**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF NEW YORK**

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| BARBARA ZOTTOLA, on behalf of herself and all others similarly situated,<br><br>Plaintiff,<br><br>v.<br><br>EISAI INC., et al.,<br><br>Defendants. | Civil Case No. 7:20-cv-02600-PMH<br><br>Judge Philip M. Halpern<br><br>Oral Argument Requested |

**DEFENDANTS EISAI INC., ARENA PHARMACEUTICALS, INC. AND CVS PHARMACY, INC.'S JOINT MEMORANDUM OF LAW IN SUPPORT OF MOTIONS TO DISMISS**

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Defendants Eisai Inc. (Eisai), Arena Pharmaceuticals, Inc. (Arena), and CVS Pharmacy, Inc. (CVS) (collectively, Defendants) submit this Joint Memorandum of Law in Support of their Motions to Dismiss Plaintiff Barbara Zottola's claims pursuant to Federal Rule of Civil Procedure 12(b)(6). In accordance with this Court's July 29, 2020 Minute Entry (Doc. 23), Defendants' Joint Memorandum of Law presents the arguments common to all three Defendants; arguments specific to individual Defendants are addressed in separately-filed supplemental briefs.

## INTRODUCTION

This putative class action arises out of Plaintiff Barbara Zottola's alleged purchase of Belviq®, the brand name for lorcaserin hydrochloride, a medication that was approved by the FDA for weight management in adults and available only by prescription from a physician. Importantly, Plaintiff does not allege that she suffered any personal injury as a result of using Belviq®. Instead, Plaintiff alleges she was economically injured because she purchased a prescription medication that she now wishes she had not purchased. Plaintiff's complaint asserts a number of claims, all of which are based on conclusory allegations that the Defendants, at some unspecified time, engaged in some unspecified misleading conduct aimed at concealing the risks of Belviq®.

Plaintiff's complaint should be dismissed because her conclusory assertions of misleading conduct fall far short of stating any plausible claim for relief.

***First***, Plaintiff's allegations do not state a claim under New York General Business Law Sections 349 and 350, which require "consumer-oriented" conduct that is "materially misleading" and resulted in a cognizable injury. New York courts have repeatedly held that the injury Plaintiff alleges here—purchasing a product she would not have purchased but for allegedly deceptive conduct—is not cognizable under New York law. *See, e.g., Small v. Lorillard Tobacco Co.*, 720 N.E.2d 892, 897 (N.Y. 1999). Moreover, Plaintiff has not identified any "consumer oriented"

conduct because under New York law, the duty to provide warnings and information about a prescription medication runs to physicians, not consumers. *See, e.g., Wholey v. Amgen, Inc.*, 165 A.D.3d 458, 459 (N.Y. App. Div. 1st Dept. 2018). Indeed, Plaintiff fails to adequately identify any misleading conduct at all—her complaint contains only conclusory assertions that "Defendants" collectively—without differentiating among them—engaged in "misleading acts" by "misrepresenting" that Belviq® was "safe" and "fit for use." *See* Complaint, Doc. 1, ¶ 59. Further, Plaintiff's claim under Section 350 fails for the additional reason that she has not identified any statements in "advertising" at all, let alone any that were materially misleading.

***Second***, Plaintiff's common law claims for fraud and fraudulent concealment, like her statutory claims, fail to state a legally cognizable injury. *See, e.g., Small*, 720 N.E.2d at 898. Separately, Plaintiff makes only general allegations that Defendants purportedly concealed information regarding the risks of Belviq®. Those allegations—which do not identify any specific misrepresentation or omission at all, much less specify who made the misrepresentation or omission or explain when, where, and how such omissions or misrepresentations were made—fall far short of the heightened pleading standard for fraud claims under Federal Rule of Civil Procedure 9(b). *See, e.g., Loreley Financing (Jersey) No. 3 Ltd. v. Wells Fargo Securities, LLC*, 797 F.3d 160, 171 (2d Cir. 2015). Having failed to identify any specific misrepresentations or omissions, Plaintiff necessarily fails to adequately allege how she or her prescribing physician relied on any such misrepresentations or omissions.

***Third***, Plaintiff fails to state a claim for unjust enrichment because that claim is entirely duplicative of her other claims. *See, e.g., Koenig v. Boulder Brands, Inc.*, 995 F. Supp. 2d 274, 290 (S.D.N.Y. 2014). And in any event, the claim is not pleaded with specificity under Rule 9(b),

which applies to claims, like Plaintiff's unjust enrichment claim, that sound in fraud. *See Rombach v. Chang*, 355 F.3d 164, 171 (2d Cir. 2004).

***Fourth***, Plaintiff's conversion claim should be dismissed because she does not allege the existence of a specific, identifiable fund of money that is in Defendants' control, and she has provided only conclusory assertions that Defendants exercised "unauthorized dominion" over her property. *See, e.g., Mazzola v. Roomster Corp.*, 849 F. Supp. 2d 395, 409 (S.D.N.Y. 2012).

***Finally***, in the alternative, the nationwide class claims on behalf of those outside New York should be dismissed or stricken because the Court lacks jurisdiction over Defendants as to those claims. *Bristol-Myers Squibb Co. v. Superior Court of California*, 137 S. Ct. 1773 (2017).

Before seeking this Court's permission to file motions to dismiss, each of the Defendants submitted pre-motion letters to Plaintiff setting out each of the above deficiencies and requesting that a more definite statement be provided. *See* Docs. 22, 24, 34. Plaintiff refused.[1] Accordingly, the Court should dismiss each of the claims described above.

## STATEMENT OF ALLEGED FACTS

This action involves Plaintiff's purchase of Belviq®, a medication which was "originally approved by the FDA in June 2012 as a prescription weight loss pill for obese individuals." Complaint, Doc. 1, at ¶ 2. Although Plaintiff alleges that FDA requested the withdrawal of Belviq in February 2020 based on its review of the results of a clinical trial, *id.* at ¶ 3, the gravamen of her complaint is that Eisai and Arena purportedly knew that Belviq® caused "high rates of cancer,"

[1] In addition to seeking a more definite statement as to the allegations underlying her claim, Defendants Eisai and Arena also sought a more definite statement as to when Plaintiff allegedly purchased Belviq®. *See* Doc. 21-1 at 6; *see also* Doc. 34, Ex. 1 at 3. Some of Plaintiff's claims are governed by limitations periods that begin at the time of purchase. *See, e.g., Gould v. Helen of Troy Ltd.*, 2017 WL 1319810, *2 (S.D.N.Y. Mar. 30, 2017) (claims under N.Y. Gen. Bus. Law. §§ 349 and 350 subject to 3-year limitation period accruing at the time of purchase). Information regarding time of purchase should be easily discernable and readily available to Plaintiff, and providing such information would avoid expending resources on claims that may ultimately be time-barred. Plaintiff declined to provide the information. *See* Doc. 21-2 at 6.

*before* FDA ever approved the drug, but nevertheless "pushed the product[] to market" by "minimizing and downplaying" or "obfuscating" the alleged "cancer risk." *Id.* ¶¶ 1, 8. Plaintiff alleges that a 2007 "long-term carcinogenicity rat study" indicated various types of tumors in rats, but she also concedes that the results of that study, including tumor data, were submitted to FDA to obtain approval to market the medication. *Id.* ¶¶ 9-15. Plaintiff further concedes that FDA ultimately approved Belviq® in 2012 after reviewing additional data. *Id.* ¶¶ 18-19.

Plaintiff alleges that she "was prescribed and purchased and used Belviq® . . . on several occasions over a period of approximately two years," though she does not specify the dates or years in which she made these alleged purchases. *Id.* ¶ 27. She also alleges that she "filled at least one of these prescriptions at a CVS location in Warwick, New York." *Id.* Plaintiff further alleges that she reviewed "accompanying labels and disclosures," *id.*, but does not identify any particular statement in those materials that she claims was fraudulent or misleading or upon which she or her prescribing physician relied.

Plaintiff seeks to represent a class of "all persons in the United States" who purchased Belviq® and a subclass of individuals who purchased Belviq® in the state of New York. *Id.* ¶¶ 33, 35. Plaintiff claims that she and the Class "were injured by the full purchased price of their Belviq® medications" because "[h]ad Defendants Eisai and Arena been forthright with the FDA regarding the animal studies conducted beginning in 2007, and the true cancer risk of the medications, the medications would never have made it to market." *Id.* ¶ 25. Based on those allegations, Plaintiff has alleged the following claims: (1) breach of implied warranty of merchantability; (2) violation of New York General Business Law § 349; (3) violation of New York General Business Law § 350; (4) unjust enrichment; (5) fraudulent concealment; (6) fraud;

and (7) conversion. *Id.* ¶ 26. For the reasons set forth below and in the supplemental briefing, each of those claims should be dismissed.

**LEGAL STANDARD**

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quotation marks omitted). "A pleading that offers labels and conclusions or a formulaic recitation of the elements" or "tenders naked assertion[s] devoid of further factual enhancement" will not suffice. *Id.* A claim has facial plausibility only "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* The plausibility standard requires "more than a sheer possibility that a defendant has acted unlawfully." *Id.* The factual allegations pleaded "must be enough to raise a right to relief above the speculative level." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007).

In addition, when a plaintiff includes claims alleging fraudulent activity or claims that sound in fraud—such as Plaintiff's unjust enrichment, fraud, and fraudulent concealment claims—she must plead the underlying facts with the particularly required by Federal Rule of Civil Procedure 9(b). *See Loreley Financing (Jersey) No. 3 Ltd.*, 797 F.3d at 171. At a minimum, plaintiffs must support their allegations with the who, what, when, where and how of the events at issue. *See id.*[2]

[2] Because this is a diversity case, this Court applies the substantive law of the forum state, including its choice-of-law rules. *See AEI Life LLC v. Lincoln Benefit Life Co.*, 892 F.3d 126, 132 (2d Cir. 2018). Under New York choice of law principles, fraud-based claims are governed by the state in which the consumer resides and the allegedly fraudulent sales took place—here, New York. *See Nat'l W. Life Ins. Co. v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 89 F. App'x 287, 288 (2d Cir. 2004); *Mendy v. JP Morgan Chase & Co.*, No 12 Civ. 8252, 2014 WL 1224549,*7 (S.D.N.Y. Mar. 24, 2014); Complaint, Doc. 1, ¶ 27.

## ARGUMENT

### I. PLAINTIFF FAILS TO STATE A CAUSE OF ACTION UNDER NEW YORK GENERAL BUSINESS LAW SECTIONS 349 AND 350.

Plaintiff's claims under New York General Business Law § 349 (Count 2) and § 350 (Count 3) should be dismissed because her allegations fail to state a cause of action under either section. Section 349 prohibits "[d]eceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state." N.Y. Gen. Bus. Law § 349(a). Section 350 prohibits materially misleading advertising. *See* N.Y. Gen. Bus. Law § 350. To recover under either section, a plaintiff must show that "a defendant has engaged in (1) consumer-oriented conduct that is (2) materially misleading and that (3) plaintiff suffered an injury as a result of the allegedly deceptive act or practice." *Kommer v. Bayer Consumer Health*, 252 F. Supp. 3d 304, 310 (S.D.N.Y. 2017) (quoting *Orlander v. Staples, Inc.*, 802 F.3d 289, 300 (2d Cir. 2015)). To recover under Section 350, a plaintiff "must further demonstrate proof of actual reliance." *Merck Eprova AG v. Brookstone Pharma., LLC*, 920 F. Supp. 2d 404, 425 (S.D.N.Y. 2013).

Plaintiff has failed to allege facts that state a plausible claim under either section because she has not alleged a legally cognizable injury, and in any event, has not alleged facts demonstrating any "consumer-oriented conduct" that was "materially misleading." Plaintiff's claim under Section 350 fails for the additional reason that she has not adequately alleged any materially misleading advertisements upon which she relied.

#### A. Plaintiff's Alleged Injury Is Not Cognizable Under New York Law.

To state a claim under Sections 349 and 350, a plaintiff must prove that "a material[ly] deceptive act or practice caused actual, although not necessarily pecuniary, harm." *Small v. Lorillard Tobacco Co.*, 720 N.E.2d 892, 897 (N.Y. 1999) (emphasis removed). It is well-settled that a plaintiff whose only claimed injury is that she purchased a product "that [she] would not

have purchased, absent a manufacturer's deceptive commercial business practices," has not suffered an injury under the statute. *Id.* at 898. In *Small*, for example, the plaintiffs alleged that had the defendants disclosed that nicotine was addictive, they would not have purchased cigarettes. *Id.* The New York Court of Appeals dismissed their claims, holding that plaintiffs' "flawed 'deception as injury' theory" failed to demonstrate that they were "actually harmed or suffered pecuniary injury by reason of any alleged deception within the meaning of the statute." *Id.* (quotation marks omitted).

Similarly, in *Baron v. Pfizer, Inc.*, the Third Department of the New York Appellate Division dismissed a claim under Section 349 for lack of cognizable injury where the plaintiff sought "a refund of the purchase price of [a medication] on the ground that she would not have purchased the drug absent defendant's deceptive practices." 840 N.Y.S.2d 445, 447–48 (N.Y. App. Div. 3d Dept. 2007); *see also, e.g., Preira v. Bancorp Bank*, 885 F. Supp. 2d 672, 679 (S.D.N.Y. 2012) (dismissing claims under Section 349 where plaintiffs' alleged injury was "identical to the deception"—*i.e.*, that she bought a product she would not have purchased but for the alleged deception); *Donahue v. Ferolito, Vultaggio & Sons*, 786 N.Y.S.2d 153, 154 (N.Y. App. Div. 1st Dept. 2004) (holding that trial court properly dismissed claims under Section 349 and 350 where plaintiffs "impermissibly set up the deception as both act and injury" by alleging that they bought beverages because the labels promised health benefits, but plaintiffs received no such health benefits).

Here, just as in *Small, Baron, Preira*, and *Donahue*, Plaintiff's only alleged injury is that she purchased a product that she would not have purchased absent Defendants' alleged misrepresentations. *See* Complaint, Doc. 1, ¶ 64 (alleging that Plaintiff was injured by Defendants' alleged deceptive conduct because she "would not have purchased Belviq Medication if [she] knew

the medications caused cancer and were unfit for use as a weight loss medications [sic]"); *id.* ¶ 75 (same). In response to Eisai's pre-motion letters, Plaintiff failed to meaningfully distinguish *Small* and *Baron*, instead asserting in a footnote that she "believes her allegations sufficiently establish injury under § 349 and § 350 in the form of having paid a premium in the amount of the full purchase price of the medication." Doc. 22 at 3 n.3. Plaintiff's invocation of the word "premium" cannot salvage her claims. Although a plaintiff may be able to assert a cognizable injury by alleging that a product's purchase price was inflated because a defendant falsely represented that its product was superior to those of competitors,[3] Plaintiff's complaint here rests on an entirely different theory. Specifically, Plaintiff alleges that Defendants engaged in deceptive conduct by purportedly concealing the risk of cancer so that consumers would purchase Belviq®. *See, e.g.*, Complaint, Doc. 1, ¶ 1. And Plaintiff's alleged injury is identical to the deception: she alleges that because the risk of cancer allegedly was concealed, she bought a product she "would not have purchased" otherwise. *Id.* ¶¶ 64, 75. In other words, Plaintiff's complaint is based on the same "deception as injury" theory that New York courts have routinely rejected. Her claims under Sections 349 and 350 should therefore be dismissed for failing to allege a legally cognizable injury.

### B. Plaintiff Fails To Adequately Plead Any "Consumer-Oriented Conduct" That Was "Materially Misleading."

Plaintiff's claims under Sections 349 and 350 should also be dismissed because she has not adequately alleged that Defendants engaged in any conduct that was both "consumer-oriented" and "materially misleading." *See Kommer*, 252 F. Supp. 3d at 310.

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[3] *See, e.g., Ackerman v. Coca-Cola Co.*, CV-09-0395, 2010 WL 2925955, at *23 (E.D.N.Y. July 21, 2010) (noting that plaintiffs had "explicitly allege[d]" that "defendants command a premium price" for their vitaminwater by "distinguishing it from soft drinks (including their own)" and falsely marketing it as "a dietary supplement in liquid form").

***First***, Plaintiff has failed to allege any conduct that was "consumer-oriented"—*i.e.*, directed at consumers. New York follows the learned intermediary doctrine, which dictates that all pharmaceutical information is directed at physicians, not patients. *Lindsay v. Ortho Pharm. Corp.*, 637 F.2d 87, 91 (2d Cir. 1980). In other words, the manufacturer's duty runs to the doctor, who then acts as an "informed intermediary" by assessing the patient's needs and evaluating the risks and benefits of available medications as to that specific patient. *Id.* For that reason, an alleged failure to provide adequate warnings or information about the risks of a drug is not "consumer-oriented" conduct. *See, e.g., Wholey v. Amgen, Inc.*, 165 A.D.3d 458, 459 (N.Y. App. Div. 1st Dept. 2018) ("[T]he generally alleged deceptive practice of failing to provide adequate warnings [for a prescription drug] by concealing information is, as a matter of law, not a practice directed at consumers."); *Gale v. Smith & Nephew, Inc.*, 989 F. Supp. 2d 243, 250 (S.D.N.Y. 2013) (dismissing claim under Section 349 where plaintiff "alleges that [defendant] deceived the FDA," but failed to "explain how this allegedly improper conduct was 'consumer-oriented'").

Plaintiff alleges that Defendants engaged in "deceptive" acts by "misrepresenting" that Belviq® was "fit for use as a weight loss medication[] when in fact it caused a significantly elevated risk of cancer" and was "generally recognized as safe for human consumption." Complaint, Doc. 1, ¶ 59. Accordingly, Plaintiff's claims appear to be based on an alleged failure to disclose the purported risks of the medication. But because the duty to disclose such information runs to physicians, not patients, Plaintiff has not alleged any "consumer-oriented" conduct. *See, e.g., Wholey*, 165 A.D.3d at 459; *Gale*, 989 F. Supp. 2d at 250.

***Second,*** setting aside whether Plaintiff has identified conduct that was "consumer-oriented," she still has not alleged facts that plausibly show that any Defendant engaged in "materially misleading" conduct. Claims based on Sections 349 and 350 cannot survive in the

absence of facts plausibly establishing that a defendant's actions were misleading. To state a claim under either section, a plaintiff "is required to set forth specific details regarding the allegedly deceptive acts or practices." *Weaver v. Chrysler Corp.*, 172 F.R.D. 96, 100 (S.D.N.Y. 1997). Where allegations "are founded upon information and belief and lack specificity," a plaintiff has failed to state a claim. *Id.*

Plaintiff's allegations, which are "based upon information and belief," (Complaint, Doc. 1, at 1) provide no specific details regarding the alleged deceptive acts or practices. Instead, Plaintiff offers only conclusory assertions that "Defendants have engaged in deceptive, unfair, and misleading acts and practices, which include, without limitation, misrepresenting that Belviq medications (i) were fit for use as a weight loss medication when in fact it caused a significantly elevated risk of cancer . . . and (ii) are generally recognized as safe for human consumption." *Id.* ¶ 59. Courts have routinely held that similarly vague and conclusory allegations are not sufficient to state a claim under Sections 349 and 350. *See, e.g., Bustamante v. Atrium Med. Corp.*, 1:18-cv-08395, 2020 WL 583745, at *8–9 (S.D.N.Y. Feb. 6, 2020) (dismissing claim under Section 349 as inadequately pleaded where plaintiff alleged that defendants "omitted material information from the website, instructions for use, literature to the medical community, advertisements, and brochures, concerning the risks associated with the device"); *Dunham v. Covidien LP*, 19 Civ. 2851, 2019 WL 2461806, at *4–5 (S.D.N.Y. May 22, 2019) (dismissing claims under Sections 349 and 350 because allegations that defendant "misrepresented and omitted material information regarding the subject products by failing to disclose known risks" were not sufficient "to support a conclusion that any of [defendant's] representations were deceptive or false"); *Perez v. B. Braun Med., Inc.*, 17 Civ. 8512, 2018 WL 2316334, at *1 (S.D.N.Y. May 9, 2018) (dismissing claims

under Sections 349 and 350 because conclusory allegations, such as claiming medical devices "were safe, effective, and fit for [the use] for which they were designed," were inadequate).

In its pre-motion letter, Eisai demanded a more definite statement as to the specific misrepresentations or omissions that Plaintiff claims constituted materially misleading conduct. Doc. 21 at 3; Doc. 21-1 at 2. Plaintiff refused, stating instead that "[m]isleading conduct may be based on omissions," and repeating her conclusory assertion that Defendants concealed that the medication was "ineffective and dangerous because it exposed users to an increased risk of cancer." Doc. 22 at 2. Plaintiff's response confirms that her claims under Sections 349 and 350 are based entirely on conclusory assertions unsupported by factual allegations that identify any actual misrepresentation or omissions. Her claims should therefore be dismissed.

### C. Plaintiff Has Not Identified Any Misleading Advertising, As Required To State A Claim Under Section 350.

Plaintiff's claim under Section 350 fails for the additional reason that she has not identified any allegedly false advertisements. To state a claim under Section 350, a plaintiff must, at a minimum, identify the allegedly false advertisements. *See, e.g.*, *Small v. Lorillard Tobacco Co., Inc.*, 252 A.D.2d 1, 15 (N.Y. App. Div. 1st Dept. 1998) (ordering dismissal of plaintiffs' Section 350 claim because "plaintiffs' complaint does not furnish sufficient examples of misrepresentations on which plaintiffs relied").

Here, Plaintiff does not identify the content of any advertisements at all. Nor does she allege the date or time on which she viewed those advertisements, or even the particular Defendant responsible for a specific advertisement. Instead, Plaintiff alleges only that Defendants "advertised"—at some unspecified time and place and in some unspecified way—that Belviq® was "safe and effective . . . for weight loss." Complaint, Doc. 1, ¶ 70. That conclusory allegation falls far short of the mark necessary to state a claim under Section 350. And having failed to

identify any advertisements, Plaintiff also fails to allege that she relied on any such advertisements. *See Merck Eprova AG*, 920 F. Supp. 2d at 425 (plaintiff must "demonstrate proof of actual reliance" under Section 350). Indeed, Eisai's pre-motion letter demanded that Plaintiff provide a more definite statement as to "the advertisements underlying her claim under G.B.L. § 350; the specific statements in those advertisements that she claims misled her; and how she and/or her physicians relied on those statements." Doc. 21 at 3. Plaintiff refused to provide a more definite statement. *See* Doc. 22. Given Plaintiff's failure to specify any advertisements upon which she relied, despite being put on notice of the pleading deficiencies in her complaint, her claim under Section 350 should be dismissed.

## II. PLAINTIFF FAILS TO STATE A CAUSE OF ACTION FOR FRAUDULENT CONCEALMENT OR FRAUD.

Plaintiff's claims for fraudulent concealment (Count 5) and fraud (Count 6) against Eisai and Arena[4] fail to state a cause of action for two reasons. First, Plaintiff's alleged injury is not cognizable under New York law. Second, Plaintiff's fraud-based claims are deficient because they are not adequately pleaded under Federal Rule of Civil Procedure 9(b).

### A. Plaintiff's Alleged Injury Is Not Cognizable Under New York Law.

Plaintiff's fraud-based claims, like her claims under New York General Business Law Sections 349 and 350, fail because Plaintiff's only alleged injury—that she purchased a product she would not have purchased but for the allegedly deceptive conduct—is not legally cognizable. *See, e.g, Small*, 720 N.Y.2d at 898 ("The flaw in plaintiffs' statutory claim foretells the inadequacy of the common-law claims: an act of deception, entirely independent or separate from any injury, is not sufficient to state a cause of action under a theory of fraudulent concealment. Thus,

[4] In response to CVS's pre-motion letter explaining why Plaintiff had not, and could not, state a fraud claim against CVS, Plaintiff agreed to drop her common law fraud claims against CVS. *See* Doc. 23-1 at 4 n.2.

plaintiffs' common-law fraud claims also fail."); *Donahue*, 786 N.Y.S.2d at 154–55 (same). For that reason alone, Plaintiff's claims for fraudulent concealment and fraud should be dismissed. *See supra* Section I.A.

### B. Plaintiff Fails To Plead Fraudulent Concealment Or Fraud With Particularity As Required By Rule 9(b).

Separately, Plaintiff's fraud-based claims should be dismissed because they are not pleaded with the specificity required under Rule 9(b). To state a claim for fraud, a plaintiff must show "(1) the defendant made a material false misrepresentation, (2) the defendant intended to defraud the plaintiff thereby, (3) the plaintiffs reasonably relied upon the representation, and (4) the plaintiffs suffered damage as a result of their reliance." *See Banque Arabe et International D'Investissement v. Md. Nat. Bank*, 57 F.3d 146, 153 (2d Cir. 1995). A claim for fraudulent concealment requires the same showing as that for fraudulent misrepresentation, with the additional requirement that the plaintiff must demonstrate that the defendant had a duty to disclose material information. *Id.* Plaintiff's allegations fall far short of pleading those elements with the requisite specificity.

#### *1. Plaintiff Fails To Adequately Allege Any Fraudulent Concealment.*

Plaintiff's fraudulent concealment claim should be dismissed because her complaint contains nothing more than conclusory assertions unsupported by factual allegations. When a fraud claim is based on concealment, the complaint must specify "(1) what the omissions were; (2) the person responsible for the failure to disclose; (3) the context of the omissions and the manner in which they misled the plaintiff; and (4) what the defendant obtained through the fraud." *Quintana v. B. Braun Med. Inc.*, 17-cv-06614, 2018 WL 3559091, at *7 (S.D.N.Y. July 24, 2018) (internal citations omitted); *see also Loreley Financing (Jersey) No. 3 Ltd.*, 797 F.3d at 171 (explaining that a complaint for fraud must "(1) detail the statements (or omissions) that the

plaintiff contends are fraudulent; (2) identify the speaker; (3) state where and when the statements (or omission) were made, and (4) explain why the statements (or omissions) are fraudulent").

Plaintiff's complaint fails to meet even the first requirement: that a particular omission be specified. Initially, the complaint alleges that Defendants "actively concealed" the risk of cancer and "doctored test results to the FDA to get the product approved." Complaint, Doc. 1, ¶ 85. But as explained in Eisai's pre-motion letter to Plaintiff, that type of fraud claim is preempted under the U.S. Supreme Court's decision in *Buckman Company v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). Doc. 21-1 at 3. In *Buckman*, the plaintiffs sought damages under state tort law under the theory that the defendant "made fraudulent representations to the Food and Drug Administration . . . in the course of obtaining approval to market" a medical device and that "[h]ad the representations not been made, the FDA would not have approved the devices, and plaintiffs would not have been injured." 531 U.S. at 343. The Supreme Court held that the plaintiffs' "fraud-on-the-FDA" claims were preempted by the Federal Food Drug and Cosmetic Act. *Id.*

In response to Eisai's first pre-motion letter, Plaintiff did not dispute that claims based on allegations that a drug manufacturer defrauded the FDA during the drug approval process are preempted. Doc. 21-2, at 3–4 (conceding that Plaintiff's fraud-based claims are allegedly "premised on . . . misleading consumers," not the FDA). Rightly so, as it is well-settled that fraud-based claims are preempted to the extent they are "premised on the interaction between the defendants and the FDA." *Utts v. Bristol-Myers Squibb Co.*, 226 F. Supp. 3d 166, 189 (S.D.N.Y. 2016); *see also A.F. by and Through Fogel v. Sorin Group USA, Inc.*, 346 F. Supp. 3d 534, 541 (S.D.N.Y. 2018) (dismissing as preempted under *Buckman* any fraud claims "to the extent they assert fraud in the premarket approval process").

In light of that authority—and Plaintiff's own concession that she is not asserting claims based on alleged misrepresentations or omissions to the FDA—Plaintiff may not base her fraudulent concealment claim on allegations that any of the Defendants concealed information from FDA during the pre-approval process to get the medication approved. Instead, Plaintiff must identify some specific information that came into Defendants' possession *after* Belviq® was approved and on the market that was not given to consumers. Plaintiff has not done that. Her complaint contains only conclusory assertions that "Defendants failed to disclose or actively obscured the true nature of the medication from the FDA, prescribing physicians, and consumers." Complaint, Doc. 1, ¶ 85.

These conclusory assertions fall short of the requisite specificity required by Rule 9(b). For example, in *Quintana*, the court dismissed a fraudulent concealment claim as inadequately pleaded where plaintiff claimed "in essence, that Defendants misrepresented the product as safe without disclosing the full breadth of the known risks of the [medical device], and that Defendants omitted that [the device] was defective and could cause dangerous side effects." 2018 WL 3559091, at *8. The court reasoned that plaintiff's allegations—like Plaintiff's—are "vague" and, among other things, "fail to specifically set forth the omitted information." *Id.*

Because Plaintiff's complaint does not identify any specific omission, it necessarily fails to specify "the person responsible for the failure to disclose" or "the context of the omissions and the manner in which the misled" Plaintiff. *See Quintana*, 2018 WL 3559091, at *7. For example—far from identifying the person responsible for the failure to disclose—the complaint asserts only that "Defendants" as a whole "actively concealed" information about the product. *See, e.g.,* Complaint, Doc. 1, ¶ 85. Such conclusory allegations that lump all defendants together do not satisfy Rule 9(b). *See In re Rezulin Prods. Liab. Litig.*, 168 F. Supp. 2d 136, 139–40 (S.D.N.Y.

2001) (no basis for claim against defendant where complaint "attribut[ed] wrongdoing to the collective 'defendants'".). Nor does Plaintiff provide any factual allegations to support the assertion that "Defendants" collectively knew, but concealed, the risks of Belviq®. Indeed, her allegations show the opposite: that Arena "reported [initial] tumor findings [in the 2007 rat study] to the FDA;" that the study was "completed and a draft of the study was sent to the FDA" that, again, reported the tumor findings; and that FDA subsequently approved Belviq® after reviewing additional information. Complaint, Doc. 1, ¶¶ 11, 12, 14, 19.

In both of its pre-motion letters, Eisai demanded a more definite statement as to the specific omissions that underlie Plaintiff's complaint. *See* Doc. 21 at 4-5; Doc. 21-1 at 3-4. Plaintiff refused to provide a more definite statement, responding only that Defendants "made misrepresentations and omissions regarding the true nature of the Belviq medications." Doc. 21-2 at 4; *see also* Doc. 22 at 5 (same). Because Plaintiff has failed to adequately allege facts showing fraudulent concealment despite being put on notice of the pleading deficiencies in her complaint, her claim for fraudulent concealment should be dismissed.

***2. Plaintiff Fails To Adequately Allege Any Fraudulent Misrepresentations.***

Like her claim for fraudulent concealment, Plaintiff's claim for fraud fails to meet Rule 9(b)'s specificity requirements. To satisfy Rule 9(b), a complaint alleging fraud must "(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." *Lerner v. Fleet Bank, N.A.*, 459 F.3d 273, 290 (2d Cir. 2006).

Plaintiff's complaint makes no effort to allege with specificity the circumstances of the alleged fraudulent misrepresentations. First, the complaint fails to identify any particular statement that Plaintiff claims was fraudulent. Instead, the complaint alleges generally that

"Defendants . . . actively represented to consumers that the medications were safe for use." Complaint, Doc. 1, ¶ 93. Plaintiff does not identify specific reports, public statements, or publications that underline her claims. Second, Plaintiff does not identify a particular Defendant responsible for any alleged fraudulent statement, or identify when or where the alleged misrepresentation was made. As with her fraudulent omission claim, Plaintiff improperly lumps all Defendants together. And because Plaintiff has not identified any fraudulent statements, she has necessarily failed to explain why those statements were fraudulent. Courts have dismissed claims based on similarly conclusory allegations. *See, e.g., Quintana*, 2018 WL 3559091, at *8 (dismissing fraud claim based on allegations of misstatements in product brochure because they failed to identify the speaker, state where and when the statements were made or viewed, and explain why statements were fraudulent); *Utts*, 226 F. Supp. 3d at 189 (dismissing fraud claims as inadequately pleaded where complaint asserted only that defendants misrepresented the safety of their drug to the FDA, healthcare providers, and the plaintiff and that defendants knew from their research that they were disseminating false information about the drug's safety and efficacy).

As with Plaintiff's fraudulent concealment claim, Defendants demanded a more definite statement as to the basis for Plaintiff's fraud claim. *See* Doc. 21 at 4-5; Doc. 21-1 at 3-4. Again, Plaintiff refused to provide a more definite statement, responding only that Defendants "made misrepresentations and omissions regarding the true nature of the Belviq medications." Doc. 21-2 at 4; *see also* Doc. 22 at 5 (same). Plaintiff's fraud claim should be dismissed because she has failed to satisfy Rule 9(b)'s specificity requirement despite being put on notice of those pleading deficiencies.

### *3. Plaintiff Fails To Adequately Allege Fraudulent Intent Or Reliance On Any Purported Misrepresentations Or Omissions.*

Plaintiff's claims for fraud and fraudulent concealment also fail because she has not adequately pleaded either fraudulent intent or reliance.

***First,*** to demonstrate fraudulent intent, a plaintiff must plead "facts that give rise to a strong inference of fraudulent intent." *Nakahata v. New York-Presbyterian Healthcare Sys. Inc.*, 723 F.3d 192, 198 (2d Cir. 2013). That requires a plaintiff to plead either (1) "that defendants had either motive and opportunity to commit fraud," or (2) "allegations of strong circumstantial evidence of conscious misbehavior or recklessness." *Prickett v. N.Y. Life Ins. Co.*, 896 F. Supp. 2d 236, 246 (S.D.N.Y. 2012) (quotation marks omitted). Plaintiff's conclusory assertion that Defendants acted with "an intent to defraud," Complaint, Doc. 1, ¶ 87, does not meet that standard.

***Second,*** "a plaintiff must allege with particularity that [she] actually relied upon the defendants' supposed misstatements." *Olson v. Major League Baseball*, 447 F. Supp. 3d 159, 167 (S.D.N.Y. 2020) (quotation marks omitted). "This is because Rule 9(b) states unequivocally that 'a party must state with particularity the circumstances constituting the fraud,' and reliance has been an essential element of what constitutes fraud from the earliest days of the common law." *Id.*

Plaintiff's complaint contains only conclusory allegations that she "reasonably relied" on Defendants' alleged misrepresentations and omissions. Complaint, Doc. 1, ¶¶ 88, 93. As explained above, the complaint does not specify what information Plaintiff or her physician received and reviewed—much less explain how they relied on any such statements. Accordingly, Plaintiff's claims for fraud and fraudulent omission fail for the additional reason that she has not adequately alleged reliance. *See Bustamante*, 2020 WL 583745, at *8 (dismissing fraud claim as inadequately pleaded where complaint contained only "conclusory allegations such as, 'Plaintiff . . . through his physicians and healthcare providers, and his physicians reasonably relied upon

Defendants' misrepresentations and omissions regarding the safety and efficacy of [the] product'"); *Quintana*, 2018 WL 3559091, at *8 (same); *Olson*, 447 F. Supp. 3d at 167–68 (concluding that complaint's "generalized allegations of reliance" were insufficient, particularly where the complaint failed to specify any particular representations). Again, Defendants demanded a more definite statement as to both reliance and intent before seeking this Court's permission to file this motion, and Plaintiff refused. Doc. 21-1 at 4–5; Doc. 21-2. Her claims for fraud and fraudulent concealment should therefore be dismissed.

## III. PLAINTIFF FAILS TO STATE A CAUSE OF ACTION FOR UNJUST ENRICHMENT.

Plaintiff's unjust enrichment claim (Count 4) should be dismissed because it is entirely duplicative of her fraud-based claims, and is not adequately pleaded in any event.

### A. Plaintiff's Unjust Enrichment Claim Is Legally Deficient Because It Simply Duplicates Her Tort Claims.

Plaintiff's unjust enrichment claim fails as a matter of law because it is based on the same alleged conduct as her fraud-based claims. "To state a claim for unjust enrichment under New York law, a plaintiff must allege that "(1) the defendant was enriched, (2) at the expense of the plaintiff, and (3) it would be inequitable to permit the defendant to retain that which is claimed by the plaintiff." *Koenig v. Boulder Brands, Inc.*, 995 F. Supp. 2d 274, 290 (S.D.N.Y. 2014) (quoting *Baron*, 840 N.Y.S.2d at 448). But "unjust enrichment is not a catchall cause of action to be used when others fail." *Corsello v. Verizon New York, Inc.*, 967 N.E.2d 1177, 1185 (N.Y. 2012). Specifically, "[a]n unjust enrichment claim is not available where it simply duplicates, or replaces, a conventional contract or tort claim." *Id.*

For example, in *Koenig*, the plaintiffs asserted claims for a violation of New York General Business Law Section 349, breach of express warranty, and unjust enrichment on the grounds that defendant's product was deceptively labeled. As to unjust enrichment, the plaintiffs alleged that

they purchased the product because of the defendant's purported misrepresentations, and that the defendants allegedly retained the revenue generated by the purchases. 995 F. Supp. 2d at 290–91. The court dismissed the unjust enrichment claim, reasoning that "to the extent that Plaintiffs' other claims succeed, the unjust enrichment claim is duplicative, and if plaintiffs' other claims are defective, an unjust enrichment claim cannot remedy the defects." *Id.* at 291. *See also Corsello*, 967 N.E.2d at 1185 (dismissing unjust enrichment claims because to the extent plaintiffs' claims for trespass and deception succeeded, the unjust enrichment claim would be duplicative, and if they failed, the unjust enrichment claim could not remedy the defects); *In re Fyre Festival Litig.*, 399 F. Supp. 3d 203, 222 (S.D.N.Y. 2019) (dismissing unjust enrichment claim because "plaintiffs have offered no distinction for how the unjust enrichment claim differs from their tort claims").

Here, as in *Koenig*, *Corsello*, and *In re Fyre Festival*, Plaintiff's unjust enrichment claim fails because it simply duplicates her tort claims. Specifically, the unjust enrichment claim is based on the same conduct as her other claims—the complaint does not set out any specific factual allegations regarding unjust enrichment, but rather "incorporates by reference the allegations contained in the preceding paragraphs." Complaint, Doc. 1, ¶¶ 77–81. As such, there is no distinction between Plaintiff's unjust enrichment claims and her other claims for fraud and deceptive business practices because they are all based on the same unspecified misleading conduct. Accordingly, if Plaintiff's other claims survive, "the unjust enrichment claim is duplicative," and if her fraud-based claims fail, "an unjust enrichment claim cannot remedy the defects." *Koenig*, 995 F. Supp. 2d at 290–91. For that reason alone, Plaintiff's unjust enrichment claim should be dismissed.

### B. Plaintiff's Unjust Enrichment Claim Is Not Pleaded With Particularity As Required By Rule 9(b).

Separately, Plaintiff's unjust enrichment claim fails because it is not pleaded with particularity. Because the allegations underlying Plaintiff's unjust enrichment claim sound in fraud, Rule 9(b)'s heightened pleading standard applies. "By its terms, Rule 9(b) applies to 'all averments of fraud,'" and "is not limited to allegations styled or denominated as fraud or expressed in terms of the constituent elements of a fraud cause of action." *Rombach v. Chang*, 355 F.3d 164, 171 (2d Cir. 2004). Accordingly, the heightened pleading requirements of Rule 9(b) apply to any claim that "sounds in fraud," regardless of whether fraud is an element of the claim. *Id.* For example, Rule 9(b) has been applied to unjust enrichment claims where the "gravamen of plaintiffs' complaint is plainly fraud." *See Tyman v. Pfizer, Inc.*, 16-cv-06941, 2017 WL 6988936, at *8-10 (S.D.N.Y. Dec. 27, 2017).

The gravamen of Plaintiff's complaint is fraud. Indeed, the complaint does not set out any specific factual allegations as to unjust enrichment, instead incorporating by reference the allegations pertaining to her other claims. Complaint, Doc. 1, ¶¶ 77–81. At bottom, Plaintiff's claim is that she purchased a medication she would not otherwise have purchased but for the same unspecified misrepresentations or omissions by Defendants. And for the reasons explained above, Plaintiff has failed to plead fraud with the specificity required under Rule 9(b), despite being put on notice of the deficiencies in her complaint before Defendants' motions to dismiss were filed. Plaintiff's unjust enrichment claim should therefore be dismissed for failure to state a claim.

## IV. PLAINTIFF FAILS TO STATE A CAUSE OF ACTION FOR CONVERSION.

Plaintiff's conversion claim (count 7) should be dismissed because her allegations fail to state a cause of action. Under New York law, "[c]onversion occurs when a defendant exercises unauthorized dominion over personal property in interference with a plaintiff's legal title or

superior right of possession." *LoPresti v. Terwilliger*, 126 F.3d 34, 41 (2d Cir. 1997) (internal citations omitted). Plaintiff's claim fails for at least two reasons. First, Plaintiff has not alleged the existence of an identifiable fund of money, as required by New York law. Second, Plaintiff has failed to allege facts showing that her purchase of a medication prescribed by a physician resulted in Defendants' exercising "unauthorized dominion" over her property.

### A. Plaintiff Fails To Allege Facts Showing The Existence Of A Specific, Identifiable Fund.

"[A]n action for conversion of money only exists when there is a specific, identifiable fund and an obligation to return or otherwise treat in a particular manner the specific fund in question." *Mazzola v. Roomster Corp.*, 849 F. Supp. 2d 395, 409 (S.D.N.Y. 2012) (quotation marks omitted). "[I]f the allegedly converted money is incapable of being described or identified in the same manner as a specific chattel, it is not the proper subject of a conversion action." *Interior by Mussa, Ltd. v. Town of Huntington*, 664 N.Y.S.2d 970, 972 (N.Y. App. Term 1997) (internal citations omitted). For example, in *Mazzola*, "the plaintiff alleged that the defendants committed conversion by debiting her debit card $29.95 three times without her permission." 849 F. Supp. 2d at 409. The court dismissed the claim as inadequately pleaded, explaining that while plaintiff sought the return of money charged to her debit card, she did not "claim ownership of a specifically identifiable, segregated fund." *Id.* (quotation marks omitted). *See also Interior by Mussa*, 664 N.Y.S.2d at 972 ("Because plaintiff's complaint only seeks the return of a sum paid to defendant, the court incorrectly determined the action one for conversion."); *Auguston v. Spry*, 282 A.D.2d 489, 491 (N.Y. App. Div. 2nd Dep't 2001) (concluding that money that is commingled with other funds is "incapable of being converted").

Plaintiff's complaint does not allege the existence of a specific, identifiable fund. Rather, the complaint merely alleges that she had "an ownership right to the monies paid for the defective

Belviq medications . . . ." Complaint, Doc. 1, ¶ 100. Like the debit card charges in *Mazzola*, the money that Plaintiff allegedly paid for Belviq® cannot be described in the same manner as a chattel. And as in *Auguston*, that money would have been commingled with other funds. Accordingly, Plaintiff's conversion claim fails as a matter of law and should be dismissed.

### B. Plaintiff Fails To Allege Facts Showing An "Unauthorized Dominion" Over Her Property.

Separately, Plaintiff's complaint contains only labels and conclusions regarding any "unauthorized dominion" over her personal property. For example, Plaintiff alleges that "Defendants have wrongly asserted dominion over the payments illegally diverted to them for the defective Belviq Medications," but she fails to explain how her purchase of a medication prescribed by a doctor resulted in an "illegal[] diver[sion]" of her money. *See* Complaint, Doc. 1, ¶ 101. As with the other claims, Defendants set out the deficiencies in this claim in pre-motion letters to Plaintiff, and Plaintiff failed to provide any further factual allegations. *See* Doc. 21-2 at 5–6. Her conversion claim should be dismissed.

## V. ALTERNATIVELY, THE NATIONWIDE CLASS CLAIMS SHOULD BE DISMISSED OR STRICKEN.

For the reasons above and set out in Defendants' supplemental briefs, all of Plaintiff's claims should be dismissed. Alternatively, the Court lacks personal jurisdiction over the claims of non-resident putative class members against Defendants under the reasoning of *Bristol-Myers Squibb Co. v. Superior Court of California*, 137 S. Ct. 1773 (2017). The Supreme Court recognizes two types of personal jurisdiction: general and specific. *See Goodyear Dunlop Tires Operations, S.A. v. Brown*, 564 U.S. 915, 919 (2011). While general jurisdiction allows the court to hear any claim against a defendant, it exists only where a defendant's contacts with the forum are "so continuous and systematic as to render [it] essentially at home in the forum State." *Daimler AG*

*v. Bauman*, 571 U.S. 117, 139 (2014) (internal quotation marks omitted). Only "in an exceptional case" will a corporation be at home in a forum other than its (1) formal place of incorporation or (2) principal place of business. *Id.* at 139 n.19. Specific jurisdiction, by contrast, "is confined to adjudication of issues deriving from, or connected with, the very controversy that establishes jurisdiction." *Bristol-Myers Squibb Co.*, 137 S. Ct. at 1780.

In *Bristol-Myers*, the Supreme Court held that a California state court lacked personal jurisdiction over the claims of non-resident plaintiffs in a mass tort action because there was an insufficient connection between the forum state and the non-resident plaintiffs' claims. 137 S. Ct. at 1781. The court reasoned that "[t]he mere fact that *other* plaintiffs were prescribed, obtained, and ingested [the medication] in California—and allegedly sustained the same injuries as did the non-residents—does not allow the State to assert specific jurisdiction over the non-residents' claims." *Id.*

Here, too, this court lacks personal jurisdiction over the claims of any plaintiff or class member who purchased Belviq® in states other than New York. Initially, the complaint does not allege that any of the Defendants are "at home" in New York for purposes of general jurisdiction—only that they "conduct[] substantial business" in the state. Complaint, Doc. 1, ¶¶ 28–30. Even accepting those allegations as true, they cannot as a matter of law support specific jurisdiction under *Bristol-Myers* over the claims of purchasers who allegedly bought Belviq® outside of New York, because such claims do not arise out of or relate to Defendants' alleged contacts with New York. As in *Bristol-Myers*, there is no "connection between the forum and the specific claims at issue," 137 S. Ct. at 1781, asserted by out-of-state putative class members. For that reason, Plaintiff's nationwide class allegations should be dismissed or stricken because this Court does not have personal jurisdiction as to those claims.

Defendants acknowledge that some courts in this district have deferred a decision on this issue until the class certification stage. *See, e.g., Suarez v. California Natural Living, Inc.*, 17-cv-9847, 2019 WL 1046662, at *6 (S.D.N.Y. Mar. 5, 2019) ("[T]he Court need not assess personal jurisdiction over plaintiff's putative out-of-state class action claims unless and until the Court decides a class comprising out-of-state class members merits certification."). Should Plaintiff be allowed to move forward with any of her claims, and if this Court is inclined to follow those decisions, Defendants respectfully request that their argument be entertained at a later stage in connection with a class certification motion.

**CONCLUSION**

For the reasons explained above, this Court should dismiss Plaintiff's claims for violations of New York General Business Law Sections 349 and 350; fraud and fraudulent concealment; unjust enrichment; and conversion.

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that on September 9, 2020, a copy of the foregoing was filed with the Clerk of Court through the CM/ECF system, which sent notice of the filing to all appearing parties of record.

*By: /s/ Michael D. Schissel*