UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re: Elysium Health-ChromaDex Litigation	Case No. 1:17-cv-07394 (LJL)

MEMORANDUM OF LAW OF PLAINTIFF CHROMADEX, INC. IN OPPOSITION TO DEFENDANT ELYSIUM HEALTH, INC.'S MOTION FOR LEAVE TO SUPPLEMENT AND AMEND ITS COUNTERCLAIMS

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I. INTRODUCTION

After over three years of litigation, numerous delays to the case calendar, *ten months* after document discovery was supposed to be completed, and just weeks before the close of fact discovery, Elysium seeks to upend the case calendar by amending its counterclaims, for the fourth time, to put at issue new allegations. Elysium's latest salvo is curious given that the "advertising" it raises (which are largely routine press releases announcing the completion or publication of preclinical and clinical research) date back to *April 2020*—nearly eight months before Elysium filed the instant motion.

As the Court is aware, during the last eight months, the parties have jointly represented multiple times that delays to the case calendar were justified due to Elysium's belated document productions and workplace restrictions that Elysium stated precluded its ability to access a consumer communications database. The document discovery deadline in this action was February 24, 2020. Yet, in the last 48 days, Elysium has produced over 7,500 documents (spanning over 45,000 pages), representing nearly 60% of all the documents it has produced in this action. Elysium now seeks to start from scratch by filing a fourth amended set of counterclaims ("Proposed 4ACC"), which will require litigation of a Rule 12 motion and reopening document discovery. Notably Elysium fails to address repeated admonitions by the Court that the case calendar will not be extended, and the parties must be ready for trial by the summer.

Elysium's proposed new claims are based on ChromaDex announcing—starting on April 20, 2020—clinical and preclinical research regarding coronavirus and nicotinamide riboside ("NR"). Indeed, Elysium recognizes that it has waited too long and attempts to gloss over its dilatory conduct by pinning its allegations to a November 17, 2020 informal "warning letter" (the "Letter") from the United States Food and Drug Administration ("FDA") and Federal Trade Commission ("FTC"). But, half the communications Elysium seeks to introduce are not even mentioned in the Letter. Further, letters from the government are not advertising. Nor do government communications give rise to claims between competitors that do not otherwise exist.

To the contrary, federal law explicitly precludes private actors from trying to step into the shoes of FDA and FTC.[1]

Elysium's motion should be denied for at least three reasons:

First, Rule 15(d) is unavailable because Elysium's new claims do not relate to its current allegations. To the extent Elysium seeks to amend under Rule 15(a) and modify the case calendar, Elysium does not come close to satisfying the "good cause" standard of Rule 16(b)(4). The deadline for adding new claims has long passed.

Second, regardless of whether the Proposed 4ACC is analyzed under Rule 15(a) or 15(d), Elysium's inexplicable eight-month delay counsels against granting leave. Elysium's delay suggests either that it knew it had no viable claim, or waited until the last minute for strategic reasons to postpone trial. Regardless of Elysium's motivation, its delay would cause undue prejudice. If leave is granted, the Court would have to address any challenge under Rule 12. Then, as Elysium concedes without elaboration, additional discovery would be required. That would entail re-opening document discovery, delaying depositions and expert discovery, and vacating the current pretrial conference and trial deadlines.

Third, the proposed amendments would be futile. Mere communications stating that a party has conducted studies and accurately announcing results do not give rise to a false advertising claim. Elysium makes no allegation that ChromaDex misrepresented the fact that it was conducting a study or the results of studies. In fact, as recently as December 15, 2020, *Elysium* issued a press release in which it emphasized the connection between clinical research involving its own product and COVID-19. In addition, Elysium's proposed claims are premised

[1] Further, Elysium's proposed new allegations willfully distort the nature of the Letter, alleging that "ChromaDex's claims were so deceptive and dangerous that the FDA and FTC took *formal* action against ChromaDex to protect the public." Redline Proposed 4ACC, ECF No. 168-2, at ¶ 40. Warning letters themselves, according to FDA regulations and procedures, are informal and advisory. *See* 21 C.F.R. § 10.85(k) (warning letters do "not necessarily represent the formal position of FDA, and [do] not bind or otherwise obligate or commit the agency to the view expressed"). The Letter invited a response from ChromaDex, which ChromaDex has provided. As a company in the field, Elysium is well aware of the informal nature of the Letter, and its willful mischaracterization of it is unfortunate.

on the informal, advisory Letter from FDA. As such, it is precluded by the FDCA, which gives FDA exclusive jurisdiction to enforce alleged violations of the Act.

Based on the foregoing, Elysium's motion for leave should be denied.[2]

II. BACKGROUND

A. ChromaDex's Complaints and Elysium's Counterclaims

ChromaDex filed its initial complaint against Elysium on October 26, 2017, seeking redress for Elysium's false and/or misleading statements and deceptive practices in advertising and marketing for Elysium's product, Basis. *See* ECF No. 23. ChromaDex's action was consolidated with a separate action filed by Elysium relating to a citizen petition ChromaDex had filed with FDA regarding the presence of toluene in Basis. *See* ECF Nos. 1, 27. The Court granted summary judgment in favor of ChromaDex and dismissed Elysium's complaint relating to the petition. *See In re Elysium Health-ChromaDex Litig.*, 354 F. Supp. 3d 330 (S.D.N.Y. Jan. 3, 2019). Elysium subsequently answered ChromaDex's complaint and asserted copycat counterclaims against ChromaDex for false advertising and deceptive practices concerning ChromaDex's product Tru Niagen. *See* ECF No. 45. ChromaDex thereafter amended its complaint against Elysium on consent. ECF No. 79. Elysium answered and filed its first amended counterclaims, adding a counterclaim for copyright infringement. ECF No. 82. Shortly thereafter, Elysium filed its second amended counterclaims. ECF No. 89. Both parties filed unopposed motions for leave to amend within the February 10, 2020 deadline set by the case management schedule ordered by the Court. *See* ECF Nos. 117, 121. On February 27 and 28, 2020, respectively, ChromaDex filed its operative Second Amended Complaint ("SAC"), ECF No. 139, and Elysium filed its operative Third Amended Counterclaims ("TAC"), ECF No. 141.

[2] In its motion, Elysium also seeks leave to withdraw its copyright infringement claim with prejudice. ChromaDex does not object to this portion of Elysium's motion.

B. The Court's Case Management Plan and Previous Extensions

On March 21, 2019, following resolution of the parties' motions to dismiss, the Court entered a Civil Case Management Plan and Scheduling Order ("CMP"), ECF No. 77, pursuant to which all discovery was to be completed by December 20, 2019. In response to a subsequent request to adjourn the CMP deadlines *sine die* pending conclusion of trial in the California action involving the same parties, Chief Judge McMahon stated:

> This case is already 2 years old. I will not adjourn *sine die*. I will push back all deadlines by 6 months, assuming the California trial actually happens. Keep me posted. If the California case settles I want to know it. If the trial date moves I want to know it.

ECF No. 92. Subsequently, in response to a letter advising the Court of the status of the California action's trial schedule, Judge McMahon stated:

> Thanks for the update. I pushed back dates by six months in August. I will not grant ANY further extensions. Be guided accordingly.

ECF No. 95 (emphasis in original).

Pursuant to the CMP as extended by the Court's Order at ECF No. 92, the deadline for completion of all discovery was June 20, 2020. The interim deadline for document discovery was February 24, 2020, and the interim deadline for fact depositions was April 11, 2020.

Prior to the February 24, 2020 document discovery deadline, Elysium sought ChromaDex's consent for an extension of the CMP's deadlines by several months. ChromaDex advised Elysium that, in light of the length of time the case had already been pending and Chief Judge McMahon's prior orders regarding discovery not being extended further, ChromaDex was proceeding based on the current schedule and prepared to meet its deadlines. Therefore, ChromaDex did not consent to Elysium's requested extension. Nonetheless, on February 14, 2020, Elysium filed a unilateral letter-motion with the Court seeking a four-month extension of the CMP's deadlines. ECF No. 129. The Court rejected Elysium's request the same day. ECF No. 130.

The Court subsequently granted a six-month extension of the deadline for completion of fact depositions and subsequent CMP deadlines in light of restrictions related to COVID-19. ECF No. 150. The Court stated that "[t]here will be no further extensions." *Id.*

C. ChromaDex's Motion to Compel and Elysium's Document Access Issues

On August 10, 2020, following months of meet-and-confer efforts, ChromaDex filed a discovery motion related to three document-production issues. *See* ECF No. 152. Specifically, ChromaDex argued that Elysium's document search and production methodology was flawed because among other issues, Elysium produced only a negligible number of records from the majority of its agreed-upon custodians (individuals who are central to this case), and a likewise *de minimis* number of documents and communications between Elysium and third-party marketing and advertising entities. In addition, Elysium had failed to produce records from ZenDesk, its customer communications database.

As for ZenDesk, Elysium repeatedly represented that it was unable to collect these records due to COVID-19 restrictions (without ever explaining its failure to collect them by the February 24th document discovery deadline, prior to any COVID-19 restrictions taking effect). At a conference with the Court regarding ChromaDex's discovery motion, Elysium's counsel downplayed the importance of these documents, claiming that "[t]here is no . . . reason to believe that any customer communication has anything to do with the at-issue statements in this case," and hypothesizing that "[i]t's very possible that, upon searching these documents, there will be no relevant documents in the production." Transcript of August 20, 2020 Conference, ECF No. 160 at 9:12-23.

The Court asked Elysium to provide "a date by which you would request that the discovery deadline be extended." *Id.* at 10:16-21. Elysium's counsel suggested "extend[ing] it another month or two to see if [Elysium's offices] can reopen at that point." *Id.* at 10:22-23. Based on the foregoing, the Court extended the fact deposition deadline by two months, to December 11, 2020, and all subsequent deadlines by two months. *See* ECF No. 159.

By joint letter motion dated November 13, 2020, the parties requested another extension based primarily on the grounds that Elysium had produced over 5,000 new documents in mid-October and early November spanning nearly 40,000 pages, and Elysium had still not produced ZenDesk records. *See* ECF No 164. In the joint letter, Elysium advised that it estimated it would be able to complete production of records from its ZenDesk database by the end of November. *Id.* Based on those representations, the Court granted the extension request, setting a February 9, 2021 deadline for completion of fact depositions and a deadline of April 23, 2021 for completion of all discovery. ECF No. 165. The Court also instructed the parties to be prepared for trial by August 9, 2021.

On December 2, 2020, after not receiving the promised production or any communication concerning a revised date for production, ChromaDex followed up with Elysium. Elysium finally made an incomplete production of ZenDesk records on December 10th that contained approximately 240 communications, and a second production of approximately 900 communications on December 18th. Just today (December 28th), Elysium made another production of an additional approximately 3,500 pages of ZenDesk and other records.

D. Summary of Elysium's Proposed 4ACC

Elysium seeks leave to add a new claim to put at issue statements from April through October 6, 2020. Elysium refers to a FDA/FTC warning letter to ChromaDex concerning certain press releases and social media posts that communicated clinical study research. Redline Proposed 4ACC, ECF No. 168-2, at ¶¶ 38-41, 153-73. Specifically, Elysium raises four press releases (and social media posts referencing the releases) dated April 20, July 7, July 9, and October 6, 2020, that the Letter cites. In addition, Elysium highlights three communications that are not referenced in the Letter: a tweet from ChromaDex's CEO Rob Fried on July 9, 2020; a July 31, 2020, interview of Mr. Fried by an Arizona news station; and an August 4, 2020 segment from a Texas news station that references quotes by Dr. Brenner, a ChromaDex-affiliated scientist.

The Letter states FDA has observed that based on the foregoing press releases and social media posts announcing studies and findings may communicate Tru Niagen is "intended to mitigate, prevent, treat, diagnose, or cure COVID-19 in people." The Letter further advises ChromaDex to review its websites, product labels, and other labeling and promotional materials to ensure that it is not misleadingly representing its products as safe and effective for a COVID-19 related use for which they have not been approved by FDA and that ChromaDex does not make claims that misbrand the products in violation of the FDCA. The Letter invites a response from ChromaDex regarding any actions taken in response to the letter and, if it believes its products are not in violation of the FDCA, its reasoning and supporting information for the agency's consideration. With respect to the FTC, the Letter notes that it is unlawful under the FTC Act to advertise a product that can prevent or cure human disease unless in possession of competent and reliable scientific evidence. Like FDA, the FTC invites a response from ChromaDex.

Elysium's proposed new claims track the Letter. Specifically, Elysium alleges that ChromaDex's press releases, social media posts, and interviews regarding its clinical research suggest that "NR, and by extension, ChromaDex's Tru Niagen, could be used as a treatment for COVID-19," and that "none of ChromaDex's statements had been approved by the FDA." Redline Proposed 4ACC, ECF No. 168-2, at ¶¶ 154-56. As summarized in its memorandum of law ("MOL"), ECF No. 167, Elysium's proposed new claims allege that ChromaDex makes deceptive claims about Tru Niagen's supposed ability to treat or prevent COVID-19 that "lack the kind of extensive clinical data FDA regulations require and FDA approval to support such statements." *See* MOL at 11.

Elysium seeks an order from the Court requiring ChromaDex to provide written notice to consumers informing them that: "(i) the FDA and FTC issued a warning letter to ChromaDex on the basis that its public statements and advertising related to COVID-19 was false, misleading, and in violation of the [FDCA] and the FTC Act; (ii) that the FDA and FTC ordered ChromaDex to cease all advertising that suggested Tru Niagen was safe or effective for a COVID-19-related

use; and (iii) that Tru Niagen has not been shown to prevent, mitigate, treat, or cure COVID-19. *See* Redline Proposed 4ACC, ECF No. 168-2, "Prayer for Relief," Part (C).

III. LEGAL STANDARD

Supplementation under Rule 15(d) is appropriate where the "supplemental facts connect the supplemental pleading to the original pleading." *Weeks v. New York State (Div. of Parole)*, 273 F.3d 76, 88 (2d Cir. 2001); *see* FRCP 15(d) ("On motion and reasonable notice, the court may, on just terms, permit a party to serve a supplemental pleading setting out any transaction, occurrence, or event that happened after the date of the pleading to be supplemented."). Separate and distinct allegations and claims should not be allowed under the guise of a supplemental pleading. *See, e.g.*, *Vance v. Venettozzi*, No. 18 Civ. 0748 (BKS) (ATB), 2019 WL 4415551, at *4 (N.D.N.Y. Sept. 16, 2019) ("Because none of the allegations contained in the supplemental pleading relate to the facts and circumstances alleged in plaintiff's original complaint, plaintiff's motion to supplemental his original complaint is denied.").

In addition, the Second Circuit has explained that a motion to supplement should only be granted "where such supplementation will promote the economic and speedy disposition of the controversy between the parties, will not cause undue delay or trial inconvenience, and will not prejudice the rights of any other party." *Borndholdt v. Brady*, 869 F.2d 57, 68 (2d Cir. 1989).

Similarly, where a party seeks to amend a pleading to add new claims after the deadline established in a scheduling order, "the lenient standard under Rule 15(a), which provides leave to amend shall be freely given, must be balanced against the requirement under Rule 16(b) that the Court's scheduling order shall not be modified except upon a showing of good cause." *Holmes v. Grubman*, 568 F.3d 329, 334 (2d Cir. 2009) (internal quotation marks and citation omitted); *see also* FRCP 16(b)(4) (a scheduling order "may be modified only for good cause and with the judge's consent."). "Good cause depends on the diligence of the moving party." *Suarez v. California Natural Living, Inc.*, No. 17 Civ. 9847 (VB), 2019 WL 5188952, at *2 (S.D.N.Y. Oct. 15, 2019) (quoting *Parker v. Columbia Pictures Indus.*, 204 F.3d 326, 340 (2d Cir. 2000)). Good cause "is lacking if the proposed amendment rests on information that the party knew, or

should have known, in advance of the deadline." *Id.* (internal quotation marks omitted). "A court may deny leave to amend for lack of diligence even if amendment would not prejudice the non-movant." *Id.* (citing *Gullo v. City of New York*, 540 F. App'x 45, 47 (2d Cir. 2013) (summary order)).

Leave may be denied under both Rules 15(a) and 15(d) "for good reason, including futility, bad faith, undue delay, or undue prejudice to the opposing party." *See Holmes*, 568 F.3d at 334 (internal quotation marks and citation omitted); *SCS Commc'n, Inc. v. Herrick Co.*, 360 F.3d 329, 345 (2d Cir. 2004) (leave "may *only* be given when factors such as undue delay or undue prejudice to the opposing party are absent" (emphasis in original)).

IV. ARGUMENT

Elysium's motion should be denied because the proposed new allegations are not connected to Elysium operative counterclaims. Even if Elysium could satisfy this threshold requirement (which it cannot), leave should be denied because (1) the motion is made in bad faith after an inordinate delay, and, if granted, would result in undue prejudice; and (2) the proposed supplementation is futile.

A. Rule 15(d) is Unavailable because the Supplemental Facts in the Proposed 4ACC are not Connected to the Operative Counterclaims

Elysium purports to tie the proposed new allegations to its existing claim regarding statements made on a blog that is unaffiliated with ChromaDex. Specifically, in its existing claim, Elysium takes issue with a website called "Right of Assembly" run by a blogger who claims to own shares of ChromaDex and be a former customer of Elysium. *See* TACC, ECF No. 141, ¶¶ 138-150. As Elysium alleges, the blog states that "ChromaDex isn't allowed to say that NR treats any disease, because the FDA has not approved that. But the FDA does not regulate me . . . ." *Id.* ¶ 146. Nonetheless, although it has not attached a single document suggesting any agency or relationship between ChromaDex and the blogger, in Elysium's telling, the blog is an "affiliate's website," *id.* ¶ 138, and ChromaDex "implicitly vouched for [the blog's] content," *id.* ¶ 147, including its "claims about the efficacy of Tru Niagen in preventing and/or curing

diseases" by placing otherwise non-actionable advertising on the blog, *id.* ¶ 148. The central issue in the TACC is whether ChromaDex is responsible for claims made by the blogger.[3]

The Proposed 4ACC's new allegations are entirely different. Elysium alleges that ChromaDex's own press releases, social media posts, and interviews falsely claim that Tru Niagen mitigates, prevents, treats, diagnoses, or cures COVID-19. Litigation of the claims does not depend on whether ChromaDex made the statements in the press release and social media posts; it plainly did. Instead, Elysium has to prove that the at-issue communications about studies actually imply to consumers that Tru Niagen mitigates, prevents, treats, diagnoses, or cures COVID-19.

None of the discovery to date applies to the new allegations. The type of discovery related to the existing claim has been appropriately targeted at establishing a connection between ChromaDex and the individual operating the blog so that Elysium can argue that ChromaDex is responsible for claims therein. Elysium's demands have thus been focused on requests for documents that refer to ChromaDex's claimed control of the blogger (of which there are none). Elysium has not sought any third-party discovery from the blogger. Notably, Elysium concedes additional discovery will be required, but, glaringly, offers no specifics as to the type of discovery and extra time needed.

The discovery necessary for its new claim would concern the substance of the alleged claim concerning ChromaDex's press releases, social media posts, and interviews, the clinical study research referenced therein, and third-party discovery from FDA and the FTC. Since April 20, 2020, the date of the first press release at issue in Elysium's Proposed 4ACC, Elysium has not served a single discovery request regarding the clinical studies that underpin the new allegations or the press releases, social media posts, and interview; or sought discovery from FDA or FTC about the Letter. Similarly, ChromaDex has not interviewed or retained any experts to opine about the validity of the new studies, which are of course relevant to the veracity

[3] Elysium has not attached any support because there is none. These claims will be subject to ChromaDex's forthcoming motion for summary judgment.

of the new communications. The lack of overlap in discovery between the proposed new allegations and any existing counterclaim demonstrates the lack of connection between them. *See, e.g.*, *Vance*, 2019 WL 4415551, at *4.

Because Elysium's purported new claims and allegations are unrelated to any existing claim in its operative Third Amended Counterclaims, Elysium fails to meet the threshold requirement of a motion to supplement under FRCP 15(d).

B. Elysium's Motion is Made in Bad Faith After Undue Delay, and Would be Unduly Prejudicial if Granted

1. Delay

It is well accepted that a motion to amend or supplement should be denied upon undue delay. *See, e.g.*, *Doran v. N.Y.S. Dep't of Health Office of the Medicaid Inspector Gen.*, No. 15 Civ. 7217 (PKC) (SN), 2018 WL 5095670, at *1-3 (S.D.N.Y. Oct. 18, 2018) (denying motion for leave to supplement complaint, finding that "there has been undue delay" where events plaintiffs sought to add "were known or knowable nine or ten months before plaintiffs first raised with the Court the possibility of moving for leave to file a Third Amended Complaint"). Each of the communications Elysium introduces concern announcements of certain clinical studies and/or their results. It is undisputed that these announcements date back to April 20, 2020.

Elysium conspicuously avoids stating in its motion when it became aware of the facts underlying its new allegations. Nor does it explain why it did not raise its allegations that are based on at least four press releases, multiple social media posts, and numerous news reports in circulation over the last eight months. To the extent Elysium claims that its decision to amend its counterclaims was prompted by the Letter or ChromaDex's 8-K filing, such an excuse is specious. A false advertising claim seeks relief for a competitor's advertising, not statements *about the advertising* that the government makes. The facts that at-issue statements have been in the public domain for eight months and Elysium waited until the close of fact discovery are dispositive. *See Lowry v. Eastman Kodak Co.*, 14 F. App'x 27, 30 (2d Cir. 2001) (summary order) (affirming denial of motion for leave to supplement because plaintiff did not seek to

amend his complaint until five months after the new evidence surfaced."); *see also Geo-Grp. Commc'ns, Inc. v. Shah*, No. 15 Civ. 1756 (KPF), 2020 WL 5743516, at *17 (S.D.N.Y. Sept. 25, 2020) (unexplained 14-month delay warranted denial of leave).

Further, Elysium has already amended its counterclaims three times, and the Court has repeatedly made clear that it will not entertain further delays to the case schedule. *See Klein v. PetroChina Co. Ltd.*, 644 F. App'x. 13, 15 (2d Cir. 2016) (holding district court did not abuse its discretion in denying motion to amend under Rule 15(d) "in light of our general interest to 'promote the economic and speedy disposition of the controversy between the parties'" because (1) the request to file a supplemental pleading was made eighteen months after the suit was commenced; (2) the moving party had already filed and amended their pleadings; and (3) the moving party was granted leave to amend with the understanding that they would not have an opportunity to file yet another pleading).

2. Prejudice

Permitting Elysium to add claims will force ChromaDex to expend substantial additional resources—after it has structured its discovery efforts based on the existing scheduling order—and further delay adjudication of claims ChromaDex first asserted in 2017.

First, the new claims will require ChromaDex to incur substantial costs redoing document discovery. ChromaDex structured its discovery efforts based on existing claims and calendar. To that end, ChromaDex imaged custodial records, hired a team of review attorneys, and produced nearly all of its responsive documents—nearly 20,000—by May 18, 2020. Since then, it has produced only a handful of documents—approximately 60—in response to miscellaneous Elysium requests. The new allegations will require ChromaDex to re-image the email accounts of relevant custodians, re-do documents searches; re-hire contract attorneys to review documents; identify additional expert witnesses; and potentially seek additional third-party discovery. Additionally, ChromaDex would be entitled to conduct discovery regarding, *inter alia*, Elysium's advertising (including its COVID-19-related press release) and its internal communications about these statements (which are relevant to injury and causation).

Second, ChromaDex initiated its action in 2017 to seek relief for Elysium's false advertising. The case calendar has been extended four times and the trial date has already been extended to August 2021, well beyond the original date of February 28, 2020 for a joint pretrial order. Yet another delay to adjudication of ChromaDex's claims is unquestionably prejudicial. *See Geo-Grp. Commc'ns*, 2020 WL 5743516, at *17 ("In gauging prejudice, courts in this Circuit consider, among other factors, 'whether an amendment would require the opponent to expend significant additional resources to conduct discovery and prepare for trial or significantly delay the resolution of the dispute.'" (quoting *Ruotolo v. City of New York*, 514 F.3d 184, 192 (2d Cir. 2008)).

3. Bad Faith

Elysium's bad faith is evidenced by the fact that it never notified ChromaDex or the Court of its intention to amend in the many months since it became aware of the basis for its new allegations, despite numerous opportunities to do so. As noted above, Elysium's new allegations date back to April 20, 2020, yet Elysium did not move to file a 4ACC until December 14, 2020. During that time, the parties engaged in extensive meet-and-confer efforts and filed several joint letter-motions with the Court making representations about the time necessary to complete discovery and factors necessitating extensions of the case management schedule. Additionally, during that time, the parties had conferences with the Court regarding discovery and case status. At no point between April 20, 2020 and December 2020 did Elysium even raise the possibility of amending its counterclaims for the fourth time.

C. Elysium's New Claims are Futile

To determine whether a proposed pleading is futile, courts analyze whether it would withstand a motion to dismiss. *See AEP Energy Servs. Gas Holding Co. v. Bank of Am., N.A.*, 626 F.3d 699, 726 (2d Cir. 2010) ("Leave to amend may be denied on grounds of futility if the proposed amendment fails to state a legally cognizable claim or fails to raise triable issues of fact"). When deciding a motion for leave to amend, the court need not decide the merits of a proposed claim "but merely satisfy itself that it is colorable and not frivolous." *Sumitomo Elec.*

Research Triangle, Inc. v. Corning Glass Works, 109 F.R.D. 627, 628 (S.D.N.Y. 1986); *see also Todd v. Exxon Corp.*, 275 F.3d 191, 198 (2d Cir. 2001) (quoting *Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974) ("The issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims.")).

1. Elysium's new claims are precluded by the FDCA

Elysium's new claims are predicated on ChromaDex's alleged violations of the FDCA—a statute that does not provide for a private right of action. *Mutual Pharm. Co. v. Ivax Pharm., Inc.*, 459 F. Supp. 2d 925, 934 (C.D. Cal. 2006). Section 337(a) of the FDCA states: "Except as provided in subsection (b), all such proceedings for the enforcement, or to restrain violation, of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337. The FDCA lists specific "prohibited acts," which include, among other things, "(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded[;] (b) The adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce[;] . . . (g) The manufacture within any Territory of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded . . . ."

FDA has significant enforcement flexibility. "This flexibility is a critical component of the statutory and regulatory framework under which the FDA pursues difficult (and often competing) objectives." *Buckman Co. v. Pls.' Legal Comm.*, 531 U.S. 341, 349 (2001). *See* 21 U.S.C. §§ 332-34, 372 (providing the FDA with a range of enforcement mechanisms). Although citizens may petition the FDA to take administrative action, 21 C.F.R. §§ 10.25(a) and 10.30, private enforcement of the statute is barred. *See, e.g., Church & Dwight Co. Inc. v. SPD Swiss Precision Diagnostics, GmbH*, 104 F. Supp. 3d 348, 361 (S.D.N.Y. 2015) (affirming "the longstanding proposition that private parties may not use the Lanham Act as a vehicle to enforce the FDCA"). Section 336 of the FDCA provides: "Nothing in this Act shall be construed as requiring the Secretary to report for prosecution, or for the institution of libel or injunction

proceedings, minor violations of this Act whenever he believes that the public interest will be adequately served by suitable written notice or warning." 21 U.S.C. § 336.

It is clear that Elysium seeks to turn the Letter into an opening to enforce the FDCA and FTC Act through this action. Elysium seeks a judgment finding that ChromaDex is "in violation of the [FDCA] and the FTC Act"; that "FDA and FTC ordered ChromaDex to cease all advertising that suggested Tru Niagen was safe or effective for a COVID-19-related use"; and that Tru Niagen "has not been shown to prevent, mitigate, treat, or cure COVID-19." That Elysium technically brings its new claim under the Lanham Act and NY Deceptive Practices Act, "does not override the fact that Plaintiff explicitly requests relief which 'lies squarely within the provisions of the FDCA.'" *Borchenko v. L'Oreal USA, Inc.*, 389 F. Supp. 3d 769, 773 (C.D. Cal. 2019) (quoting *Elkind v. Revlon*, No. 14 Civ. 2484 (JS), 2015 WL 2344134, at *9 (E.D.N.Y. 2015)).

2. Elysium's new allegations fail to state a claim

i. The statements at issue in Elysium's Proposed 4ACC are from accurate, factual press releases regarding scientific research

Contrary to Elysium's characterizations, the at-issue communications do not state or imply that Tru Niagen may be used to prevent or treat COVID-19 or any other disease. For example, proposed Exhibit 12 to the 4ACC states ChromaDex "*commits to* COVID-19 *research*" and report the results of early studies demonstrating the effect of SARS-CoV-2 on NAD levels. ECF No. 168-14. The press release describes in detail the specific preclinical study and does not include any language suggesting Tru Niagen may be used to prevent or treat a disease. Similarly, proposed Exhibit 13 states that there will be a study on NR "at NIH-NIAID's Rocky Mountain Labs." The study—conducted by a division of the National Institutes of Health—"will *assess* if administration of Niagen *can* reduce viral burden and inflammation in *mouse and hamster models* of COVID-19." ECF No. 168-15 (emphasis added).

Proposed Exhibit 14 announces preclinical findings regarding Niagen's anti-viral effects on "a form of Coronavirus" and was clear that the study was performed "in mouse cells." ECF

NO. 168-16. The press release specifically states that "Dr. Brenner and the team of scientists are continuing their investigations into the antiviral potential of Niagen in order to translate the findings from the lab to the clinic. Ultimately, clinical trials are required to determine whether Niagen impacts COVID-19 infection in humans." *Id.*

Finally, proposed Exhibit 15 announced the results of a study examining the effect on recovery of patients with mild-to-moderate COVID-19 when receiving the standard of care in combination with a "nutritional protocol consisting of nicotinamide riboside (NR), L-serine, N-acetyl-L cysteine (NAC), and L-carnitine tartrate." ECF No. 168-17.

ii. Elysium fails to point to any false or misleading statements, and its conclusory allegations are directly contradicted by the exhibits to the Proposed 4ACC

Elysium's Proposed 4ACC alleges that the above press releases were "false and misleading" because "[i]n reality, the research ChromaDex pointed to were preclinical studies involving different forms of coronavirus in animal models or studies examining the effect of nutritional support regiments where NR was merely one of multiple supplements added to patients' nutritional protocols." Proposed 4ACC ¶ 157 (citing the July 9 and October 6 press releases). According to Elysium, "ChromaDex's press releases obscured these important details with misstatements that explicitly and implicitly connected the studies to the COVID-19 epidemic." *Id.* But the press releases themselves, which Elysium filed with its motion, contradict Elysium's allegations, and should therefore be rejected. *See In re Bristol-Myers Squibb Sec. Litig.*, 312 F. Supp. 2d 549, 555 (S.D.N.Y. 2004) ("The court need not accept as true an allegation that is contradicted by documents on which the complaint relies."); *In re Livent, Inc. Noteholders Sec. Litig.*, 151 F. Supp. 2d 371, 405-06 (S.D.N.Y. 2001) ("[A] court need not feel constrained to accept as truth conflicting pleadings . . . that are contradicted either by statements in the complaint itself or by documents upon which its pleadings rely, or by facts of which the court may take judicial notice.").

As highlighted above, the press releases were clear and accurate in describing the nature of the studies and their results. In particular, contrary to Elysium's baseless assertions, the July 9 press release explicitly stated that the study being described involved "a form of Coronavirus" and "mouse cells," ECF No. 168-16, and the October 6 press release was clear that the nutritional protocol being studied *included* NR among other ingredients, and explicitly specified the other protocol components, ECF No. 168-17. Elysium does not, and cannot, point to any "misstatements" that purportedly "obscured these important details." Elysium's failure to identify the specific statements that allegedly give rise to its proposed new claim is fatal. *See, e.g.*, *Nat'l Lighting Co. v. Bridge Metal Indus., LLC*, 601 F. Supp. 2d 556, 565 (S.D.N.Y. 2009) (dismissing Lanham Act claim where amended complaint failed to allege a specific false statement and "it [was] impossible to tell from the [a]mended [c]omplaint what alleged statements the advertising claim [was] predicated upon.").

iii. Accurately presenting a study's results does not constitute actionable false advertising

Courts have consistently held that accurately presenting a study's results constitutes scientific discourse that is entitled to First Amendment protection, not commercial speech. *See ONY, Inc. v. Cornerstone Therapeutics, Inc.*, 720 F.3d 490 (2d Cir. 2013). Elysium has not claimed—and cannot claim—that the at-issue communications are false in stating that ChromaDex's Niagen and Tru Niagen products are being studied, or the results of preclinical studies. Nor has Elysium cited any authority for the proposition that announcing a study or reporting results (including accurately describing the ingredients studied and scientists' finding) is actionable false advertising. Instead, Elysium has constructed its Proposed 4ACC by creating strawmen and attributing to ChromaDex statements that clearly do not exist in the at-issue articles and posts: that Tru Niagen may be used to prevent or treat COVID-19 and other diseases.

As discussed below, Elysium's claims are disingenuous at best given that Elysium has linked research of its own product to COVID-19 symptoms as recently as December 15, 2020 in a press release.

V. IF ELYSIUM'S MOTION IS GRANTED, CHROMADEX SHOULD BE PERMITTED TO SUPPLEMENT ITS SECOND AMENDED COMPLAINT WITH ALLEGATIONS OF ELYSIUM'S CONDUCT

For the reasons set forth above, Elysium's motion for leave to file its Proposed 4ACC at this stage in the litigation should be denied. However, should the Court grant Elysium's motion, ChromaDex respectfully requests leave, pursuant to FRCP 15(d), to supplement its Second Amended Complaint with allegations concerning Elysium's above-referenced December 15, 2020 press release touting the impact of one of its studies on COVID-19 symptoms. In contrast to Elysium, ChromaDex has an already-pending claim in this action to which the supplemental allegations would connect—namely, that Elysium makes unsubstantiated disease prevention claims. *See* SAC ¶¶ 107-118.

Elysium's motion seeks leave to assert new claims against ChromaDex focused on press releases announcing clinical research being conducted regarding NR and coronavirus. Yet, as recently as *December 15th*, Elysium announced the initiation of a clinical trial to evaluate the efficacy of Basis for prevention of Acute Kidney Injury ("AKI") in a press release that emphasized that AKI is "a noted complication for hospitalized patients with severe COVID-19 infections throughout the pandemic."[4] Elysium's focus on COVID-19 was picked up in subsequent reporting on the study. For instance, in a December 17, 2020 article on NMN.com about Elysium's announcement, the first paragraph focused on the link between Elysium's study and COVID-19.[5]

[4] https://www.prnewswire.com/news-releases/elysium-health-announces-initiation-of-phase-ii-clinical-trial-at-mayo-clinic-to-evaluate-basis-for-prevention-of-acute-kidney-injury-after-cardiac-surgery-301193167.html

[5] https://www.nmn.com/news/elysium-health-acute-kidney-injury-nad-antioxidant-supplement

Elysium should not be permitted to levy baseless accusations in order to hide its own conduct. Accordingly, while ChromaDex respectfully requests that the Court deny Elysium's motion based on all the reasons discussed in this opposition, if the Court grants Elysium leave to file its Proposed 4ACC, ChromaDex should be also permitted to amend its claims to put Elysium's own conduct at issue.

VI. CONCLUSION

For the foregoing reasons, Elysium's motion for leave to file fourth amended counterclaims should be denied.

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