UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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

REPLY MEMORANDUM OF LAW IN SUPPORT OF ELYSIUM HEALTH, INC.'S MOTION FOR LEAVE TO SUPPLEMENT AND AMEND ITS COUNTERCLAIMS

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PRELIMINARY STATEMENT

The FDA and FTC sent ChromaDex a warning letter on November 17 directing ChromaDex to stop deceiving the public into believing that its products could help fight COVID-19. ChromaDex's opposition tries to portray its misconduct as some isolated and insignificant incident. It was neither. As detailed in Elysium's proposed pleading, ChromaDex engaged in a campaign of false advertising through the spring, summer, and fall, which included multiple press releases, television spots, social media posts, and webpage updates, all of which caused escalating consumer confusion. Many of these false and misleading statements remain accessible to this day. ChromaDex filed an 8-K in late November in recognition of the seriousness of the situation, and it became public on December 1 that the FDA had added Tru Niagen to the agency's list of fraudulent COVID-19 products.

All of this misconduct occurred after Elysium filed its operative counterclaims in February of last year. And ChromaDex's false advertising about COVID-19 is part of a broader pattern of deceptive disease-curing claims that are already being litigated in this action. This is precisely the situation for which Rule 15(d) exists.

Faced with the reality that leave to supplement is proper in these circumstances, ChromaDex tries to distract with an opposition brief that appears to confuse the present motion with a discovery dispute or a scheduling disagreement. ChromaDex's one-sided presentation of those issues is misleading—ChromaDex itself just served additional discovery requests last month, and the parties have not yet scheduled depositions—but that is beside the point. If ChromaDex has discovery or scheduling complaints, it can present them at the appropriate time and in the appropriate form. Such complaints do not provide a basis on which to deny Elysium's motion to supplement with allegations of recent and highly relevant misconduct that continues to harm Elysium and endanger public health.

ChromaDex fares no better trying to establish futility with spurious preemption and First Amendment arguments that are contrary to settled law. And it certainly cannot show futility with a preemptive merits defense when the FDA and FTC have flatly said that ChromaDex's advertising "misleadingly represent[s] [its products] as safe and/or effective for the treatment or prevention of COVID-19," and ChromaDex itself filed an 8-K announcing the regulators' warning letter as a material event to shareholders.[1]

ARGUMENT

Federal Rule of Civil Procedure 15(d) applies to a motion seeking leave to plead new events "that happened after the date of the pleading to be supplemented." Fed. R. Civ. P. 15(d). It is undisputed that ChromaDex's COVID-19 advertising occurred after Elysium filed its operative counterclaims. *See* ECF 141. Rule 15(d) is, accordingly, the applicable rule. *See Ruotolo v. City of New York*, No. 03 Civ. 5045, 2005 WL 1253936, at *4 (S.D.N.Y. May 25, 2005). ChromaDex's effort to recast Elysium's motion as an untimely Rule 15(a) motion ignores the plain language of Rule 15(d) and should be rejected.[2]

I. THE SUPPLEMENTAL ALLEGATIONS CONNECT TO ELYSIUM'S PENDING COUNTERCLAIMS ABOUT CHROMADEX'S DISEASE-CURING CLAIMS.

Where proposed supplemental allegations connect to the operative claims, "[l]eave to file a supplemental pleading should be freely permitted." *Kleeberg v. Eber*, 331 F.R.D. 302, 315 (S.D.N.Y. 2019). As detailed in Elysium's proposed supplemental pleading, the proposed

[1] ChromaDex does not oppose Elysium's Rule 15(a) motion to withdraw its copyright infringement claim. Opp. at 3 n.2. ChromaDex also does not address—and thus does not appear to oppose—Elysium's Rule 15(d) motion to supplement its counterclaims with allegations about ChromaDex's October 2020 changes to the "Is Your Nicotinamide Riboside Authentic, Safe & Effective?" page of its website. *See* ECF 168, Ex. A ¶ 106; ECF 167 at 4-5.

[2] Relatedly, ChromaDex's extended discussion of Rule 16(b)(4) is a red herring: a deadline for *amended* pleadings that passed before ChromaDex's deceptive COVID-19 advertising even began has no bearing on the Rule 15(d) analysis here. *See Mason Tenders Dist. Council of Greater N.Y. v. Phase Constr. Servs., Inc.*, 318 F.R.D. 28, 36 n.10 (S.D.N.Y. 2016) (noting that Rule 16(b)(4) does not apply to a Rule 15(d) motion).

supplemental allegations connect to the existing counterclaims here. ECF 168, Ex. A ¶¶ 38, 153, 164; *see also* ECF 167 at 11-12.

Since the beginning of this case, Elysium has alleged that ChromaDex's deceptive marketing practices mislead the public into believing that its Tru Niagen product cures and treats diseases such as Alzheimer's, heart disease, Parkinson's, and breast cancer. *See* ECF 45 Counterclaims ¶¶ 80-91; *see also* ECF 82 Counterclaims ¶¶ 96-108; ECF 89 Counterclaims ¶¶ 115-127; ECF 141 ¶¶ 138-151. When COVID-19 hit, ChromaDex adapted its deceptive practices to new circumstances. As a result, customers are again being deceived into believing that Tru Niagen offers hope in their fight against a life-threatening condition. C*ompare* ECF 141 ¶ 149 *with* ECF 168, Ex. A ¶¶ 158-160. And Elysium is being harmed in the form of lost sales and injury to its reputation. *Compare* ECF 141 ¶ 149 *with* ECF 168, Ex. A ¶¶ 158-160; ECF 141 ¶ 152 *with* ECF 168, Ex. A ¶ 173.

ChromaDex argues that the proposed supplemental counterclaims are "entirely different" than the existing counterclaims because the deceptive disease-curing claims appeared on different webpages. *See* Opp. at 10. More specifically, ChromaDex argues that the proposed supplemental counterclaims relate to false advertising on ChromaDex's own website and social media accounts, whereas the existing counterclaims relate to false advertising that appeared on websites associated with a ChromaDex affiliate. The distinction is not as sharp as ChromaDex would have it, and it is a distinction without a difference in any event.

First, Elysium's proposed supplemental pleading alleges that ChromaDex is currently using the very same affiliate websites that it has used in the past to further its deceptive advertising campaign around COVID-19. *See* ECF 168, Ex. A ¶ 164. These allegations are identical to

existing allegations concerning ChromaDex's false advertising about other diseases. *Compare* ECF 141 ¶¶ 140-148 *with* ECF 168, Ex. A ¶ 164.

Second, the existing counterclaims allege that ChromaDex directs and endorses the content on its affiliate websites and is thus liable for false disease-curing claims made on those sites. *See* ECF 141 ¶¶ 138-148. Those allegations are taken as true for purposes of this motion. *See Verizon N.Y. Inc. v. Global NAPS, Inc.*, No. 03 Civ. 5073, 2007 WL 9706459, at *1 (E.D.N.Y. July 20, 2007) (stating that under Rule 15(d), the "Court must accept the facts as alleged to be true and view them in the light most favorable to [the movant]"). ChromaDex cites no authority to support treating the false disease-curing claims on its own homepage or social media differently from those it puts out on other websites under its direction. Indeed, that sort of hair-splitting would be inconsistent with Rule 15(d)'s "liberal policy favoring merit-based resolution of the entire controversy between the parties" over multiple related actions involving the same parties and issues. *Witkowich v. Gonzales,* 541 F. Supp. 2d 572, 590 (S.D.N.Y. 2008) (quotations omitted).[3]

II. THE OPPOSITION FAILS TO ESTABLISH UNDUE DELAY, BAD FAITH, OR UNDUE PREJUDICE.

ChromaDex next argues that Elysium has acted improperly in bringing its supplemental allegations, and that ChromaDex will be unduly prejudiced as a result. ChromaDex's contentions ignore the timeline of relevant events and rely on speculative assertions about discovery burden and scheduling delay that are easily managed. Because ChromaDex has not met its burden in opposition, leave to supplement is appropriate. *See Bodum Holding AG v. Starbucks Corp.*,

[3] ChromaDex also incorrectly asserts that discovery on the existing claims has focused solely on ChromaDex's control over its affiliate websites. In fact, Elysium's first set of document requests requested all documents concerning Tru Niagen's "efficacy . . . in preventing, treating, and/or curing diseases or health conditions," as well as all documents concerning consumers' "belief or impression" that Tru Niagen can prevent, treat, or cure diseases. *See* Elysium Health, Inc.'s First Set of Requests for Production to ChromaDex, Inc. 35-36, *In re: Elysium Health-ChromaDex Litigation*, No. 17 Civ. 7394 (S.D.N.Y. Mar. 19, 2019). ChromaDex agreed to produce documents responsive to those requests. *See* Plaintiff's Responses and Objections to Defendant's First Set of Requests for Production of Documents 35-36, *In re: Elysium Health-ChromaDex Litigation*, No. 17 Civ. 7394 (S.D.N.Y. Apr. 18, 2019).

No. 19 Civ. 4280, 2020 WL 6135714, at *9 (S.D.N.Y. Oct. 16, 2020) ("[T]he party opposing the amendment/[supplement] carries the burden of showing undue prejudice or bad faith.").

A. ChromaDex Fails to Show Undue Delay or Bad Faith.

In arguing undue delay and bad faith, ChromaDex leans heavily on a supposed "eight month" gap that it conjures up by focusing exclusively on the first deceptive COVID-19 press release it issued on April 20, 2020. Opp. at 11. But measuring from April 2020 ignores the next seven months of ChromaDex's misleading press releases, television appearances, social media posts, and website updates that Elysium details in its proposed pleading. *See* ECF 168, Ex. A ¶¶ 154-164. As ChromaDex's false advertising became increasingly pervasive, the consumer confusion and the harm to Elysium escalated. *See, e.g.*, ECF 168, Ex. A ¶¶ 157, 172 (documenting specific ChromaDex misstatements as late as October 2020 and documenting how much of ChromaDex's COVID-19 deception is still available to the public).

ChromaDex's timeliness argument also ignores the November 17 warning letter from the FDA and FTC (the "Warning Letter"), which provides sufficient basis for granting Elysium's motion. *See POM Wonderful LLC v. Organic Juice USA, Inc.*, No. 09 Civ. 4916, 2010 WL 3912222, at *3 (S.D.N.Y. Sept. 29, 2010) (McMahon, J.) (permitting amendment of Lanham Act counterclaims because "it is the FDA's *finding* that these statements violate the FDCA that lays the foundation for [Defendant's] proposed new counterclaims") (emphasis in original). Elysium gave ChromaDex notice of this motion just ten days after the Warning Letter was posted online on December 1, 2020. In these circumstances, there is no credible argument that Elysium has unduly delayed or acted in bad faith. *See Aktiebolag v. Andrx Pharm., Inc.*, 695 F. Supp. 2d 21, 30 (S.D.N.Y. 2010) (finding no undue delay where supplementing party moved within four months); *see also Blagman v. Apple, Inc.*, No. 12 Civ. 5453, 2014 WL 2106489, at *3 (S.D.N.Y. May 19, 2014) (granting motion to amend notwithstanding twenty-month delay).

B. ChromaDex Fails to Show Undue Prejudice.

ChromaDex also fails to establish undue prejudice. ChromaDex begins by arguing that the proposed pleading would require ChromaDex "to incur substantial costs redoing document discovery." Opp. at 12. This is overstated—of course targeted discovery is feasible, and ChromaDex likely compiled much of the relevant material already in responding to the Warning Letter and preparing its 8-K. In all events, it is well-settled that "the adverse party's burden of undertaking discovery, standing alone, does not suffice to warrant denial of a motion to amend a pleading." *United States ex rel. Maritime Admin. v. Continental Ill. Nat'l Bank & Trust Co.*, 889 F.2d 1248, 1255 (2d Cir. 1989). And courts have found no undue prejudice where, as here, the opposing party "already possesses most documents relevant to its defense, and any additional discovery, including additional depositions, is unlikely to be onerous." *Fancaster, Inc. v. Comcast Corp.*, No. 08 Civ. 2922, 2010 WL 4320422, at *2, 5 (D.N.J. Oct. 26, 2010) (granting motion to supplement "to add new infringing activities . . . committed after the close of discovery").

As for scheduling, Elysium recognizes that the deadlines in this case have been previously extended to account for the ongoing challenges posed by the pandemic. But "[t]his is not a case where the [supplement] came on the eve of trial and would result in new problems of proof." *State Teachers Ret. Bd. v. Fluor Corp.*, 654 F.2d 843, 856 (2d Cir. 1981). Fact discovery remains ongoing, and ChromaDex itself served additional written discovery on Elysium as recently as December 18, 2020. Not a single deposition has been scheduled, much less taken. Under these circumstances, ChromaDex has not established undue prejudice. *See Bodum Holding AG*, 2020 WL 6135714, at *9-10 (granting motion to amend in part and finding no undue prejudice where moving party filed when "the majority of depositions are still outstanding," and noting that "although the amendment may warrant additional discovery, it should not significantly prolong the resolution of the action").

III. THE OPPOSITION FAILS TO ESTABLISH FUTILITY.

ChromaDex also fails to establish that the proposed supplemental counterclaims would be futile. ChromaDex first attempts to insulate its false advertising from review with a misleading preclusion argument and a specious invocation of the First Amendment, but both efforts are foreclosed by controlling law, as reflected in the very decisions that ChromaDex cites. ChromaDex then attempts to portray its deceptive COVID-19 claims as technically true, but that preemptive merits defense disregards Elysium's proposed pleading, the Warning Letter, and ChromaDex's own 8-K. Clearly the FDA and FTC did not agree that ChromaDex's campaign of consumer-oriented statements about COVID-19 were "[m]ere communications stating that a party has conducted studies and accurately announcing results." *See* Opp. at 2.

A. Elysium's Lanham Act Claims Are Not Precluded by the FD&C Act.

The Supreme Court and the Second Circuit have held in other contexts that the Federal Food, Drug, & Cosmetic Act ("FD&C Act") does not preclude Lanham Act claims premised on marketing statements that are also regulated under the FD&C Act. *See POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 106 (2014) (food and beverage label false advertising claim not precluded); *Church & Dwight Co., Inc. v. SPD Swiss Precision Diagnostics, GmBH*, 843 F.3d 48, 62-65 (2d Cir. 2016) (Lanham Act claim not precluded where FDA approved product under Section 510(k)). This is because "[t]he two statutes complement each other"—the FDA is charged with enforcing the FD&C Act's statutory prescriptions, while the Lanham Act enables competitors to bring more traditional false advertising claims. *POM Wonderful*, 573 U.S. at 115.

In *Church & Dwight*, the Second Circuit affirmed Judge Nathan's decision finding that defendant's pregnancy test label was impliedly false under the Lanham Act, even though the label had been previously reviewed and approved by the FDA. 843 F.3d at 53-54. The Second Circuit rejected defendant's preclusion argument in that case, explaining that "FDA [action] is no

substitute for the intervention of a competitor, which by dint of its 'market expertise' is uniquely qualified to 'provide incentives for manufacturers to behave well.'" 843 F.3d at 63 (quoting *POM Wonderful*, 573 U.S. at 115). The same reasoning applies here to Elysium's competitor claims against ChromaDex for its COVID-19 advertising.

To get around this authority, ChromaDex misrepresents Elysium's pleading, suggesting that Elysium "seeks a judgment finding that ChromaDex is "in violation of the [FDCA] and the FTC Act." Opp. at 15. Not so. Elysium seeks an order directing ChromaDex to inform its customers that "the FDA and FTC issued a warning letter to ChromaDex" in which *those agencies asserted* that ChromaDex's advertising was "in violation of the FD&C Act and the FTC Act." ECF 168, Ex. A ¶ C. Such an order would not require the Court to make any independent judgments about either statute's applicability. *See* ECF 168, Ex. 19 at 3 ("You [ChromaDex] should take immediate action to correct the violations [of the FD&C Act] cited in this letter.").[4]

B. ChromaDex's Deceptive Press Releases Are Not Protected by the First Amendment.

ChromaDex also attempts to shield its false advertising from review by invoking the First Amendment. Citing *ONY, Inc. v. Cornerstone Therapeutics, Inc.*, 720 F.3d 490 (2d Cir. 2013), ChromaDex asserts that its press releases constitute "scientific discourse" with robust First Amendment protection. Opp. at 17. In *ONY*, the Second Circuit rejected defamation and false advertising liability for scientific conclusions set forth in an article published by a leading peer-reviewed medical journal. 720 F.3d at 496-98. But the court made clear that "secondary distribution of excerpts of such an article" in press releases and promotional materials were only shielded from liability "*so long as the excerpts do not mislead* a reader about the conclusions of

[4] Even if some alteration to the language of the proposed remedial statement were appropriate, that would not provide a basis on which to deny Elysium's motion. *Cf. Church & Dwight*, 843 F.3d at 73 (noting "the court's wide discretion to fashion the terms" of relief).

the article." *Id.* at 492 (emphasis added). ChromaDex's press releases *are* misleading. *See* ECF 168, Ex. A ¶¶ 155-160. And they are even farther outside the zone of protected scientific discourse because they "tout[ed] the benefits of Defendant's product" and "are principally directed to a consumer audience, not a scientific one." *Mimedx Grp., Inc. v. Osiris Inc.*, No. 16 Civ. 3645, 2017 WL 3129799, at *8 (S.D.N.Y. July 21, 2017).

C. ChromaDex Fails to Show that Elysium's Proposed Counterclaims Fail as a Matter of Law.

Finally, ChromaDex strains to argue that the statements in their press releases were literally true and that, as a result, Elysium's proposed counterclaims fail as a matter of law. Opp. at 15-18. This argument fundamentally misapprehends how the Lanham Act works.

First, ChromaDex's COVID-19 claims were literally false, both on their face and under the "false by necessary implication" doctrine. *See Time Warner Cable, Inc. v. DIRECTV, Inc.*, 497 F.3d 144, 158 (2d Cir. 2007). Under that doctrine, a court assessing literal falsity considers "the message conveyed in full context," and "[i]f the words or images, considered in context, necessarily imply a false message, the advertisement is literally false and no extrinsic evidence of consumer confusion is required." *Id*. Such is the case here. *See* ECF 168, Ex. A ¶¶ 153-173.

Second, even if ChromaDex could muster an argument that some of its statements did not cross the line into literal falsity, they were nevertheless "impliedly false." *Church & Dwight*, 843 F.3d at 65; *see also Weight Watchers Int'l, Inc. v. Noom, Inc.*, 403 F. Supp. 3d 361, 369 (S.D.N.Y. 2019). A statement is "impliedly false if although . . . literally true, it is likely to deceive or confuse customers." *Dentsply Sirona, Inc. v. Dental Brands for Less LLC*, No. 15 Civ. 8775, 2020 WL 1643891, at *3 (S.D.N.Y. Apr. 2, 2020) (quotations omitted). The customer reviews documented in Elysium's proposed supplemental pleading provide significant evidence that consumers were "confused" about Tru Niagen's potential to fight COVID-19. *See* ECF 168, Ex. A ¶¶ 41, 158-60;

ECF 168-17; ECF 168-18. These alone are sufficient to establish at this stage that ChromaDex's statements are, at a minimum, impliedly false. *See Church & Dwight*, 843 F.3d at 65.

Under either doctrine, ChromaDex cannot escape the Warning Letter. ChromaDex tries to wave the letter away by noting that it did not commence a formal action, but the issuance of a warning letter is serious, and the letter's language speaks for itself.[5] The FDA determined that statements in each of ChromaDex's four press releases (and social media posts linking to them) "establish the intended use of [ChromaDex's] products and misleadingly represent them as safe and/or effective for the treatment or prevention of COVID-19." *See* ECF 168-19 at 2. This eviscerates any contention of futility. *See Organic Juice*, 2010 WL 3912222, at *3 (holding that FDA's finding that statements violate the FD&C Act supported proposed new false advertising counterclaims); *see also Church & Dwight Co., Inc. v. SPD Swiss Precision Diagnostics, GmbH*, No. 14 Civ. 585, 2014 WL 2526965, at *12 (S.D.N.Y. June 3, 2014) ("[A] number of courts have held that courts may consider the FDA's positions on a matter as evidence of falsity in considering a Lanham Act claim.") (collecting cases). And ChromaDex's own 8-K underscores the Warning Letter's significance—8-Ks are reserved for "disclosures of *material* nonpublic information" to investors. 17 C.F.R. § 243.100(a); *see also* 17 C.F.R. § 249.308 (emphasis added).[6]

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[5] Per the FDA, warning letters "are issued only for violations of regulatory significance." Food & Drug Admin. Regulatory Procs. Manual § 4-1-1 (Mar. 2020); *see also Okla. Police Pension Fund & Ret. Sys. v. Teligent, Inc.*, No. 19 Civ. 3354, 2020 WL 3268531, at *13 (S.D.N.Y. June 17, 2020) (FDA warning letters "convey the FDA's 'find[ing] that a manufacturer has significantly violated FDA regulations'") (quoting *About Warning and Close-Out Letters*, Food & Drug Admin., https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/about-warning-and-close-out-letters).

[6] ChromaDex's threat to bring a Rule 12 motion in the event Elysium is given leave to supplement rings hollow. If ChromaDex had a real Rule 12 argument, it would present it now. *See POM Wonderful LLC v. Organic Juice USA, Inc.*, 769 F. Supp. 2d 188, 202 (S.D.N.Y. 2011) (deeming Rule 12 motion directed at amended pleadings on same grounds as unsuccessful futility arguments frivolous, and awarding fees and costs). And ChromaDex's tit-for-tat threat to supplement its own pleading is pure gamesmanship. The Elysium press release that ChromaDex points to made a single, passing reference to COVID-19 in the course of discussing research into acute kidney injury for which the FDA has accepted Elysium's Investigational New Drug application. If ChromaDex brings an appropriate motion (with an appropriate proposed pleading), Elysium will respond in accordance with the applicable rules.

CONCLUSION

For the reasons set forth above and in Elysium's memorandum of law in support of its motion, Elysium respectfully requests leave to file its Proposed Supplemented and Fourth Amended Counterclaims.

Dated: January 4, 2021

Respectfully submitted,

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