UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

IN RE CURALEAF HOLDINGS, INC. SECURITIES LITIGATION	:	**MEMORANDUM DECISION AND ORDER** 19-cv-4486 (BMC)

COGAN, District Judge.

This securities action is before me on defendants' motion to dismiss. Plaintiffs allege that defendants misled investors about the legality of their cannabidiol ("CBD") products, causing loss when the truth was revealed. Because plaintiffs' claims are premised on the nondisclosure of information that was actually disclosed and further amendment to the complaint would be futile, the motion is granted and the case dismissed.

BACKGROUND[1]

I. Regulation of cannabis products

CBD is a chemical compound derived from plants in the cannabscae family. Both marijuana and hemp contain CBD and can be used to make CBD products, such as oils. Marijuana has a higher delta-9-tetrahydrocannabinol ("THC") content (up to 30%) and can come from both the *cannabis indicia* and *cannabis sativa* families of plants; hemp is derived only from the latter family and has a lower THC content (less than 0.3%).

CBD has been incorporated into a variety of products – beverages, lotions, supplements, vape pens, bath bombs, pet treats, and more. Retailers claim that it provides various health benefits, ranging from treatment of pain and anxiety to cancer and Alzheimer's disease, but the

[1] Unless otherwise noted, the below facts are taken from plaintiffs' Amended Complaint and assumed to be true for purposes of this motion. See Kolbasyuk v. Capital Mgmt. Servs., LP, 918 F.3d 236, 239 (2d Cir. 2019).

FDA has warned that there is little to no scientific evidence supporting such claims. Further, the FDA has warned that CBD has the potential to cause liver injury, male reproductive toxicity, and changes in alertness and mood, among other harm and side effects.

There is a conflict between state and federal regulation of cannabis and cannabis-based products. Marijuana is listed in Schedule I of the Controlled Substances Act ("CSA"), meaning it is categorized as a drug with no currently accepted medical use and a high potential for abuse. But 33 states and Washington D.C. have legalized the use of medical marijuana, 11 of those states and Washington D.C. have legalized recreational marijuana, and 17 states have legalized the use and possession of CBD, although "legalization" means different things in different states. Most states also regulate hemp.

On August 29, 2013, U.S. Attorney General James M. Cole issued a memorandum advising the federal government to exercise prosecutorial discretion in enforcing federal marijuana laws. This memorandum was rescinded on January 4, 2018 by the issuance of a new memorandum from U.S. Attorney General Jeff Sessions, who similarly instructed prosecutors to weigh relevant considerations in deciding whether to prosecute marijuana offenses. On December 20, 2018, the Agriculture Improvement Act of 2018 ("Farm Act") was enacted. The Farm Act amended the CSA by removing hemp from the definition of marijuana and thus from Schedule I of the CSA, allowing hemp to be grown under federal law in some circumstances.

That same day, the FDA issued a statement confirming that it retained the authority to regulate cannabis or cannabis-derived compounds, including CBD products. The FDA explained that such compounds are "subject to the same authorities and requirements as FDA-regulated products containing any other substance." The FDA further explained that it:

> continue[s] to be concerned at the number of drug claims being made about products not approved by the FDA that claim to contain CBD . . . . [T]he FDA

> requires a cannabis product (hemp-derived or otherwise) that is marketed with a claim of therapeutic benefit, or with any other disease claim, to be approved by the FDA for its intended use before it may be introduced into interstate commerce. . . . Cannabis and cannabis-derived products claiming in their marketing and promotional materials that they're intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases . . . are considered new drugs or new animal drugs and must go through the FDA drug approval process for human or animal use before they are marketed in the U.S.

The FDA's website, referred to in the statement, states its position that "[s]elling unapproved [CBD] products with unsubstantiated therapeutic claims is not only a violation of the law, but also can put patients at risk, as these products have not been proven to be safe or effective." It also notes that the FDA has approved only one drug containing CBD (Epidiolex, for the treatment of seizures). The website further explains that CBD products cannot be sold as dietary supplements and that it is illegal to sell a food (including any animal food) to which CBD has been added.

II. Defendants' products and disclosures

Curaleaf Holdings, Inc. ("Curaleaf Holdings" or the "Company") was created in a reverse takeover between the Canadian company Lead Ventures, Inc. (renamed Curaleaf Holdings, Inc.) and the Delaware corporation PalliaTech, Inc. (renamed Curaleaf, Inc. ("Curaleaf")). This action is brought on behalf of purchasers or acquirers of Curaleaf Holdings securities on the OTCQX, a United States market for companies already listed on a qualified international stock exchange. Curaleaf Holdings is listed on the Canadian Stock Exchange ("CSE").

On October 26, 2018, the same day that the Company announced the completion of the business combination, it filed its Listing Statement with the System for Electronic Document Analysis and Retrieval ("SEDAR"). SEDAR is the Canadian equivalent of the Electronic Data Gathering, Analysis, and Retrieval system ("EDGAR") in the United States – it is the filing system designed to facilitate the electronic filing of securities information and allow for the

public dissemination of Canadian securities information collected in the securities filing process.[2] The Listing Statement is a document that "must be used for all initial applications for Listing and for Issuers resulting from a fundamental change" and "contains comprehensive disclosure about the issuer."[3]

A. Disclosures and public statements

The October 26, 2018 Listing Statement – filed with SEDAR that day, with the CSE on November 2, 2018, and with the OTCQX on January 15, 2019 – included the following discussion about the cannabis industry:

> Curaleaf Holdings, Inc. will derive a substantial portion of its revenues from the cannabis industry in certain states of the United States, which industry is illegal under United States federal law. Curaleaf Holdings, Inc. will be directly involved (through its licensed subsidiaries) in the cannabis industry in the United States where local state laws permit such activities. . . .
>
> The United States federal government regulates drugs through the Controlled Substances Act (21 U.S.C. § 811), which places controlled substances, including cannabis, in a schedule. Cannabis is classified as a Schedule I drug. Under United States federal law, a Schedule I drug or substance has a high potential for abuse, no accepted medical use in the United States, and a lack of accepted safety for the use of the drug under medical supervision. The United States Food and Drug Administration has not approved marijuana as a safe and effective drug for any indication.
>
> In the United States marijuana is largely regulated at the state level. State laws regulating cannabis are in direct conflict with the federal Controlled Substances Act, which makes cannabis use and possession federally illegal. Although certain states authorize medical or adult-use cannabis production and distribution by licensed or registered entities, under U.S. federal law, the possession, use, cultivation, and transfer of cannabis and any related drug paraphernalia is illegal and any such acts are criminal acts under federal law. The Supremacy Clause of the United States Constitution establishes that the United States Constitution and federal laws made pursuant to it are paramount and in case of conflict between federal and state law, the federal law shall apply. . . .

[2] Available at: www.sedar.com.

[3] Form 2A - Listing Statement, CSE (last visited Feb. 15, 2021), https://thecse.com/en/resources/form-2a-listing-statement#:~:text=The%20Listing%20Statement%20must%20be,comprehensive%20disclosure%20about%20the%20issuer.

> There is no guarantee that state laws legalizing and regulating the sale and use of cannabis will not be repealed or overturned, or that local governmental authorities will not limit the applicability of state laws within their respective jurisdictions. Unless and until the United States Congress amends the Controlled Substances Act with respect to medical and/or adult-use cannabis (and as to the timing or scope of any such potential amendments there can be no assurance), there is a risk that federal authorities may enforce current federal law. If the federal government begins to enforce federal laws relating to cannabis in states where the sale and use of cannabis is currently legal, or if existing applicable state laws are repealed or curtailed, Curaleaf Holdings, Inc.'s business, results of operations, financial condition and prospects would be materially adversely affected.

The Listing Statement further explained that "[v]iolations of any federal laws and regulations could result in significant fines, penalties, administrative sanctions, convictions or settlements arising from civil proceedings conducted by either the federal government or private citizens, or criminal charges, including, but not limited to, disgorgement of profits, cessation of business activities or divestiture." This could have a "material adverse effect" on the Company, including to its "reputation and ability to conduct business," its licenses, "the listing of its securities on the CSE, its financial position, operating results, profitability or liquidity or the market price of its publicly traded shares."

The Listing Statement provided additional disclosures specific to the Company's CBD products. The Company's products "are not approved by the [FDA] as 'drugs' or for the diagnosis, cure, mitigation, treatment, or prevention of any disease. Accordingly, the FDA may regard any promotion of the cannabis-based products as the promotion of an unapproved drug in violation of the [FDCA]." The Listing Statement proceeded to explain that the FDA has issued letters to a number of companies selling CBD products in recent years "warning them that the marketing of their products violates the FDCA." Any FDA enforcement against the company "could result in a number of negative consequences, including fines, disgorgement of profits, recalls or seizures of products, or a partial or total suspension of the [Company's] production or

distribution of its products," and "[a]ny such event could have a material adverse effect on the Resulting Issuer's business, prospects, financial condition, and operating results."

On October 29, 2018, Curaleaf Holdings began trading on the CSE. A press release from that date included comments from defendant Lusardi that the Company was committed to aggressive organic growth, that the Curaleaf brand was "a premium mainstream cannabis brand" and the products met the "highest standards for safety, effectiveness, [and] quality."

On November 21, 2018 – the proposed beginning of the class period – Curaleaf Holdings issued a press release announcing that the Company had launched "a line of premium hemp-based CBD products," described as "natural," having undergone "strict laboratory testing," meeting "the strictest quality standards" and "supporting overall wellness." The CBD products were advertised and sold on the Company's website, which stated that the products could treat chronic pain, anxiety, depression, PTSD, Parkinson's disease, and Alzheimer's disease, reduce opioid-related withdrawal, counteract the growth and spread of cancer, and deter heart disease. The first press release did not discuss FDA approval, nor did another issued that same day, nor did press releases issued on November 26 and 28 and December 4, 5, and 14 – all of which contained similar language regarding "premium" products and "highest standard for safety, effectiveness," and quality.

On November 26, 2018, on a 2018 3Q earnings call, Lusardi discussed the new CBD product line, explaining that "[t]he interstate regulations for CBD are vastly different than that of our THC products, which will give us the opportunity to offer these products through ecommerce, major third party retailers, pharmacy chains and grocery stores, in addition to vape shops and dispensaries." He discussed the Company's plans for rapid growth and indicated that

the 2018 Farm Act would be "a catalyst for more and more retailers and more and more outlets to take on" CBD products.

On November 29, 2018, Curaleaf Holdings filed its Management Discussion and Analysis ("MD&A") for the nine months ending September 30, 2018 with the CSE (subsequently filed with OTCQX on January 15, 2019). This document only addressed the risk factors that applied to the Company's business before the completion of the reverse takeover and thus only addressed risks within the mining industry.[4] "For details of the risks and uncertainties relating to the Company subsequent to completion of the Business Combination," it referred readers to "the Company's Listing Statement, dated October 26, 2018, which is available under the Company's SEDAR profile."

On December 20, 2018, the Farm Act was enacted. A slew of press releases followed, each of which referred to the safety, effectiveness, and quality of the Company's cannabis products and none of which disclosed that the products were not FDA-approved.

On March 20, 2019, Curaleaf Holdings held a 2019 4Q call in which its Executive Director discussed the Company's successful rapid growth but also acknowledged the quickly changing legal regime around cannabis in the United States, referring to an "evolving landscape in the hemp industry," legal "conflict between the federal government and the states," and the expectation that "numerous pieces of legislation will be introduced over the next quarter."

[4] Although not annexed to the Amended Complaint, I may take judicial notice of this document and the statements contained within because it is referenced in the complaint and plainly relevant and there is no apparent dispute as to its authenticity or accuracy. See Faulkner v. Beer, 463 F.3d 130, 134 (2d Cir. 2006). Further, "[i]n securities fraud cases, . . . a court may consider 'public disclosure documents required by law to be, and that have been, filed with the SEC . . . ., and documents that plaintiffs either possessed or knew about and upon which they relied in bringing the suit.'" In re Keyspan Corp. Sec. Litig., 383 F. Supp. 2d 358, 372 (E.D.N.Y. 2003) (quoting Rothman v. Gregor, 220 F.3d 81, 88 (2d Cir. 2000)). This reasoning extends to public disclosure documents filed with foreign exchanges like the CSE.

On April 23, 2019, Curaleaf Holdings filed its Management's Discussion and Analysis of Financial Condition and Results of Operations for the Year Ended December 31, 2018 with SEDAR (subsequently filed with OTCQX on May 14, 2019 and CSE on December 13, 2019). Its disclosures contained a section titled "Regulatory Action and Approvals from the Food and Drug Administration" detailing the possible risks to the Company from the FDA regulatory regime. It noted that the Company's products are not approved by the FDA and "the FDA may regard any promotion of the cannabis-based products as the promotion of an unapproved drug in violation of the" FDCA. It further disclosed that the "FDA has asserted that CBD is not a lawful ingredient in foods and beverages, supplements and pharmaceuticals (unless FDA-approved), although FDA has generally refrained from taking enforcement action against those products." Explaining that the FDA has issued warning letters to companies selling CBD products, the disclosure noted that any enforcement action could result in a variety of negative consequences. "The Company sells and distributes certain products containing CBD. There is a risk that the FDA or state or local Departments of Health will seek to stop the Company from selling its CBD products or seek to have the claims made for those products revised."

On May 10, 2019, the Company announced a new hemp-based CBD product for pets, called "Bido," claiming that the product supports a pet's overall wellness, is natural and safe, and has the potential to manage pain and anxiety. Many more press releases followed, each of which referred to the safety, effectiveness, and quality of its cannabis-based products and none of which disclosed that the products were not FDA-approved.

B. The warning letter

On July 22, 2019, the FDA issued a warning letter to Curaleaf regarding several CBD products sold on its website. The FDA determined that these products are unapproved new drugs

and misbranded drugs sold in violation of the FDCA. The letter detailed dozens of the Company's claims about the products demonstrating that they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or intended to affect the structure or any function of the body and thus constituted unapproved new and misbranded drugs. Further, to the extent that the Company intended to market its CBD products as dietary supplements, the FDA explained that is impermissible because the "FDA has concluded . . . that CBD products are excluded from the dietary supplement definition" under the Act, subject to an exception that does not apply here. Further, the letter explained that the Bido products are unapproved new animal drugs that are considered unsafe and adulterated under the FDCA, and detailed dozens of the Company's claims about these products demonstrating that they are intended to mitigate, treat, or prevent disease in animals. Accordingly, the FDA concluded that "introducing or delivering [any of the listed] products for introduction into interstate commerce for such uses violates" the FDCA.

The letter instructed the Company to "take prompt action to correct the violations cited in this letter" and noted that "[f]ailure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and injunction."

The Company's share price fell in the days following the issuance of the warning letter. On July 26, 2019, Curaleaf Holdings issued a press release reporting that it had responded to the FDA, removed the statements highlighted in the warning letter, and discontinued many of the products referred to within it.

DISCUSSION

In deciding a motion to dismiss under Rule 12(b)(6) of the Federal Rules of Civil Procedure, the Court must "construe the complaint liberally, accept[] all factual allegations in

the complaint as true, and draw[] all reasonable inferences in the plaintiff's favor." Elias v. Rolling Stone LLC, 872 F.3d 97, 104 (2d Cir. 2017) (quoting Chase Grp. All. LLC v. City of New York Dep't of Fin., 620 F.3d 146, 150 (2d Cir. 2010)). To survive a motion to dismiss, a complaint must plead "enough facts to state a claim to relief that is plausible on its face," Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007), and to "allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009).

I. Section 10(b) and Rule 10b-5 of the Exchange Act

"To state a cause of action under section 10(b) and Rule 10b-5, a plaintiff must plead that the defendant made a false statement or omitted a material fact, with scienter, and that plaintiff's reliance on defendant's action caused plaintiff injury." San Leandro Emergency Med. Grp. Profit Sharing Plan v. Philip Morris Cos., 75 F.3d 801, 808 (2d Cir. 1996). Under the Private Securities Litigation Reform Act ("PSLRA"), the complaint must specify each statement alleged to have been misleading and the reasons why the statement is misleading. 15 U.S.C. § 78u-4(b)(1). "Specificity is also required by the Federal Rules of Civil Procedure, which provide that '[i]n all averments of fraud . . . the circumstances constituting fraud . . . shall be stated with particularity.'" In re Scholastic Corp. Sec. Litig., 252 F.3d 63, 69 (2d Cir. 2001) (quoting Fed. R. Civ. P. 9(b)).

A. Failure to disclose

Plaintiffs allege that throughout the class period, public statements made by the Company were false and misleading because defendants failed to fully disclose the illegality of the sale of CBD products under federal law due to the lack of FDA approval. Defendants contend that the Company repeatedly disclosed that its cannabis-based products are not approved by the FDA as

drugs, that the FDA may regard their promotion as the promotion of an unapproved drug in violation of federal law, and the risk that the Company could be subject to an FDA enforcement action with significant negative consequences. Defendants argue that these disclosures are fatal to plaintiffs' allegations that defendants deliberately withheld material information from investors. I agree.

"Even at the pleading stage, dismissal is appropriate where the complaint is premised on the nondisclosure of information that was actually disclosed." In re Keyspan Corp. Sec. Litig., 383 F. Supp. 2d 358, 377 (E.D.N.Y. 2003) (citing Debora v. WPP Group, P.L.C., No. 91 Civ. 1775, 1994 WL 177291, at *5 (S.D.N.Y. May 5, 1994) ("A complaint fails to state a § 10(b) claim when the alleged omission has actually been disclosed."); Sable v. Southmark/Envicon Capital Corp., 819 F. Supp. 324, 333 (S.D.N.Y. 1993) ("The naked assertion of concealment of material facts which is contradicted by published documents which expressly set forth the very facts allegedly concealed is insufficient to constitute actionable fraud.") (citation and quotation marks omitted)).

Here, starting on its first day in existence, the Company publicly and repeatedly acknowledged the very information that plaintiffs contend it concealed: its cannabis-based products are not approved by the FDA and thus the FDA may regard their promotion as violating established law. After describing the complex and contradictory nature of cannabis regulation in the United States and the risks attendant to operating a company that derives its revenues from the cannabis industry, the Listing Statement – the key disclosure document filed in connection with the Company going public – expressly disclosed that:

- the Company's cannabis-based products "are not approved by the [FDA] as 'drugs'"
- the FDA may regard their promotion "as the promotion of an unapproved drug in violation of the [FDCA]"

- the "FDA has issued letters to a number of companies selling products that contain CBD . . . warning them that the marketing of their products violates the FDCA"
- an "FDA enforcement action against the [Company] could result in a number of negative consequences, including fines, disgorgement of profits, recalls or seizures of products, or a partial or total suspension of the [Company's] production or distribution of its products," and
- "[a]ny such event could have a material adverse effect on the [Company's] business, prospects, financial condition, and operating results."

What more need the Company disclose about this risk? The Listing Statement says it all.

Plaintiffs argue that the Listing Statement does not disclose that selling a CBD-based product is "illegal" under federal law. But "illegal" and in "violation" of federal law mean the same thing. The information that plaintiffs contend was not disclosed was clearly disclosed from the Company's inception. There is no requirement that a Company disclose its risk in any magic words preferred by plaintiffs.

The Company disclosed the relevant information regularly and repeatedly. The Listing Statement was filed in October 2018. In November 2018, the Company's MD&A referred to the Listing Statement for details of its risks and uncertainties. About a month before the Company was listed on the OTCQX market (which occurred on February 19, 2019), the Company filed these same disclosures with OTC Markets, including the Listing Statement and its specific warnings about the Company's cannabis-based products. On April 23, 2019, the Company filed another MD&A with SEDAR containing the same warnings about CBD products from the Listing Statement, an additional explanation about the effect of the new Farm Act on the hemp industry, and underscoring that "[t]here is a risk that the FDA or state or local Departments of Health will seek to stop the Company from selling its CBD products or seek to have the claims made for those products revised."

Plaintiffs further argue that the Company only disclosed the risk that the FDA "could potentially" take regulatory action against it for its unapproved cannabis-derived products, ignoring "unambiguous" guidance from the FDA that CBD products were illegal. But "a defendant that makes specific cautionary statements, such that no reasonable investor would have been misled about the nature of the risk, is not liable when that risk materializes, contrary to the defendant's optimistic statements." In re Delcath Sys., Inc. Sec. Litig., 36 F. Supp. 3d 320, 334 (S.D.N.Y. 2014). Here, the Company clearly disclosed the risk that the FDA could act against it and that the FDA had done so to other companies selling similar products. Describing this risk in terms of potentiality rather than certainty – when certainty of enforcement could not be known anyway – does not violate securities law.

Perhaps recognizing the weakness of their claim that the Listing Statement did not adequately disclose this information, plaintiffs focus primarily on various press releases that they contend should *also* have noted that the Company's products were "illegal" under federal law. But not every public statement made by the Company need contain the full roster of disclosures detailed in the Company's securities filings. See In re Keyspan, 383 F. Supp. 2d at 378-79 (securities laws require disclosure only of information that is not otherwise in the public domain, and there can be no liability for failure to disclose where securities filings adequately disclose the relevant information); see also Emerson v. Mut. Fund Series Tr., 393 F. Supp. 3d 220, 247-49 (E.D.N.Y. 2019) (plaintiffs could not have lacked the necessary information to adequately understand the Company's risks where the risks were disclosed in securities filings); La Pietra v. RREEF America, LLC., 738 F. Supp. 2d 432, 441-42 (S.D.N.Y. 2010) (no basis for plaintiffs to claim that defendants failed to disclose riskiness when the prospectus described the business strategy and possible negative consequence); In re Cross Media Mktg. Corp. Sec. Litig., 314 F.

Supp. 2d 256, 268 (S.D.N.Y. 2004) (reasonable investor would have reviewed securities filings and not been misled by forward-looking, optimistic statements in press releases). The issue can be described in terms of materiality because additional disclosure would not alter the "total mix" of information available to a reasonable investor, Halperin v. eBanker USA.com, Inc., 295 F.3d 352, 357 (2d Cir. 2002); or as the lack of a duty to disclose matters of public record, In re Keyspan, 383 F. Supp. 2d at 378-79. Either way, the Company's on-point public disclosures are fatal to plaintiffs' claims, and those claims cannot be revived merely because the disclosures were not repeated in every press release issued by the Company.

B. Representations regarding health and wellness

In opposition to defendants' motion to dismiss, plaintiffs appear to assert a new, slightly different theory. In the Amended Complaint, plaintiff had described the suggestion that the Company's CBD products were "safe" or "effective" as misleading in terms of FDA approval; plaintiffs alleged only that defendants "created the misleading impression that the CBD products were safe, effective, had the health and medical benefits advertised and met medical/scientific standards when, in fact, the products had not be approved by the federal agency responsible for certifying the safety, effectiveness and quality of food and medical products sold in the U.S." Every allegedly misleading statement regarding safety, effectiveness, or quality featured in the Amended Complaint's Addendum similarly focused on the lack of FDA approval. However, in their opposition brief, plaintiffs also argue that some of defendants' statements were false and misleading because "Curaleaf's products did not have the health benefits touted" and were "not beneficial for human and animal health."

Defendants argue that the Court should not consider this claim but, if the Court is inclined to do so, the claim should be dismissed because it cannot satisfy loss causation. I will

consider the claim because it was set out in plaintiffs' opposition motion and thus afforded defendants the opportunity to address it on reply, and defendants identify no prejudice.

"Loss causation is 'the causal link between the alleged misconduct and the economic harm ultimately suffered by the plaintiff.'" Lentell v. Merrill Lynch & Co., 396 F.3d 161, 172 (2d Cir. 2005) (quoting Emergent Cap. Inv. Mgmt., LLC v. Stonepath Grp., Inc., 343 F.3d 189, 197 (2d Cir. 2003)). To plead loss causation, plaintiffs must "allege facts sufficient to show that the 'relevant truth' that had been concealed by [d]efendants' purportedly false statements was disclosed to the market, which in turn caused [the Company's] stock price to decline." Janbay v. Canadian Solar, Inc., No. 10 CIV. 4430, 2012 WL 1080306, at *14 (S.D.N.Y. Mar. 30, 2012) (citing Dura Pharms., Inc. v. Broudo, 544 U.S. 336, 342-43, 347 (2005)). "An alleged corrective disclosure that does not reveal the falsity of [d]efendants' challenged public statements cannot establish loss causation, a pleading failure that 'is fatal under Second Circuit precedent.'" Id. (quoting Lentell, 396 F.3d at 175). The requirement to plead and prove loss causation exists because "private securities fraud actions are 'available, not to provide investors with broad insurance against market losses, but to protect them against those economic losses that misrepresentations actually cause.'" In re Omnicom Grp., Inc. Sec. Litig., 597 F.3d 501, 510 (2d Cir. 2010) (quoting Dura Pharms., 544 U.S. at 345).

Plaintiffs claim that the FDA warning letter "revealed" the "truth" that Curaleaf's products did not have the "overall wellness" health benefits touted. However, as to Curaleaf's products for human use, the letter does not contain any information demonstrating the falsity of the Company's advertising statements regarding the safety or effectiveness of its products. Instead, the letter details the Company's statements on its website to demonstrate that the products "are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of

disease," and thus constitute unapproved new drugs. The FDA notes that it "approves a new drug on the basis of scientific data and information demonstrating that the drug is safe and effective" but does not state anywhere that the Company's CBD products for human use are *not* safe and effective. The reason that this letter exists at all is because the FDA has not been provided adequate information to determine whether the CBD products are safe or effective for any use whatsoever. The letter doesn't opine on whether the products are safe and effective; it just explains that defendants cannot say that they are. And, for the reasons described above, plaintiffs' claims fail to the extent that they are based on the lack of FDA approval.

It is a slightly closer issue as to the Company's statements about its CBD pet products. Plaintiff notes that the Company advertised these products as being "natural and safe" and effective at treating various ailments in pets, but the FDA's letter stated that the products "are not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling." Further, because "[t]hese products are not approved or index listed by the FDA . . . [they] are considered unsafe under" the FDCA. Thus, technically, the Company made statements about the safety and effectiveness of their pet products and the FDA's letter reveals that the FDA believes that the products are not "generally recognized" as safe and effective and that the FDA considers them "unsafe."

But, again, the letter doesn't state that the products cannot effectively treat the various ailments or are categorically unsafe – just that they are not approved by the FDA to be advertised as such under the applicable regulatory framework. The FDA's letter is simply the materialization of the risk that was disclosed. It is a public warning that the products are unapproved and being sold and/or marketed in violation of the FDCA, and that the FDA may

pursue enforcement against the Company. That the products were not FDA-approved was amply disclosed, as was the risk that the FDA might issue a letter to the Company "warning them that the marketing of their products violates the FDCA" as had been done to a number of companies selling CBD products. The FDA does not say that any statement is false, only that such statements cannot legally be made. Plaintiff's new theory thus does not satisfy loss causation based on a claim for false representation.

The problem with this new claim is that it is still fundamentally based on the lack of FDA approval. That is clear enough from plaintiff's arguments in their brief:

- Once Curaleaf spoke about the medical benefits of its products, the Company had a duty to fully inform investors that *its products were not approved for medicinal use*.
- Plaintiff identified distinct instances where the Company states that its products were of medicinal quality, yet *had received no such approval from the FDA* and were thus illegal.
- Defendants have similarly made unsupported statements that its products were beneficial for 'human and pet health' despite *lacking any approval for such use or marketing*.

(Emphasis added). I have already found that the lack of FDA approval cannot support plaintiffs' securities fraud claim because that issue and its attendant risks were fully disclosed by defendants. The only previously unknown information that may have been "corrected" by the warning letter was the uncertainty as to whether the FDA would pursue any enforcement action against the Company. That risk was adequately disclosed, and no reasonable investor can claim to have been misled as to it. Accordingly, to the extent that plaintiffs would like to assert a claim for securities fraud based on allegedly false statements about the Company's products' safety and efficacy, that claim fails.

II. Section 20(a)

In the absence of an underlying violation of the Exchange Act, plaintiffs' claim for control person liability under section 20(a) also fails. In re China Valves Tech. Sec. Litig., No. 11 CIV. 0796, 2012 WL 4039852, at *8 (S.D.N.Y. Sept. 12, 2012) (citing S.E.C. v. First Jersey Sec., Inc., 101 F.3d 1450, 1472 (2d Cir. 1996)).

III. Leave to amend

A "'court should freely give leave when justice so requires,' and it is the usual practice upon granting a motion to dismiss to allow leave to replead." Cruz v. TD Bank, N.A., 742 F.3d 520, 523 (2d Cir. 2013) (citations omitted). However, a court need not grant leave to amend if amendment would be futile. In re Am. Exp. Co. Shareholder Litig., 39 F.3d 395, 402 (2d Cir. 1994). "Proposed amendments are futile if they 'would fail to cure prior deficiencies or to state a claim under Rule 12(b)(6) of the Federal Rules of Civil Procedure.'" IBEW Local Union No. 58 Pension Tr. Fund & Annuity Fund v. Royal Bank of Scotland Grp., PLC, 783 F.3d 383, 389 (2d Cir. 2015). "Thus, the standard for denying leave to amend based on futility is the same as the standard for granting a motion to dismiss." Id.

Plaintiffs seek leave to amend the complaint should I find that it fails to state a claim but have not included any proposed amended pleading or indicated what they might allege to cure the deficiencies. Plaintiffs have already been permitted to file one amended pleading through the filing of the Amended Class Action Complaint. I cannot identify any further amendment that would improve upon the complaint; repleading cannot change the fact that the lack of FDA approval and risk of enforcement were adequately disclosed. Leave to amend is thus denied as futile. See In re WorldCom, Inc. Sec. Litig., 303 F. Supp. 2d 385, 391 (S.D.N.Y. 2004).

CONCLUSION

Defendant's motion to dismiss is granted and the case dismissed.

SO ORDERED.

Digitally signed by Brian M. Cogan

U.S.D.J.

Dated: Brooklyn, New York
February 15, 2021