third-party researchers as possible," to which end Dellinger "facilitated a significant number of 'material transfer agreements' where ChromaDex would provide NR to third parties to use in their research." Dkt. No. 252 ¶¶ 4–5. Dellinger also testified that the value of the NR donated pursuant to these agreements was not "millions of dollars' worth," because "at

b. Statements Regarding the Safety and Efficacy of ChromaDex's Products

Elysium's Counterclaim alleges that various statements made by ChromaDex about the safety and efficacy of Niagen and Tru Niagen are false.

i. Tru Niagen Increases NAD+ Levels by 40–50%

First, Elysium's Counterclaim alleges that ChromaDex falsely advertises that Tru Niagen increases NAD by 40–50%. Counterclaim ¶¶ 10, 45–46. ChromaDex's website includes a graphic that states:

- "Tru Niagen increases NAD by 40–50%" along with the qualifier that this is "on average at 300 mg / day for 8 weeks," and a citation to the 2019 Conze Study. Dkt. No. 245, Ex. LLL.

ChromaDex asserts that this statement is true, because "the Conze Study did in fact show that NIAGEN increased NAD levels by 40-50% on average after eight weeks in study participants taking a 300 mg daily dose, the recommended daily dose of Tru Niagen." Dkt. No. 210 at 15. Elysium responds that the Conze Study is unreliable to establish this proposition. Dkt. No. 250 at 12–13.

A similar standard applies to Elysium's allegations regarding ChromaDex's statements that applied to ChromaDex's challenges to Elysium's statements regarding the outcome of the studies it cited. Because the challenged statement cites to the Conze Study, Elysium must demonstrate a genuine issue of fact whether the study "is not sufficiently reliable to permit one to conclude with reasonable certainty that [it] established the claim made." *McNeil-P.C.C., Inc. v. Bristol-Myers Squibb Co.*, 938 F.2d at 1549; *McNeil-PPC, Inc. v. Pfizer Inc.*, 351 F. Supp. 2d at

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the time [h]e worked at ChromaDex, it could manufacture 1 kilogram of NR for approximately [redacted]" *Id.* ¶ 6. But that testimony, even construed favorably to Elysium as it must on this motion, does not establish that ChromaDex did not make millions of dollars out investments outside of the agreements.

248–49. Elysium does not dispute that the results of the Conze Study showed that Niagen increased NAD+ levels at a 300 mg dose; however, it argues that those results are unreliable because the Conze Study artificially depleted participants' NAD+ levels before the study began. Dkt. No. 250 at 13.

The Conze Study included a two-week run-in period and an eight-week supplementation period. Dkt. No. 230, Ex. 15 at 2. The study explains that "[t]o minimize the effect of dietary influences on NAD^+ metabolite levels, subjects were instructed to avoid foods that contain high amounts of tryptophan and forms of vitamin B3 during the run-in and NR supplementation periods." *Id.* The study's clinical protocol, which lists Dellinger in his then-capacity as ChromaDex's Director of Scientific Affairs as the sponsor contact, *see* Dkt. No. 251, Ex. EEE at 1, included an extensive list of "foods to avoid/limit during the study," explaining that the "goal [was] to standardize the ingestion of niacin equivalents to approximately 20 mg/day throughout the study," and that "[s]ubjects will be instructed to ensure that they are consuming greater than 16 mg/day with the goal of approximately 20 mg/day," *id.* at 32. Foods to avoid included poultry, fortified breads and bread products, fortified ready-made cereals, energy drinks, soy products (excluding tofu), and other game; foods to limit included beef, pork, eggs, milk and dairy products, seeds and nuts, fish, lobster, and crab. *Id.*

At deposition, Kruger—one of the study's authors and, at the time of the study, President of Spherix Consulting Inc., which provided scientific and regulatory consulting to ChromaDex—stated that the purpose of the run-in period was "to take out the variability in baseline levels amongst subjects." Dkt. No. 230, Ex. 20 at 186. She conceded, however, that the study did not account for potential effects of this diet protocol on NAD+ levels, testifying that "we cannot

draw a conclusion as to what a dietary control over two weeks would do to NAD levels." Dkt. No. 251, Ex. PP at 192.

Dellinger, who at the time and as noted above was employed at ChromaDex as its Director of Scientific Affairs and was listed as the sponsor contact on the study protocols, but who is now employed by Elysium as their Vice President of Scientific Affairs, submitted a declaration in which he calls into question to the reliability of the Conze Study. Dkt. No. 252. He states that:

> In or around mid-2015, after ChromaDex received the initial test results from the Trammell Study showing that a 300 mg dose of NR did not significantly increase NAD+ levels, Dr. Kruger shared with me her hypothesis that NR supplementation cannot increase NAD+ levels unless such NAD+ levels are already depleted. Dr. Kruger advocated for ChromaDex to design a study in which participants' NAD+ levels were artificially depleted through dietary restrictions in order to show an increase when NR was administered.

Id. ¶ 10. In his account, the Conze Study was manipulated to reach a preordained result. He states that, when the study was being designed, Kruger sent him two studies from 1989 demonstrating that NAD+ levels can be depleted through a diet limiting niacin and tryptophan intake, and that "a single administration of nicotinamide could increase NAD-related metabolites at the end of each dietary-restrictive period." *Id.* ¶¶ 11–12. He further states that

> Thus, Dr. Kruger advocated that ChromaDex design a study to restrict participants' niacin and tryptophan intake in advance of the administration of NR in order to deplete the participants' NAD+ levels, as shown in the 1989 Studies. Then, administration of NR would replenish those depleted NAD+ levels, also as shown in the 1989 Studies, which would create the impression of a significant increase in NAD+ levels rather than a return to normal levels. Dr. Kruger convinced ChromaDex to design such a study, which was ultimately published on July 5, 2019 as the "2019 Conze Study." Further confirmation that the 2019 Conze Study was modeled after the 1989 Studies, the 2019 Conze Study cites the Fu 1989 Study for its statistical power calculation. They could not use the data for the power calculation unless they were planning to lower NAD+ levels on purpose just like the 1989 Studies. Also Figure 3A in the 2019 Conze Study clearly shows that NAD+ levels of the placebo group decrease significantly during the study demonstrating a successful depletion of NE intake due to the dietary restrictions.

Id. ¶ 13. Finally, he states that he "opposed the design of the 2019 Conze Study because [he] thought it was unnecessary," because he "believed in the effectiveness of NR in a well-designed study," but he was overruled. *Id.* ¶ 14. He states that he nonetheless "refused to sign a clinical study protocol with a dietary restriction of 10.1 NE [niacin equivalents] per day (the 'low' group in the 1989 Studies) due to potential health risks to participants," and "insisted that participants receive[] at least 20 NE per day, the 'adequate' level of niacin intake, but still below normal dietary levels. *Id.*

ChromaDex's motion for summary judgment asserts that "there is no triable issue concerning the reliability of the Conze Study." Dkt. No. 262 at 8. It points out that Dellinger ultimately signed onto the study protocols as the study's sponsor contact and thus questions the credibility of Dellinger's later declaration, made after he switched to Elysium. It also points to evidence that the study was well-designed.[23] However, credibility is paradigmatically a jury question. *See, e.g.*, *Altomare v. Wells Fargo Securities, LLC*, 2012 WL 489200, at *9 (S.D.N.Y. Feb. 15, 2012) ("[I]t is not the role of the Court to make these credibility determinations on summary judgment; rather, it must assume that [the nonmoving party's] testimony will be credited and draw all reasonable inferences in [the nonmoving party's] favor." (internal quotation marks omitted) (quoting *Catalano v. Lynbrook Glass & Architectural Metals Corp.*, 2008 WL 64693, at *9 n.5 (E.D.N.Y. Jan 4., 2008) (quoting *Shager v. Upjohn Co.*, 913 F.2d 398, 402 (7th Cir. 1990)))). And Elysium need only raise more than a "metaphysical doubt," *see*

[23] Guarente testified that he reviewed the study and did not "have anything that would have caused [him] to question any portion of it." Dkt. No. 230, Ex. 21 at 19. Kruger testified that the protocol was designed only to reduce baseline variability, and that the protocol amount of niacin equivalent to consume was "well within the normal range." Dkt. No. 251, Ex. PP at 194. The Conze Study also was published and peer-reviewed. *See Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 593 (1993) (discussing peer review as one indicium of reliability).

Matsushita Elec. Indus., 475 U.S. at 586, to defeat summary judgment. If Dellinger's declaration is to be believed, then the study design was manipulated and biased, and there is reason to question "the objectivity . . . of the persons conducting the tests." *Proctor & Gamble Co.*, 747 F.2d at 119. A jury, if it credited Dellinger's testimony, could find that the Conze Study was not designed objectively, and thus was not reliable to substantiate the proposition for which ChromaDex in its advertisement cites it—that Tru Niagen raises NAD+ levels by 40–50%. It follows that ChromaDex is not entitled to summary judgment on this point.

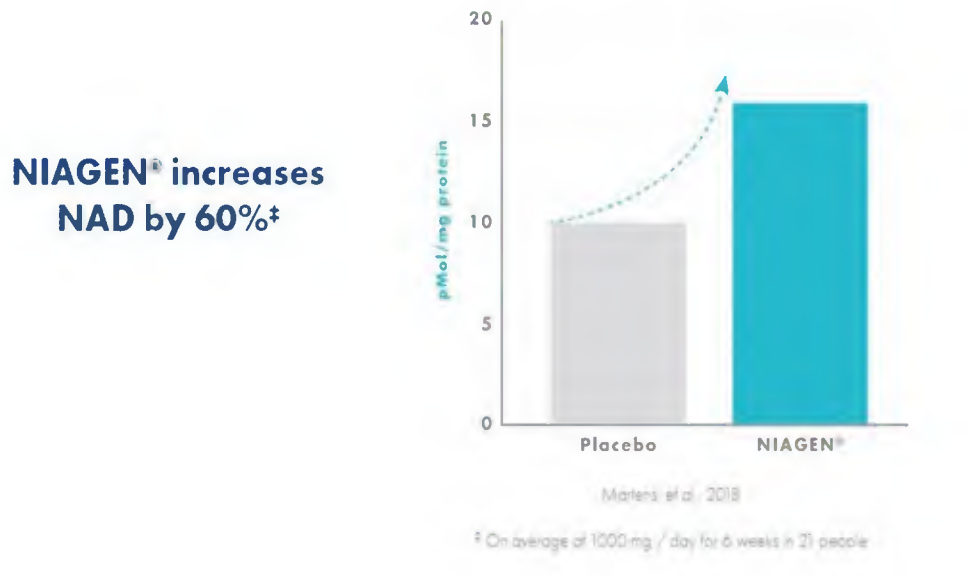
ii. Niagen increases NAD+ levels by 60%

Second, Elysium's Counterclaim asserts that before ChromaDex advertised that Tru Niagen raised NAD+ levels by 40–50%, it advertised on its website that the Martens Study showed that Niagen increased NAD+ by 60%. *See* Dkt. No. 210 at 17 (citing Counterclaim ¶¶ 11–12, 47). The Counterclaim includes a graphic stating that "NIAGEN® increases NAD by 60%," with a citation to the 2018 Martens Study and the qualifier that this is "[o]n average of 1000 mg / day for 6 weeks in 21 people." Counterclaim ¶ 47; *see also* Dkt. No. 210 at 17.

The Martens Study was a 2 x 6 week randomized, double-blind, placebo-controlled, crossover clinical trial of Niagen. Dkt. No. 230-14 at 1. In the study, participants were randomized into one of two groups: Group A received placebo capsules during the first six weeks of the study and then crossed over to receive NR capsules at a dosage of 500 mg twice a day, i.e., 1000 mg per day, for the remaining six weeks. Group B did the opposite, receiving NR capsules first and then placebo capsules for the last six weeks. *Id.* at 3–4. The study found that "NR was well tolerated at the dose tested, and no serious adverse effects occurred." *Id.* at 4. It concluded that "[o]ral NR supplementation effectively elevated levels of NAD^+ in [peripheral blood mononuclear cells] by ~60% compared with placebo." *Id.* at 3.

ChromaDex argues that the Martens Study substantiates the claim made and thus that it is entitled to summary judgment. Elysium does not dispute that the Martens Study itself showed that Niagen, at a 1000 mg per day dose, increased NAD+ levels by 60%. In its Counterclaim, Elysium alleged that the Trammell Study, which preceded the Martens Study, "debunked this claim," because it showed "no statistically significant increase in NAD levels even at an intake of 1,000 mg per day." Counterclaim ¶ 48. In its opposition to ChromaDex's summary judgment motion, however, Elysium no longer repeats this specific claim, and the Court therefore deems it abandoned. It contests ChromaDex's motion for summary judgment as to this statement only on the basis that ChromaDex's "argument that the falsity is clarified by a small notation on the graphic is misplaced." Dkt. No. 250 at 17 n.4. Elysium relies on *Church & Dwight Co. v. SPD Swiss Precision Diagnostics, GmbH*, 2015 WL 4002468, at *19 (S.D.N.Y. July 1, 2015), for the proposition that "as many courts have found, a footnote or disclaimer that purports to change the apparent meaning of the claims and render them literally truthful, but which is so inconspicuously located or in such fine print that readers tend to overlook it, will not remedy the misleading nature of the claims." *Id.*

Elysium's argument is not well-founded for two independent reasons, and ChromaDex is entitled to summary judgment. First, the notation that the results are "[o]n average of 1000 mg / day for 6 weeks in 21 people" does not "purport to change the apparent meaning of the claims and render them literally truthful"; the claim at issue here is literally true, and the notation merely explains the parameters in which it is true. Second, the notation is not "a footnote or disclaimer" that is "inconspicuously located or in such fine print that readers tend to overlook it." It is the only other text on the graphic, displayed immediately below the graphic itself.



ChromaDex is thus entitled to summary judgment on this claim—there is no evidence that the challenged statement is anything other than literally true.

iii. October 2014 Press Release

Next, Elysium's Counterclaim asserts that in an October 25, 2018 press release, ChromaDex stated that "Niagen was clinically-studied at 300 mg to increase NAD in 2016, published in the journal *Nature Communications*." Dkt. No. 210 at 19 (citing Counterclaim ¶¶ 9, 14). Elysium's Counterclaim alleges that "[t]he Trammel Study demonstrated that Tru Niagen does *not* work to raise NAD levels." Counterclaim ¶ 46. The parties' Joint 56.1 Statement of Undisputed Facts states that "[t]he Trammell Study reported that a single dose of NR increased NAD+ levels in blood over a 24-hour period," and that "[t]he Trammell Study reported dose-dependent increases in NAD+ levels following administration of 100, 300, and 1000 mg single doses of NR in adults." Joint 56.1 ¶¶ 10–11. ChromaDex reasons based on this that "Elysium appears to have withdrawn this claim." Dkt. No. 210 at 19. Indeed, in its opposition papers, Elysium does not reference its allegations regarding this press release directly. With regard to the Trammell Study, it no longer puts forward the blanket assertion that the Trammell

Study did not show that Tru Niagen (or, Niagen at a 300 mg dose) raises NAD+ levels at all, but rather repeatedly emphasizes—in other contexts—that "[t]he Trammell Study did not show a *statistically significant increase* in NAD+ levels in participants taking 300 mg/day of NR." Dkt. No. 250 at 3; *see also id.* at 13. To the extent that Elysium has not withdrawn its claim as to the falsity of the statement that "Niagen was clinically-studied at 300 mg to increase NAD in 2016," by virtue of its concession in the Joint 56.1 Statement that the Trammell Study did report that NR dose-dependently raised NAD+ levels in 100 mg, 300 mg, and 1000 mg doses, ChromaDex is entitled to summary judgment on this claim. It is literally true that "Niagen was clinically-studied at 300 mg to increase NAD in 2016." Elysium cannot argue that it is simultaneously true, as the Joint 56.1 states, that the Trammell Study showed a dose-dependent increase in NAD levels at 300 mg but that the study is also not sufficiently reliable to establish that exact proposition with reasonable certainty.

Elysium does not argue that the statement either expressly or necessarily and unambiguously conveyed that the increase was statistically significant. Nor does it identify any extrinsic evidence to demonstrate implied falsity. Had the press release asserted that Niagen was therefore *effective*, or something else along those lines, it might be relevant that the results of the Trammell Study did not show a statistically significant increase, but the press release makes no such statement. Accordingly, ChromaDex is entitled to summary judgment.

iv. Other NAD-Dependent Clinical Study Results

ChromaDex further asserts that it is entitled to summary judgment as to Elysium's allegation that "ChromaDex makes other statements that 'depend on the false premise that Tru Niagen increases NAD,' and are thus 'rendered false by the falsity of the fundamental proposition on which they rest, that Tru Niagen increases NAD.'" Dkt. No. 210 at 19 (quoting Counterclaim ¶ 54). Neither party makes clear exactly what statements fall into this category.

However, ChromaDex's sole argument is that "Elysium's claim fails for the same reasons the claims addressed above fail—namely, that abundance of clinical studies demonstrating that NIAGEN and TRU NIAGEN do raise NAD levels." *Id.* The Court has denied summary judgment as to the reliability of the Conze Study. The Court has also rejected ChromaDex's arguments about the Dollerup Study and the Martens Study, because they tested a 1000 mg dose and 2000 mg dose of Niagen, respectively. The Court further noted that while the Trammell Study undisputedly demonstrated that Niagen raises NAD+ levels, the evidence is similarly undisputed that it did not do so at a statistically significant level. Because ChromaDex's motion for summary judgment as to this point relies solely on its previous arguments about its various clinical studies which the Court has rejected, summary judgment is not warranted.

v. Safety and Trustworthiness of Tru Niagen

Elysium's Counterclaim also alleges that "ChromaDex falsely touts Tru Niagen as 'safe' and 'trusted,'" Counterclaim ¶¶ 62–83, in the following statements:

- Advertising that Tru Niagen is "the Trusted NAD Supplement." *Id.* ¶ 64.
- A statement made "[s]hortly before publication of the trial" in ChromaDex's updated Tru Niagen Amazon.com advertising, which claims that "more than 4 published trials have confirmed Tru Niagen is safe and effective," and "currently advertises its product as 'SAFE TO USE' with 'NO known negative side effects.'" *Id.* ¶ 65.
- A press release announcing the clinical trial results and containing the following statements:

  a. "'The results of this large human trial directly support the efficacy and safety of our NAD-boosting consumer product Tru Niagen,' says ChromaDex CEO Rob Fried.

  b. 'The study also joints previous chronic supplementation studies to support the safety of chronic Niagen supplementation.'" *Id.* ¶ 66 (citing Ex. 1).

- A statement by Charles Brenner in an article on the "Investor Relations" page of the ChromaDex website about the Conze Study that: "This is a timely publication in the history of Niagen as it clearly shows safe, dose-dependent and time-dependent increases in blood NAD in human populations," and "[w]ith so much global interest in NAD-boosting supplementation strategies, our approach to human translation has been to put safety first." *Id.* ¶ 67 (citing Ex. 1).

- A statement in a blog post on blog.truniagen.com that "Tru Niagen is a safe, effective supplement" and that the Conze Study "further validates the safety and efficacy of Tru Niagen." *Id.* ¶ 68 (citing Ex. 2).

The Counterclaim also alleges that these "false claims of its product's safety" are "paired with affirmative attacks on Elysium and Basis," which juxtaposition "seeks to convince consumers that no harm will come to them as a result of their ingestion of ChromaDex's product and that Tru Niagen is in fact 'the Trusted NAD Supplement' and more trustworthy than Elysium's basis," which they allege is "false and misleading." *Id.* ¶ 70–72.

Elysium alleges that the statements are false: "the July 2019 Conze Study shows that Tru Niagen is clinically proven to injure consumers by dramatically decreasing their white blood cell count (WBC), posing serious risk to consumers, particularly the elderly customers who might be most attracted to ChromaDex's supposed 'anti-aging' product." *Id.* ¶ 62. Elysium contends: "[i]n reality, Tru Niagen is far from safe and trustworthy, as established by ChromaDex's own clinical trial, which showed that Tru Niagen is unsafe and dangerous to consumers," because of the alleged white blood cell count decrease shown in the study. *Id.* ¶ 73.

The Conze Study reports a statistically significant decrease in the white blood cell count of patients taking 300mg of NR (the dosage of Tru Niagen) compared to placebo:

> *Hematology and clinical chemistry.* Some differences were observed in the hematology parameters at day 56 (Table 3, Supplemental Figure). Specifically, decreases occurred in the white blood cell count and the monocyte count in the placebo-treated group, white blood cell, neutrophil, and lymphocyte counts in the 100 mg-treated group, white blood cell, neutrophil, lymphocyte, monocyte, and basophil counts in the 300 mg-treated group, and the white blood cell, neutrophil, and lymphocyte counts in the 1000 mg-treated group. . . . Statistically significant

> differences also occurred in the white blood cell count in the 300 mg group compared to the placebo-, 100 mg-, and 1000 mg-treated groups . . . .

Dkt. No. 230, Ex. 15 at 8. The study reported its findings in each group in a table that presented mean levels (x 10^9/L) at screening and at day 56, as well as the change from screening, plus/minus the standard deviation. *Id.* at 9. With regard to white blood cell count, the study's specific findings were that in the placebo group, white blood cell counts went from 6.31 ± 1.21 to 5.83 ± 1.25, representing a change of -0.49 ± 1.13; in the 100 mg of Niagen group, white blood cell counts went from 6.29 ± 1.63 to 5.65 ± 1.68, representing a change of -0.59 ± 0.84; in the 300 mg of Niagen group, white blood cell counts went from 6.17 ± 1.45 to 4.96 ± 1.01, representing a change of -1.10 ± 1.29; and finally, in the 1000 mg Niagen group, white blood cell counts went to 6.54 ± 1.90 to 5.69 ± 1.41, representing a change of -0.99 ± 1.23. *Id.* With regard to the neutrophil[24] count, in the placebo group, neutrophil counts went from 3.63 ± 0.96 to 3.34 ± 1.00, representing a change of -0.31 ± 0.96; in the 100 mg of Niagen group, neutrophil counts went from 3.52 ± 1.12 to 3.11 ± 1.12, representing a change of -0.41 ± 74; in the 300 mg of Niagen group, neutrophil counts went from 3.68 ± 1.23 to 2.78 ± 0.96, representing a change of -0.82 ± 1.22; and finally, in the 1000 mg Niagen group, neutrophil counts went from 3.83 ± 1.26 to 3.17 ± 0.93, representing a change of -0.76 ± 0.96. *Id.*

The Study concluded that "[i]mportantly, the differences were not dose-dependent, within the healthy clinical reference ranges for the laboratory and clinic location, and deemed to be not clinically meaningful or an AE [adverse effect]." *Id.* Its bottom-line conclusion was that "[o]ral NIAGEN is safe and well-tolerated up to 1000mg/day for 8 weeks." *Id.*

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[24] Neutrophils are a type of white blood cell; Merriam-Webster defines neutrophil as "a granulocyte that is the chief phagocytic white blood cell of the blood." Merriam-Webster Online Dictionary, accessible at https://www.merriam-webster.com/dictionary/neutrophil (last accessed February 3, 2022).

The 2020 Marinescu Study, a toxicity study of Elysium's NR conducted by, among others, Guarente, Morris, and Dellinger of Elysium, cites the Conze Study along with various other studies for the proposition that "[s]ubsequent human clinical studies have demonstrated the safety and tolerability of NR at doses up to 2,000 mg/d for 12 weeks and confirmed the efficacy of NR for inducing NAD+ biosynthesis." Dkt. No. 230, Ex. 18 at 308.

At deposition, however, Guarente expressed some hesitation about the decrease in neutrophil levels that the study revealed:

> Q. Did you have anything that would have caused you to question any portion of [the Conze Study]?
>
> A. There's a lot of data here.
>
> (Witness reviews document.)
>
> No. The one thing I remember noticing in this study is the effect on neutrophils.
>
> Q. And what did you notice about the effect on neutrophils?
>
> A. It looked like there was a dose-dependent decline in neutrophils.
>
> Q. What's a neutrophil?
>
> A. It's a white blood cell.

Dkt. No. 230, Ex. 21 at 209.

Elysium argues that the decreases in white blood cell count in the Conze Study show that Tru Niagen is unsafe. It offers an unauthenticated copy of what purports to be a page from the Leukemia & Lymphoma Society website that includes a table of "normal ranges of blood cell counts for healthy adults and children." Dkt. No. 245, Ex. RR. According to the table, the normal range of white blood cells per microliter of blood in men is 5,000 to 10,000 (which is, in the metric used by the Conze Study, 5.0 to 10.0 x 10^9/L) and the normal range of white blood cells per microliter of blood in women is 4,500 to 11,000 (4.5 to 11.0 x 10^9/L). *Id.* It also states

that neutrophils should typically make up 55% to 70% of white blood cells. *Id.* Elysium argues, based on this, that for participants taking 300 mg per day of Niagen—i.e., Tru Niagen—"the *average* WBC count dropped to 4.96 ± 1.01, meaning the average WBC count could be as low as 3.95—below the normal healthy range for men [5.0 to 10.0]." Dkt. No. 250 at 15. It adds that "the results were also at the lower bound of the normal healthy range for women, which suggests that many participants' [sic] showed abnormally low WBC counts, but such data was concealed through averaging." *Id.* at 15–16.

ChromaDex responds that the cited webpage does not suggest that any deviation from the normal range is "unsafe," and reiterates that the Conze Study itself found that deviations in white blood cell counts were "within the healthy clinical reference ranges for the laboratory and clinic location, and deemed not to be clinically meaningful or an [adverse event]." Dkt. No. 262 at 10–11.

ChromaDex's argument is well-taken. A jury could find, relying on the fact that the study showed declines in white blood cell counts and Guarente's testimony about the potential dose-dependency of the neutrophil decline, that the study did raise a concern that there was a relationship between Niagen and white blood cell counts. A jury could not find, however, based only on a web page purporting to show "normal" white blood cell count ranges along with speculation that "the average WBC count *could* be as low as 3.95," that the study demonstrated that white blood cell counts in people taking Tru Niagen dropped below the "normal" range. Nor could the jury find, based on the evidence in the summary judgment record—or rather, the lack thereof—that white blood cell counts that are at the low end of normal or slightly below normal are *unsafe*. Such a conclusion requires a leap that is unsupported by the evidence. The jury would have to speculate. A plaintiff prosecuting a Lanham Act claim "must show falsity,

not merely uncertainty." *Apotex*, 823 F.3d at 66. As such, ChromaDex is entitled to summary judgment on this claim.

c. Statements Regarding FDA Regulation of ChromaDex's Products

Elysium's Counterclaim further alleges that "ChromaDex falsely advertised that Tru Niagen had been rigorously reviewed for safety and efficacy by the FDA, when in fact, FDA did neither." Counterclaim ¶¶ 105–135. Broadly, its claims fit into three categories: (1) that ChromaDex's advertisements represent that the FDA reviewed Niagen for efficacy in connection with ChromaDex's GRAS and NDI submissions, when in fact both of those submissions relate only to safety and not to efficacy, *see id.* ¶¶ 131–135; (2) that ChromaDex's GRAS and NDI submissions related only to Niagen, not Tru Niagen, *see id.* ¶ 130; and (3) that the FDA does not conduct an independent safety review of GRAS and NDI submissions for safety, *see id.* ¶¶ 106–113. ChromaDex moves for summary judgment on all three of these categories; in its opposition, Elysium defends only the first two. As such, the Court deems Elysium to have abandoned its argument that the FDA conducted no safety review of Niagen in connection with ChromaDex's GRAS and NDI submissions.[25]

[25] Even if Elysium had not abandoned this argument, it would not be successful. The record is undisputed that the FDA does conduct an independent review in connection with such submissions and does not merely "accept those submissions," as Elysium initially alleged, *see* Counterclaim ¶ 108. Both parties' experts—Martin for Elysium and Weisman for ChromaDex—testify extensively about the FDA's review process in connection with GRAS submissions. *See* Dkt. No. 230, Ex. 12 ("Martin Dep.") at 64–70 (explaining that under the current FDA GRAS notification system, the "FDA would review that document, review the safety of it and so forth," and that "[t]he people involved in that would be a consumer safety officer, a chemist, toxicologist, sometimes a microbiologist, sometimes a food scientist, sometimes a nutritionist," and calling the FDA's review "thorough"); Dkt. No. 230, Ex. 11 ("Weisman Report") (explaining that "[w]hen the FDA receives a notice, it 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," and then either "respond[s] without question to the GRAS conclusion (by issuing a 'no objection' letter) or . . . conclude[s] the notice does not provide sufficient evidence of a GRAS conclusion"). Weisman

The motion for summary judgment with respect to statements in the first category is granted in part and denied in part. Elysium's claim has two components: It challenges ChromaDex's historical advertising that the GRAS and NDI submissions that the submissions included testing for efficacy and it challenges ChromaDex's current advertising which does not explicitly reference efficacy but that, according to Elysium, "gives consumers the false impression that Tru Niagen has been reviewed for effectiveness by the FDA." Dkt. No. 250 at 16.

As to the first of these, ChromaDex's website historically stated:

- "NIAGEN® is the only nicotinamide riboside that has been rigorously tested for safety *and efficacy* with the US FDA GRAS (Generally Recognized As Safe) and two 'New Dietary Ingredient' (NDI) Notifications." Counterclaim, Ex. 6.

ChromaDex does not dispute that GRAS and NDI submissions relate only to safety and not to efficacy. ChromaDex's submissions related to Niagen's use as a food ingredient and not as a drug. ChromaDex also does not dispute that it published and used the statement that appears in Exhibit 6. Accordingly, summary judgment with respect to this statement is denied.

The second set of challenged statements present a closer question. ChromaDex's current advertising includes the following statements:

- "Why NIAGEN®" followed by bulleted list that includes "3 FDA Safety Reviews." Counterclaim, Ex. 5.
- "Niagen is the world's first and only known FDA-safety reviewed form of NR." Counterclaim, Ex. 8.
- "Niagen®, the sole active ingredient in Tru Niagen® from ChromaDex, was successfully notified to the U.S. FDA as Generally Recognized as Safe (GRAS) and as a New Dietary Ingredient (NDI)."

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also describes the FDA's NDI notification review process, Weisman Report at 10, and both experts testified that NDI notifications have a high failure rate, *id.*; Martin Dep. at 54.

The statements refer exclusively to safety. They do not mention efficacy. Elysium argues that the statements nonetheless "giv[e] consumers the false impression that Tru Niagen has been reviewed for effectiveness by the FDA." Dkt. No. 250 at 16. It supports the argument by the testimony of its survey expert, Brian Sowers, who conducted a survey which found that there are "a net 23.3% of respondents who take away the mistaken belief that the FDA has reviewed Tru Niagen for effectiveness" from viewing the Tru Niagen homepage.[26]

The Second Circuit has held that representations in advertising that are "commensurate with information in an FDA label generally cannot form the basis for Lanham Act liability." *Apotex*, 823 F.3d at 64. The only caveat it has offered is that "Lanham Act liability might arise if an advertisement uses information contained in an FDA-approved label that does not correspond substantially to the label, or otherwise renders the advertisement literally or implicitly false." *Id.* at 64 n.10. The Circuit has explained that the "principle rightfully insulates pharmaceutical companies from liability when they engage in First Amendment speech that is consistent with the

[26] ChromaDex's argument that the Sowers survey is not relevant because the Counterclaims refer to "a previous version of the 'Unauthorized NR' page on ChromaDex's Tru Niagen website [which] included a statement that 'NIAGEN® is the only nicotinamide riboside that has been rigorously tested for safety . . . with the US FDA GRAS (Generally Recognized as Safe) and two "New Dietary Ingredient" (NDI) notifications,'" which is Exhibit 6 to the Counterclaim, whereas "the Sowers report tests a completely different page—the Tru Niagen website's homepage as it appeared when the Sowers Survey was conducted—which makes no reference to efficacy," Dkt. No. 210 at 27 (omission in original), is unavailing. The omitted phrase, as quoted in full in Elysium's Counterclaim and as seen in Exhibit 6, is "has been rigorously tested for safety *and efficacy* with the US FDA [GRAS] and two [NDI] notifications." Counterclaim ¶ 111, Ex. 6. The Sowers survey did not test whether this statement *implied* to consumers that the FDA reviewed Niagen for efficacy; the statement *explicitly* states this and is thus subject to a challenge of literal falsity, not implied falsity. Rather, the Sowers survey seeks to demonstrate that statements about FDA review of Niagen that do not explicitly reference efficacy nonetheless convey to consumers that the FDA has reviewed Niagen for efficacy, and thus are impliedly false; thus, it is proper that that the Sowers survey tested statements "which make[] no reference to efficacy," *see* Dkt. No. 210 at 27.

directive of the regulatory body having oversight of product labels" and is necessary "to avoid chilling speech that ought to be protected." *Id.* at 64.

The same principles apply to and foreclose Elysium's claim based on ChromaDex's communication that it was "safety-reviewed" by the FDA or successfully notified as GRAS. The Congress (and the FDA) have determined that nutritional ingredients—unlike drugs—are only to be reviewed for safety and not for effectiveness. If the challenged statements regarding GRAS and FDA review for safety could have led consumers to any confusion that the FDA also reviewed the product for efficacy, such confusion could have been based only in confusion about the FDA and what it means for the FDA to review a nutritional product. It could not have resided in anything that ChromaDex said about the FDA review of its product. It did not say anything other than that FDA reviewed its product for safety and that Tru Niagen was notified as GRAS and as an NDI, not anything about efficacy. In these circumstances, to hold that ChromaDex or any other company could be held liable for statements such as these based on the notion that while they refer only to safety they could be understood to mean efficacy would "chill" all companies from informing the public that their nutritional products have been reviewed by or notified to the FDA and would run counter both to the FDCA and to First Amendment principles.

d. Statement that ChromaDex is the Only Seller of NR

Elysium alleges that ChromaDex "falsely represents to consumers . . . that ChromaDex is the only seller of NR, which according to the website, can only be found under ChromaDex's trade name, 'Niagen.'" Counterclaim ¶ 94. The website states, under the heading "Look For NIAGEN® on the Label":

- "NR is a patented ingredient, only sold as NIAGEN®. ChromaDex holds the patent rights to NR, and sells the ingredient to consumers as TRU NIAGEN®." Dkt. No. 201 at 25 (citing Dkt. No. 192, Ex. 7).

- "If you are taking or plan to purchase an NR supplement, look at your label to ensure 'NIAGEN®' appears under the 'Supplement Facts.' Any nicotinamide riboside product that does not say 'NIAGEN®' on its label does not contain nicotinamide riboside that has been successfully notified to the FDA." *Id.* (citing Dkt. No. 192, Ex. 7).

Both parties move for summary judgment. Elysium argues that the statement that NR is a patented ingredient only sold as Niagen and that ChromaDex holds the patent rights to NR is false because "[t]he NR in Basis is not 'counterfeit' or 'inauthentic.' NR exists in nature. ChromaDex does not own a patent on NR. It licenses a patent for one method of manufacturing NR. While methods of manufacturing NR may vary, NR is NR." Dkt. No. 222 at 24. ChromaDex responds by arguing that it "does not state anywhere on the page that it is 'the only seller of NR.'" Dkt. No. 210 at 25. It claims that the advertisement should be read to state "that ChromaDex's NR is only sold as NIAGEN and that NIAGEN is the only nicotinamide riboside that has been successfully notified to the FDA as GRAS and successfully reviewed twice under the FDA's NDI notification program." *Id.*

The advertisement is not capable of being read as ChromaDex now would read it. It does not state, as ChromaDex suggests, that "*ChromaDex's NR* is only sold as NIAGEN," Dkt. No. 210 at 25 (emphasis added). As Elysium points out, it states "*NR* is a patented ingredient, only sold as NIAGEN®," Dkt. No. 192, Ex. 7 (emphasis added), without any qualifier that this statement refers only to ChromaDex's NR and not NR in general. *See* Dkt. No. 250 at 9. Moreover, the website uses "NR" as shorthand for nicotinamide riboside, not ChromaDex's NR. *See* Dkt. No. 192, Ex. 7 at 1 ("How to tell if your nicotinamide riboside (NR) supplement is authentic, and why you should know whether your product is counterfeit."). The advertisement unambiguously conveys that ChromaDex is the only seller of NR and that NR is only sold as Niagen.

ChromaDex does—and cannot—not claim that it held a patent to all NR or that NR was only sold as Niagen. The evidence demonstrates that NR exists naturally and that it is also sold in dietary supplements that do not contain Niagen. The record is devoid of evidence to the contrary. Elysium has established that there is no genuine dispute that the statement is literally false. ChromaDex's motion for summary judgment as to this claim is denied, and Elysium is entitled to summary judgment on this claim.

e. Statements that Basis is Inauthentic, Unsafe, and Ineffective

Elysium moves for partial summary judgment on liability on its affirmative false advertising claims related to what it calls the "Counterfeit Page," a page on ChromaDex's website. Elysium characterizes the page as "dedicate[d] . . . to attacking Elysium" and asserts that it "states that any NR product that is not sold by ChromaDex is 'counterfeit' and that NR is only sold as Niagen"; "directs customers to question any other NR product's authenticity, safety, and effectiveness"; "targets . . . directly at Basis by intentionally using an image similar to Basis's bottle on the website"; and was "updated . . . to expressly refer to Basis in its false comparison," to convey that "TruNiagen is authentic, safe, and effective, Basis is not." Dkt. No. 222 at 24. Elysium argues that it is entitled to summary judgment on liability on these claims because Basis is not counterfeit and is safe and effective.

The Counterfeit Page includes a large photo of a Tru Niagen bottle and pills, and an unlabeled white container and pills, with the captions "IS YOUR NICOTINAMIDE RIBOSIDE AUTHENTIC, SAFE, & EFFECTIVE?" and "How to tell if your nicotinamide riboside (NR) supplement is authentic, and why you should know whether your product is counterfeit."

Dkt. No. 213, Exs. S, T.

Underneath this graphic, the Counterfeit Page—as updated with references to Basis specifically—states:

> As a science-based company for over 20 years, we value safety, accuracy and transparency, and that ingredients matter – especially when it comes to ingredients you put into your body. That is why it's important to clarify misleading marketing materials from Elysium Health's so-called "NR-E" ingredient. While the marketing language references "NR-E," that is not what was used in the 2017 study cited by Elysium. In fact, the study actually used Niagen® which was in Basis™ at the time (but is no longer). "NR-E" is a newly listed ingredient on the Basis™ label as of 2020, and there is no published, peer-reviewed human data on "NR-E" nor has it been reviewed by any regulatory bodies.
>
> In contrast, Niagen®, the sole active ingredient in Tru Niagen® from ChromaDex, was successfully notified to the U.S. FDA as Generally Recognized as Safe (GRAS) and as a New Dietary Ingredient (NDI). In addition, Tru Niagen® has been approved for sale by Health Canada, the European Commission and Therapeutic Goods Administration (TGA) of Australia—four of the most stringent regulatory bodies in the world. Lastly, Niagen® is shown to safely and effectively increase NAD+ levels in 9 published human studies, which you can find listed on ClinicalTrials.gov.

Dkt. No. 213, Ex. T.

Elysium's motion for summary judgment does not focus on individual statements within these paragraphs, such as the statements pertaining to ChromaDex's FDA regulation or ChromaDex's clinical studies, but rather on its assertion that the Counterfeit Page represents that Basis is inauthentic, unsafe, and ineffective.

The record is undisputed that ChromaDex intended to communicate the message that Basis was inauthentic, unsafe, and ineffective. At deposition, then–ChromaDex CEO Jaksch testified at length about the Counterfeit Page:

Q. Why is this page included on your website?

A. To inform people that not all nicotinamide riboside is the same.

Q. And you're saying that not all nicotinamide riboside is authentic, safe and effective; is that true?

A. That's what it says.

Q. And what products are you claiming are not authentic, safe and effective?

A. Well, anybody that doesn't have nicotinamide riboside from ChromaDex.

Q. But do you identify any product specifically on this web page?

A. Well in the paragraphs on the page that you said, it does, yeah.

Q. What product does it identify?

A. Well, it says Elysium Health so-called NRE.

Q. And it talks about it being in Basis, right?

A. Yeah, it says that.

Q. So your claim is that Basis is not authentic, safe and effective, right?

A. Yes.

Q. And the picture on the cover image here, one is a bottle of Tru Niagen, the other is an unlabeled bottle. Is that supposed to be a bottle of Basis?

A. Well, I don't know if Basis owns that bottle design or if Elysium owns that bottle design, but it's similar to Elysium's bottle design.

Q. It was intended to appear like Basis, right? It looks like Basis, correct?

A. Yes, it looks like it.

Dkt. No. 223, Ex. J at 88–90.

In the absence of extrinsic evidence, a Lanham Act plaintiff may establish the falsity of a communication only by demonstrating either that it is literally false, meaning the false message is explicitly stated, or that the false message is "conveyed by necessary implication when, considering the advertisement in its entirety, the audience would recognize the claim as readily as if it had been explicitly stated." *Time Warner Cable*, 497 F.3d at 158 (internal quotation marks omitted) (quoting *Novartis Consumer Health, Inc. v. Johnson & Johnson–Merck Pharm. Co.*, 290 F.3d 578, 586–87 (3d Cir. 2002)); *see also Church & Dwight*, 843 F.3d at 66 (same). Elysium cannot establish that the Counterfeit Page explicitly conveys the message it contends is false. The page does not explicitly state that Basis—or even that all NR products not containing ChromaDex's NR—is inauthentic and counterfeit, unsafe, or ineffective. *See* Dkt. No. 213, Exs. S, T. It simply asks the question "IS YOUR NICOTINAMIDE RIBOSIDE AUTHENTIC, SAFE, & EFFECTIVE?" and conveys that ChromaDex's NR is authentic, safe and effective. Nor does the Counterfeit Page convey the proscribed message by necessary implication such that the audience would recognize the claim as it had been explicitly stated. On its face, the page simply flags potential concerns to look out for regarding the authenticity, safety, and effectiveness of NR-containing supplements other than Tru Niagen. It leaves open the possibility that other such supplements—including the supplement that is packaged in the unlabeled container on the page—may also be authentic, safe, and effective.

The Counterfeit Page conveys the message that Basis is inauthentic, unsafe, and ineffective by "clever innuendo." It suggests that while Tru Niagen and Niagen, which are named, are authentic, safe, and effective, the products of other companies (including that of

Elysium) are not. However, under Second Circuit law, a statement that may be false by innuendo but is susceptible to more than one reasonable interpretation must be supported by evidence that the intended message was the one that was actually received by the audience. *See American Home Products Corp. v. Johnson & Johnson*, 577 F.2d 160, 165 (2d Cir. 1978) (holding that representations that are not literally false, such as "clever use of innuendo, indirect intimations, and ambiguous suggestions . . . should usually be tested by the reactions of the public"). Elysium has not done so. Its motion thus must be denied.

C. Materiality

Both parties move for summary judgment on the other's claims, arguing that the other party has failed to adduce extrinsic evidence of materiality, and that such evidentiary deficiency is fatal to the claims. For the reasons that follow, the motions are both denied.

The motions squarely raise the question whether to establish what the courts have called materiality in a Lanham Act case, a plaintiff must produce extrinsic evidence that a challenged statement is likely to influence purchasing decisions or may rely on the nature and content of the statement alone to satisfy its burden. The two most recent Second Circuit cases that address materiality are *Apotex* and *Church & Dwight*.

In *Apotex*, the defendant had used a brochure in connection with its marketing of a pharmaceutical product that conflated two measures of concentration of the central ingredient of a drug in the blood of patients taking it in tablet form leading to an overstatement of the mean concentration of the product's central ingredient. The district court had concluded that the defendant "at most, . . . 'overstated the increase in mean tinzanidine plasma concentration' but that this evidence ultimately does not 'reveal anything about the impact on consumers' purchasing decisions.'" *Apotex*, 823 F.3d at 68 (quoting *Apotex Inc. v. Acorda Therapeutics, Inc.*, 2014 WL 5462547, at *9 (S.D.N.Y. Oct. 23, 2014)). On appeal, the plaintiff argued that it

was not required to show that the relevant misrepresentation would have had an effect on consumers' purchasing decisions and that when a statement is literally false, consumer deception was presumed. The Second Circuit rejected those arguments. It concluded that the first argument ignored precedent from the Circuit that had endorsed a definition of materiality that the misstatement was likely to influence purchasing decisions and that the second argument conflated falsity with materiality. When a statement is literally false, a plaintiff may be relieved from presenting "extrinsic evidence showing consumer deception," but the plaintiff "is not thereby relieved of showing materiality." *Id.* at 68. The latter element "require[d] that the allegedly 'false or misleading representation involved an inherent or material quality of the product,' – i.e., that the representation was 'likely to influence purchasing decisions.'" *Id.* (quoting *Nat'l Basketball Ass'n*, 105 F.3d at 855 (internal quotation marks omitted)). Applying that materiality standard, the Circuit concluded that the district court had not erred in granting summary judgment and determining that the misrepresentation was not material. The Second Circuit reasoned:

> This conclusion was sound; the only plausible effect attributable to the misrepresentation in the graph was an exaggeration of the scale of the mean drug concentration curves, or an improper conflation of the mean Cmax with the highest mean drug concentration for a given treatment. However, there is no record evidence that this inaccuracy would dissuade consumers from purchasing [the product]. Certainly, Apotex has provided none. Apotex's showing on this point consists of generalized evidence that Acorda's increased sales of [the product] stemmed from its advertisement efforts. Apotex fails to make the necessary showing that the specific misrepresentation in the graphic—in any of Acorda's advertisements—was likely to influence consumers' purchasing decisions.

Apotex, 823 F.3d at 68.

In *Church & Dwight*, which was issued just months after *Apotex*, the Second Circuit reviewed the district court's findings after a bench trial that defendant's misstatement was false and material and had caused injury. The product at issue was a pregnancy test. The defendant's

packaging and advertising had misrepresented the product's ability to measure pregnancy duration. The measure it used was different from the measure of pregnancy duration used in the medical profession. The defendant argued on appeal that the district court had failed to make findings necessary to support the conclusion of materiality. The district court had made findings as to injury and that the misstatement had related to an "inherent quality or characteristic" of the product that was a key feature that differentiated it from others in the market, but it did not make an explicit finding that the misstatement was likely to affect purchasing decisions. The Second Circuit identified that "the essential elements of the materiality standard" and, in particular, whether that standard required a finding of likelihood of an effect on purchasing decisions, was "somewhat unsettled" and that it "need not resolve that issue now." *Church & Dwight*, 843 F.3d at 70. In a footnote, however, the court stated that the Circuit had decided the issue that in the text it indicated was unsettled: "*Apotex* . . . recently settled the materiality standard in this Circuit, explaining that the standard is whether the deception is 'likely to influence purchasing decisions.'" *Id.* at 70 n. 11 (quoting *Apotex*, 823 F.3d at 63). The court rejected the appeal, holding that "the district court's conclusion, although uttered in connection with the element of likely injury, also constituted a finding that Defendant's misrepresentations were likely to influence purchasing decisions and were therefore material to Plaintiff's claim." *Id.* at 71. It emphasized that "the materiality of the falsity and the likelihood of injury to the plaintiff resulting from the defendant's falsity are separate essential elements," but concluded that "in many cases the evidence and the findings by the court that a plaintiff has been injured or is likely to suffer injury will satisfy the materiality standard—especially where the defendant and plaintiff are competitors in the same market and the falsity of the defendant's advertising is likely to lead consumers to prefer the defendant's product over the plaintiff's." *Id.*; *see also id.* at 71 ("If

consumers, faced with the choice to purchase either the plaintiff's product or the defendant's, are likely to prefer the defendant's product by reason of the defendant's false advertising, the falsity of the defendant's advertising is material to the plaintiff's Lanham Act claim.").

The court reasoned: "It is entirely reasonable to expect that for a significant number of women interested in learning whether they are pregnant—especially those who have not previously been pregnant or are otherwise ignorant of the details of the reproductive cycle—the information that Defendant's Product will tell them something different from what a doctor would provide would make them less likely to trust Defendant's Product, and more likely to purchase from Plaintiff, Defendant's closest competitor." *Id.* at 71. It then concluded that the evidence and the district court's findings that the plaintiff likely suffered a loss of sales by reason of the defendant's false advertising "adequately supported both the materiality element and the likely injury element." *Id.*

Neither case directly answers the question whether and when extrinsic evidence is necessary to support a finding of materiality. *Apotex* involved the question whether evidence of literal falsity would alone establish materiality. The court answered that question in the negative, adding that the plaintiff had to establish that the misrepresentation involved an inherent or materiality quality of the product—a standard that it treated as equivalent to a likelihood that the misrepresentation would affect consumers' purchasing decisions. In affirming the district court's conclusion that the nature of the misrepresentation did not "reveal anything" about whether it would affect consumers' decisions, it noted the absence of "record evidence" that the misrepresentation would dissuade consumers from purchasing the plaintiff's product. 823 F.3d at 68. But it did not state that extrinsic evidence of materiality was required. Its only reference to extrinsic evidence was in connection with implied falsity, a question that it expressly

distinguished from materiality. *Apotex*, 823 F.3d at 67–68. While *Church & Dwight* started with the nature of the statement, it purported ultimately to rely on the district court's finding that "Plaintiff likely suffered a loss of sales by reason of Defendant's false advertising," which was based on the district court's express finding that the plaintiff lost sales because of the false advertising. 843 F.3d at 71. Evidence of lost sales could be considered to be extrinsic evidence, and evidence of the type not presented here by either party. But *Church & Dwight*'s discussion of that evidence tends to support the notion that extrinsic evidence is not strictly required. On appeal, the defendant argued that the plaintiff's lost sales were not due to the false advertising but rather to an important new feature that the defendant was offering. *Id.* The court assumed that defendant was correct in that argument but nonetheless concluded that the district court's finding that plaintiff "likely" lost market share because of the false advertising was amply supported by the evidence the circuit court had previously discussed (*viz* the reasonable notion that the misstatement would have been important for a significant number of women) as well as by the fact that the plaintiff and the defendant were direct competitors. *Id.* at 71 & n.12. In other words, the court ultimately fell back on the nature of the misrepresentation as well as on the fact that the parties were competitors to support the finding that the plaintiff likely lost sales because of the false advertising, which in turn supported a finding that the false advertising was material.

The Court concludes that *Apotex* and *Church & Dwight* establish that, at a minimum, a plaintiff can survive summary judgment and establish materiality when, based on the misstatement on its face and the nature of the product, the court can conclude that the misstatement likely would matter to consumers and influence their purchasing decisions, at least under circumstances where the parties are direct competitors. Not every misstatement about a product necessarily relates to an inherent or material quality of that product such that it is likely

to influence consumer purchasing decisions. The rate of absorption of tizanidine did not on its face relate to an inherent or material quality; as such, some further evidence of materiality was required. Some statements clearly would matter to consumers. At oral argument in this case, the Court posited a statement that a competitor's vitamin pill—if ingested—would cause a certain and extraordinarily painful death for most people. Counsel effectively conceded that no useful purpose would be served by extrinsic evidence in such case; it would simply confirm the obvious. Oral Argument Tr. at 74. Likewise, as in *Church & Dwight*, a misstatement about a product's ability to measure the length of pregnancy duration consistent with the metrics used by the medical profession did tend to support materiality particularly when the evidence showed that the plaintiff and the defendant's products were marketed to women who would wish to know both whether they were pregnant and when they were likely to give birth.

With these principles in mind, the Court turns to the competing claims of the parties.

1. ChromaDex's Claims

Elysium argues that it is entitled to summary judgment on ChromaDex's false advertising claim because ChromaDex does not present evidence to show that the challenged statements were material, and because "[w]ithout evidence of materiality, ChromaDex's false advertising claims fail." Dkt. No. 222 at 19–20. In essence, Elysium's argument is that ChromaDex cannot demonstrate materiality without extrinsic evidence.[27] The Court rejects this argument. As outlined above, when the plaintiff and defendant are direct competitors and the misrepresentation

[27] Elysium also argues that ChromaDex's only extrinsic evidence of materiality—the materiality survey conducted by its expert Bruce Isaacson—"was so flawed as to render it unreliable." Dkt. No. 222 at 19. The Court addresses the parties' arguments regarding the reliability of the Isaacson survey in the accompanying Opinion and Order on the parties' *Daubert* motions. Nonetheless, whether the survey is excluded is immaterial to the question whether Elysium is entitled to summary judgment. Even assuming that the Court excludes the survey, it nonetheless rejects Elysium's argument that resulting absence of extrinsic evidence of materiality is fatal to ChromaDex's claims.

is of the nature that would reasonably matter to consumers in deciding which of those companies to purchase from—as in *Church & Dwight*—there is evidence from which a jury could find that the misrepresentation is material. Here, there is no doubt that Elysium and ChromaDex compete directly in the direct-to-consumer NR-containing dietary supplement market; Elysium does not engage with the nature of each of ChromaDex's alleged misrepresentations, nor does it attempt to argue that they are not such misrepresentations that would reasonably matter to consumers in deciding whether to purchase Basis from Elysium or Tru Niagen from ChromaDex. As such, the Court rejects Elysium's argument that absent extrinsic evidence of materiality, ChromaDex cannot demonstrate materiality, and accordingly denies Elysium's motion for summary judgment on ChromaDex's claims as to materiality.

2. Elysium's Counterclaims

ChromaDex's motion for summary judgment on Elysium's counterclaims as to materiality relies on the identical argument that the Court rejected in Elysium's motion. ChromaDex argues that it is entitled to summary judgment because Elysium has not adduced evidence of materiality. Dkt. No. 210 at 28. It notes that Elysium's survey expert, Brian Sowers, testified that he did not test materiality, and was not retained to do so, Dkt. No. 201, Ex. 5 at 22, and it argues that Elysium has not identified any other extrinsic evidence of materiality.

Elysium does not dispute that it has adduced no extrinsic evidence of the impact of ChromaDex's challenged advertising on consumer purchasing decisions. Dkt. No. 250 at 7. It relies on the nature and content of the challenged statements for their materiality asserting that since the statements relate to an inherent quality of Basis they are material by definition. *See, e.g.*, Dkt. No. 250 at 12 ("Again, ChromaDex's false statements regarding the evidence of Tru Niagen's effectiveness and superiority to Basis is inherently material."); *id.* at 15 ("Moreover, such deception is material because it relates to an inherent quality of Tru Niagen—its

effectiveness."); *id.* at 17 ("ChromaDex's false advertising that the FDA has confirmed the effectiveness of Tru Niagen also relates to an inherent quality of the product—its efficacy."); *id.* at 18 ("ChromaDex's false advertising that the FDA has confirmed the safety of Tru Niagen three times also relates to an inherent quality of the product—its safety."). In its reply, and at oral argument, ChromaDex reiterates its position that extrinsic evidence of materiality is strictly required, and that it is entitled to summary judgment on that basis. *See* Dkt. No. 262 at 2; Oral Argument Tr. at 4, 8 (arguing that "the courts have been clear that you need extrinsic evidence of materiality" and that "based on the fact that there is no extrinsic evidence of materiality, whether via survey or other evidence that Elysium has presented, . . . summary judgment should be granted in our client's favor as to the counterclaims").

The Court again rejects the argument that extrinsic evidence of materiality is required. Where, as here, the parties are direct competitors, there is no categorical requirement that extrinsic evidence is always required. It will depend on the nature of the alleged misrepresentations and whether it would reasonably influence consumers' decisions as to which company to purchase from. Because the Court rejects ChromaDex's argument, and because ChromaDex does not attempt to analyze the nature of each alleged misrepresentation to argue that it is not such a misrepresentation that would reasonably lead consumers to purchase Elysium's product rather than ChromaDex's product, ChromaDex's motion for summary judgment as to materiality is denied.

Elysium also moves for summary judgment on materiality for the portion of its counterclaims that relate to the Counterfeit Page. Dkt. No. 222 at 25–26. Elysium does not rely on any extrinsic evidence. Rather, it argues that "ChromaDex's claims that Tru Niagen's NR is superior to Basis's NR is a representation regarding the inherent quality of the products," and

that "[t]he false statements on the Counterfeit Page are, therefore, material. *Id.* The alleged misrepresentations on the Counterfeit Page are that the NR in Basis—in contrast to the NR in Tru Niagen—is inauthentic, unsafe, and ineffective. As in *Church & Dwight*, "[i]f consumers, faced with the choice to purchase either [Elysium's] product or the [ChromaDex's], are likely to prefer the [ChromaDex's] product by reason of the [ChromaDex's] false advertising, the falsity of [ChromaDex's] advertising is material to [Elysium's] Lanham Act claim." 843 F.3d at 71. Here, it is entirely reasonable to conclude that the alleged misrepresentations—that while the NR in Tru Niagen is authentic, safe, and effective, the NR in Basis is counterfeit, unsafe, and ineffective—would matter to consumers choosing whether to purchase Tru Niagen or Basis. The evidence is sufficient to create a triable claim as to the materiality of these statements, but it does not entitle Elysium to summary judgment on materiality.

D. Injury

Both parties move for summary judgment as to the injury element of a Lanham Act false advertising claim. Elysium moves for summary judgment as to ChromaDex's Complaint, arguing that ChromaDex has not adduced evidence as to causation or damages. Dkt. No. 222 at 20. ChromaDex moves for summary judgment as to Elysium's Counterclaim, arguing that Elysium "has no evidence or quantification of harm." Dkt. No. 210 at 1. Elysium also moves for partial summary judgment as to the injury element of the portion of its Counterclaim related to the Counterfeit Page. Dkt. No. 222 at 26. For the reasons that follow, Elysium's motion for summary judgment on injury as to ChromaDex's Complaint is granted; ChromaDex's motion for summary judgment as to Elysium's Counterclaim on injury and damages is granted in part in that, at trial, Elysium will be held to its assertion that it is seeking relief only in the forms of injunctive relief and disgorgement, and not in the form of damages for lost profits; and finally,

Elysium's motion for summary judgment on injury as to the portion of its Counterclaim that relates to the Counterfeit Page is granted.

1. ChromaDex's Claims

Elysium argues that, even if ChromaDex had adduced evidence of a false or misleading statement, it is entitled to summary judgment on ChromaDex's Lanham Act false advertising claim because ChromaDex has not adduced evidence as to causation or damages. Dkt. No. 222 at 20. The only evidence ChromaDex points to as proof of injury is the expert report of its damages expert, Lance Gunderson.

First, in an Opinion and Order addressing the parties *Daubert* motions accompanying this Opinion and Order, the Court has granted Elysium's *Daubert* motion and excluded Gunderson's expert testimony because his report assumed, without any facts or data or evidence, the central propositions upon which the analysis rested—both that without Elysium's allegedly false statements, Elysium would not have made *any* sales of Basis, and that ChromaDex would have made *all* of those sales. It thus is unreliable and fails to satisfy Federal Rule of Evidence 702. In fact, there is uncontradicted evidence that Elysium made sales of Basis prior to any of the allegedly false statements and there is also uncontradicted evidence that Elysium has competitors in the marketplace other than ChromaDex.

Second, even if it were not excluded, Gunderson's report would not be evidence of causation or injury because Gunderson did not seek to demonstrate causation or injury, but rather he simply assumed it. He took the fact of an allegedly false statement and then showed what Elysium's sales were and did the math as to what ChromaDex's sales would have been if each sale that Elysium made had been made by ChromaDex. That is not evidence of causation of injury. It begs the critical question in that analysis, assuming causation rather than

demonstrating it. ChromaDex points to no other evidence that would demonstrate that Elysium's allegedly false statements caused it injury.

Absent any evidence of causation of injury, ChromaDex relies on *Merck Eprova*, in which the Second Circuit held that a presumption of injury would arise in a Lanham Act false advertising case where each of two conditions was satisfied (1) the "plaintiff has met its burden of proving deliberate deception"; and (2) the relevant market is a two-player market. 760 F.3d at 260–61. Some discussion of the case is required to address ChromaDex's argument.

In *Merck Eprova*, the Second Circuit recognized that in the ordinary false advertising case involving non-comparative advertising, no presumption of injury arises and the plaintiff must provide "some indication of actual injury and causation" because the injury "accrues equally to all competitors; none is more likely to suffer from the offending broadcasts than any other." *Id.* at 259 (internal quotation marks omitted) (quoting *McNeilab*, 848 F.2d at 38). The court reiterated the concerns it had previously expressed in *McNeilab* and that the Eighth Circuit echoed in *Porous Media* about speculative injury: "Where a defendant is guilty of misrepresenting its own product without targeting any other specific product, it is erroneous to apply a rebuttable presumption of harm in favor of a competitor. Otherwise, a plaintiff might enjoy a windfall from a speculative award of damages by simply being a competitor in the same market." *Id.* at 260 (internal quotation marks and alteration omitted) (quoting *Porous Media Corp. v. Pall Corp.*, 110 F.3d 1329, 1334 (8th Cir. 1997)). The court reiterated that it had previously found that a presumption of injury would arise only in two specific circumstances: (1) where the defendant made a false comparative advertising claim, *see McNeilab*, 848 F.2d at 38, and (2) where the statement at issue was derogatory and undoubtedly referred only to the plaintiff, *see Time Warner Cable*, 497 F.3d at 162. In the former circumstance, "[a] misleading

comparison to a *specific competing product* necessarily diminishes that product's value in the minds of the consumer." *Id.* at 259 (internal quotation marks omitted) (quoting *McNeilab*, 848 F.2d at 38). In the latter circumstance, a presumption could arise that the plaintiff was injured because, even though the commercial did not identify the plaintiff by name, consumers would "undoubtedly understand" the derogatory comments it made about a competitor to refer only to plaintiff, *id.* (quoting *Time Warner Cable*, 497 F.3d at 162). In short, the presumption would apply either where the advertisements explicitly directed consumers to abandon the competitor in favor of the advertiser or where they implicitly did so because the disparaging comparative comments would be understood necessarily to refer to the competitor.

The *Merck Eprova* court held that the same logic supported the recognition of a presumption in a "two-player market" where there is evidence of "deliberate deception." In such a market, where there are only two companies—the plaintiff and the defendant—who are "obviously in direct competition," it would follow that the party who had not engaged in false advertising would be injured by the false advertising of the other and thus there would be "no risk of speculative injury." *Id.* at 260–61; *see also Dependable Sales & Serv., Inc. v. TrueCar, Inc.*, 394 F. Supp. 3d at 374.

ChromaDex, however, has not identified evidence to support either of the two conditions necessary for the *Merck Eprova* presumption to apply. First, the record is devoid of any evidence that, if Elysium's statements were deceptive, such deception was deliberate. ChromaDex argues—in context of its argument that it is entitled to disgorgement of Elysium's profits—that "[t]he undisputed record shows that Elysium repeatedly disregarded its scientific advisory board, its employees, and even its own customers in continuing to advertise Basis based on outright falsehoods, purposefully misleading messages, and stolen pedigree." Dkt. No. 255 at

26. But ChromaDex points to no evidence to support its assertion that Elysium's messages were "*purposefully* misleading." "[C]onclusory statements, conjecture, or speculation by the party resisting the motion will not defeat summary judgment." *Kulak v. City of New York*, 88 F.3d 63, 71 (2d Cir. 1996).

Second, although it is undisputed that Elysium and ChromaDex are direct competitors in the market for sale of supplements to consumers, the evidence demonstrates that they are not the only competitors in a two-player market. Indeed, ChromaDex concedes that there were other NR-containing dietary supplements that competed with Basis and Tru Niagen during the relevant time period, including Life Extension, Thorne, and others. *See* Dkt. No. 209, Ex. A, Schedule 9.1.[28]

ChromaDex argues that the Court should deem it and Elysium to be the only two competitors in the market for the sale of NR-based supplements to consumers because "[t]he only other companies that sold NR-containing supplements in the U.S. during the relevant period sold ChromaDex's NIAGEN wholesale ingredient." Dkt. No. 232 at 2. There is some dispute whether that is true. Elysium points to evidence to the contrary, *see* Dkt. No. 273 at 5, and at argument even ChromaDex admitted that some NR that others use may come from abroad, *see*

[28] The parties dispute how to define the relevant market with which they each compete. ChromaDex would define it narrowly, as "companies that sell NR-containing dietary supplements." Dkt. No. 232 at 2. Elysium would define it more broadly; it asserts that it "competes with many products other than NR supplements," Dkt. No. 273 at 5, and cites the testimony of Dan Alminana, its 30(b)(6) witness on Basis's competitors, *see* Dkt. No. 257, Ex. 9 at 15, that "its competitors include any supplements that contain NAD+ precursors—such as NR, NMN and other combination products—along with resveratrol supplements and other products that target sirtuins, as well as products that purport to create a particular effect in the user, most often products that purport to boost energy, support metabolic and cellular health, and increase metabolism," Dkt. No. 273 at 5 (citing Dkt. No. 257, Ex. 9 at 113–16). Because the Court finds that ChromaDex's argument fails even under its narrower market definition, it assumes but does not decide that the narrower definition applies.

Oral Argument Tr. at 80–81 (stating that ChromaDex "was the only supplier *in the U.S. marketplace* of NR" (emphasis added)), but construing the evidence in favor of ChromaDex, the Court is prepared assume that a jury could find that every other competitor to Elysium used NR purchased from ChromaDex.

Even assuming the truth of ChromaDex's claim, however, it would not convert the direct-to-consumer dietary supplement market into a two-player market such that a presumption of injury arises. On ChromaDex's theory, it could bring and win a Lanham Act case even if Elysium's advertising did not cause any customer to purchase a product from Elysium rather than from ChromaDex and even if Elysium's advertising caused no injury to ChromaDex's reputation on the sole basis that the sales lost by another of Elysium's competitors to whom ChromaDex sold its NR also presumptively caused injury to ChromaDex.

The Supreme Court considered a related issue in *Lexmark Intern. v. Static Control*, 572 U.S. 118, 128 (2014). A retailer who could prove that Elysium's advertising injured its reputation or diverted sales from it to Elysium would have a cause of action under the Lanham Act and could recover damages for its injury. It would be able to show proximate causation. Section 43(a) of the Lanham Act incorporates a proximate causation requirement, meaning that the "statutory cause of action is limited to plaintiffs whose injuries are proximately caused by violations of the statute." *Id.* at 132. "Put differently, the proximate-cause requirement generally bars suits for alleged harm that is 'too remote' from the defendant's unlawful conduct. That is ordinarily the case if the harm is purely derivative of 'misfortunes visited upon a third person by the defendant's acts.'" *Id.* at 133 (quoting *Holmes v. Sec. Investor Protection Corp.*, 503 U.S. 258, 268–69 (1992)). The *Lexmark* Court thus held that:

> a plaintiff suing under § 1125(a) ordinarily must show economic or reputational injury flowing directly from the deception wrought by the defendant's advertising;

> and that that occurs when deception of consumers causes them to withhold trade from the plaintiff. That showing is generally not made when the deception produces injuries to a fellow commercial actor that in turn affect the plaintiff. For example, while a competitor who is forced out of business by a defendant's false advertising generally will be able to sue for its losses, the same is not true of the competitor's landlord, its electric company, and other commercial parties who suffer merely as a result of the competitor's "inability to meet [its] financial obligations."

Id. at 133–34 (quoting *Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451, 458 (2006)).

It follows that even assuming ChromaDex is the sole supplier to all of several customers who themselves may have suffered injury as a result of Elysium's advertising that fact would not create an inference that ChromaDex itself suffered cognizable injury. The only persons to have suffered injury may have been ChromaDex's retail customers who were competing with Elysium. ChromaDex might be able to establish injury but it would have to prove it; it could not ask the jury to presume it.[29]

Accordingly, a presumption of injury against it and absent anything in the record to support "some indication of actual injury and causation" from its allegedly false advertising, *Merck Eprova*, 760 F.3d at 259, Elysium is entitled to summary judgment on ChromaDex's false advertising claims against it.

ChromaDex additionally argues that it is entitled to disgorgement of Elysium's profits as an alternative measure of damages. However, ChromaDex's inability to demonstrate actual

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[29] A plaintiff need not be a direct competitor to establish injury and to bring a Lanham Act action. In *Lexmark* itself, the Court held that a company which was not a direct competitor had suffered injury caused by the defendant's conduct within the meaning of the Lanham Act both because the defendant had disparaged its business and because it alleged that the products it designed, manufactured, and sold were necessary for and had no other use than in the product or service (refurbishing Lexmark toner cartridges) that defendant disparaged. *Id.* at 139. But to establish injury under either theory, ChromaDex would have to offer proof. It has not done so here. Indeed, the *Lexmark* Court emphasized that "[a]lthough we conclude that [the plaintiff] has *alleged* an adequate basis to proceed under § 1125(a), it cannot obtain relief without *evidence* of injury proximately caused by Lexmark's alleged misrepresentations. We hold only that Static Control is entitled to a chance to prove its case." *Id.* at 140.

injury and causation is not merely a flaw in its damages calculation, but it is also a flaw inherent in its Lanham Act claim which precludes a finding of Lanham Act liability and thus any measurement of damages. *See Dependable Sales*, 394 F. Supp. 3d at 372 ("[P]laintiffs' failure to come forward with evidence of injury precludes their disgorgement claim."). ChromaDex's claim for injunctive relief similarly fails. Even under the lower standard applied when the plaintiff seeks injunctive relief—"whether it is likely that [the defendant's] advertising has caused or will cause a loss of [the plaintiff's] sales, not whether [plaintiff] has come forward with specific evidence that [the defendant's] ads actually resulted in some definite loss of sales"—it is still true that "the likelihood of injury and causation will not be presumed, but must be demonstrated." *Johnson & Johnson*, 631 F.2d at 190. There is no triable issue as to whether ChromaDex has demonstrated a likelihood of injury and causation, because the record is devoid of any evidence that would support such a finding.

2. Elysium's Counterclaims

ChromaDex argues that it is entitled to summary judgment on Elysium's Lanham Act false advertising claims because although the Counterclaim includes a request for monetary damages, Elysium has not offered any theory or quantification of damages. Dkt. No. 210 at 29. Elysium responds that it is not seeking damages, but rather is seeking injunctive relief and disgorgement. Dkt. No. 250 at 23.[30] ChromaDex's motion for summary judgment is granted in

[30] Elysium's memorandum appears to suggest that an award of disgorgement could be warranted even absent a showing of injury and causation. *See* Dkt. No. 250 at 23 (citing *Dependable Sales & Serv., Inc. v. TrueCar, Inc.*, 377 F. Supp. 3d 337, 342 (S.D.N.Y. 2019), *on reconsideration*, 394 F. Supp. 3d 368 (S.D.N.Y. 2019), as stating that "[u]nder the law of the Second Circuit, even where a plaintiff has not demonstrated injury, the equitable disgorgement of a defendant's profits may be ordered in the interests of deterrence if the plaintiff can show that defendant willfully violated the Lanham Act"). However, on reconsideration in *Dependable Sales*, the court held that "plaintiffs' failure to come forward with evidence of injury precludes their disgorgement claim." 394 F. Supp. 3d at 372.

that at trial Elysium will be held to its representation that it is not seeking relief in the form of damages.[31] To be entitled to any form of relief, Elysium will have to demonstrate injury and causation; however, since ChromaDex makes no arguments regarding Elysium's ability or inability to do so on this motion, and instead focuses on quantification of damages, the Court does not consider whether the evidence in the record is sufficient to create a triable issue as to causation and injury on Elysium's Counterclaim.

Elysium also moves for partial summary judgment on liability on the portion of its Counterclaim that relates to the Counterfeit Page. Because this page refers to Basis by name and—even in prior versions that did not include explicit mention of Basis—includes a picture of Basis's bottle, thus clearly referring to Basis, Elysium is entitled to rely on the presumption of injury recognized in *McNeilab* and *Time Warner Cable*. A presumption of injury arises where the false or misleading advertising makes reference "to a specific competing product," which "necessarily diminishes that product's value in the minds of the consumer," *McNeilab*, 848 F.2d at 38, and where "even though [the challenged advertising] does not identify [the competitor] by name, consumers . . . undoubtedly understand [the] derogatory statement . . . as referring to [the

[31] In its reply brief, ChromaDex briefly argued that Elysium has not "presented any evidence or opinion . . . on causation." Dkt. No. 262 at 14. It further argued that to obtain an injunction, Elysium must first "establish that there is no adequate remedy at law," and that because Elysium "has not even attempted to quantify that remedy," it cannot obtain relief in the form of an injunction. *Id.* At oral argument, ChromaDex extended this reasoning to disgorgement, arguing that disgorgement is only available under the Lanham Act where damages would be insufficient to compensate the plaintiff, and that as such, because Elysium does not seek damages, they cannot get disgorgement. None of these arguments appear in ChromaDex's initial briefing of its motion for summary judgment; as such, the Court does not consider them here. *See American Hotel Intern. Group, Inc. v. OneBeacon Ins. Co.*, 611 F. Supp. 2d 373, 375 (S.D.N.Y. 2009); ("[A] district court is free to disregard argument raised for the first time in reply papers, especially on a motion for summary judgment."); *Playboy Enters., Inc. v. Dumas*, 960 F. Supp. 710, 720 n.7 (S.D.N.Y. 1997) ("Arguments made for the first time in a reply brief need not be considered by a court.").

competitor]," *Time Warner Cable*, 497 F.3d at 162. Because the Counterfeit Page fits squarely into this category of advertising, a presumption of injury applies, and Elysium is entitled to summary judgment as to the injury element of its Lanham Act claim.

II. The Parties' Remaining Federal and State Law Claims

The same conclusions as reached in the Lanham Act context apply to the parties' remaining federal claims of unfair competition under the Lanham Act and state law claims under New York General Business Law § 349.

A. Unfair Competition Under the Lanham Act

Both parties assert claims for unfair competition under the Lanham Act in addition to their false advertising Lanham Act claims; however, both parties agree this claim rises or falls with their false advertising claim. *See* Dkt. No. 210 at 30; Dkt. No. 222 at 10. "[T]here is no specific Federal cause of action for unfair competition. Instead unfair competition under the Lanham Act is a category of claims consisting primarily of causes of action for false designation of origin and false advertising." *Pot Luck, L.L.C. v. Freeman*, 2009 WL 693611, at *4 (S.D.N.Y. Mar. 10, 2009); *see also Sussman-Automatic Corp. v. Spa World Corp.*, 15 F. Supp. 3d 258, 273 (E.D.N.Y. 2014) ("For this reason, the Court dismisses the Plaintiff's unfair competition claim under the Lanham Act as duplicative of the Plaintiff's trademark infringement and false advertising claims under that statute."); *C=Holdings B.V. v. Asirim Corp.*, 992 F. Supp. 2d 223, 242 (analyzing "false advertising and unfair competition under Section 43(a)(1)(B) of the Lanham Act" jointly).

B. New York General Business Law § 349

New York General Business Law Section 349 prohibits "[d]eceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service." "The standards for bringing a NYGBL § 349 claim 'are substantially the same as those applied to

claims brought under' § 43(a) of the Lanham Act." *Davis v. Avvo, Inc.*, 345 F. Supp. 3d 534, 540 (S.D.N.Y. 2018) (quoting *Avon Prods., Inc. v. S.C. Johnson & Son, Inc.*, 984 F. Supp. 768, 800 (S.D.N.Y. 1997)); *see also Johnson & Johnson-Merck Consumer Pharm. Co. v. Smithkline Beecham Corp.*, 1991 WL 206312, at *9 (S.D.N.Y. Oct. 1, 1991), *aff'd*, 960 F.2d 294 (2d Cir. 1992) ("The legal test for liability under §§ 349 and 350 of the New York General Business Law is the same as the test for violation of § 43(a) of the Lanham Act." (citing *Proctor & Gamble Co. v. Chesebrough–Pond's, Inc.*, 588 F. Supp. 1082, 1083 n.4 (S.D.N.Y.), *aff'd*, 747 F.2d 114 (2d Cir. 1984); then citing *Bi-Rite Enterprises, Inc. v. Button Master*, 555 F. Supp. 1188, 1192–93 (S.D.N.Y. 1983))).

CONCLUSION

The motions for summary judgment are each GRANTED IN PART and DENIED IN PART. Because the Court has granted summary judgment for Elysium on the injury element of ChromaDex's Lanham Act false advertising claim, ChromaDex's Complaint is dismissed in full. Elysium's Counterclaim survives in part; all counterclaims as to statements as to which the Court has granted ChromaDex's motion for summary judgment on the falsity element of Elysium's Lanham Act false advertising claim are dismissed.

SO ORDERED.

Dated: February 3, 2022
New York, New York

LEWIS J. LIMAN
United States District Judge

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DOC #:
DATE FILED: 2/11/2022

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 Pacífico, 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 Familienstiftung 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