UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

IN RE: ORAL PHENYLEPHRINE MARKETING AND SALES PRACTICES LITIGATION	:	23-md-3089-BMC
THIS DOCUMENT APPLIES TO: ALL CASES	:	**MEMORANDUM DECISION AND ORDER**

COGAN, District Judge.

Before the Court is defendants' motion to dismiss plaintiffs' Initial Streamlined Consolidated New York Bellwether Class Action complaint. Plaintiffs bring nearly one hundred cases, consolidated in this multidistrict litigation, against defendant retailers and manufacturers of over the counter ("OTC") cough and cold medicines containing the drug phenylephrine ("PE"). Plaintiffs, purchasers of these medicines, allege that defendants knew that PE was ineffective as a nasal and sinus decongestant but produced, marketed, and sold products containing PE to consumers anyway.

The parties agreed that plaintiffs would file this streamlined complaint, and defendants would move to dismiss it, to test claims and defenses common across the consolidated cases. As its title suggests, the complaint brings various claims under New York state law, as well as a civil Racketeer Influenced and Corrupt Organizations Act ("RICO") claim. Defendants contend that the state claims are preempted by the Federal Food, Drug, and Cosmetic Act (the "FDCA"), that plaintiffs lack standing to assert the RICO claim, and that the RICO claim is precluded by the FDCA. For the reasons set forth below, defendants' motion is granted.

SUMMARY OF STREAMLINED COMPLAINT

The Food and Drug Administration (the "FDA") has approved PE as a "safe and effective" nasal decongestant since 1985. In 2007, three individuals petitioned the FDA to increase the allowed maximum dose of PE because a meta-analysis of existing studies indicated that, at the current dosage level, PE was likely no better than a placebo. The FDA's Nonprescription Drug Advisory Committee ("NDAC") reviewed the petition but, finding further study was needed, did not recommend that the FDA declassify PE as "safe and effective" or change any regulations governing the labeling and dosage of PE products.

Around this time, plaintiffs allege, a group of manufacturers – Bayer Healthcare LLC, Haleon PLC, Haleon U.S. Holdings L.L.C., Perrigo Company, Proctor & Gamble Co., RB Health LLC, Kenvue, Inc., and Johnson & Johnson (the "RICO defendants") – began to associate with one another, including through the Phenylephrine Task Group of the Consumer Healthcare Products Association, to defend the effectiveness of PE. Plaintiffs allege that the task group provided deliberately misleading submissions to the NDAC on multiple occasions and disseminated similarly misleading information to the public in the form of press releases, studies, and surveys.

Based on studies conducted after 2007, plaintiffs assert that "by 2016, there was no doubt that oral phenylephrine is no better than placebo at relieving congestion," and defendants knew it. Indeed, in 2023, the NDAC found that scientific data did not support the use of PE as a decongestant. Despite these developments, with one exception, defendants have continued to manufacture, market, and sell PE products without change. Defendant Johnson & Johnson added a message on its website next to pictures of all its PE products stating that the NDAC had

reviewed the efficacy of PE and linking the FDA's statement. Yet Johnson & Johnson, like the other defendants, continues to market and sell PE products.

Plaintiffs allege that they relied on defendants' representations regarding the products' efficacy and would have paid significantly less, or would not have purchased the products at all, had they been aware of PE's ineffectiveness. Plaintiffs also seek to represent several different classes made up of individuals who, between 2016 and the present, purchased an oral nasal decongestant containing PE manufactured by defendants.

DISCUSSION

I. Standard of Review

"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) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). A plaintiff must allege "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. (cleaned up).

II. State Law Claims

The streamlined complaint asserts state claims under New York's consumer-protection and false-advertising statutes, the New York commercial code, and New York common law. Because the claims are all expressly preempted, I need not reach defendants' implied- and obstacle-preemption arguments.

A. Legal Framework

i. Preemption

The Supremacy Clause dictates that "the Laws of the United States . . . shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any state to the Contrary

notwithstanding." U.S. Const. Art. VI, cl. 2. As a corollary, when "state and federal law directly conflict," federal law preempts state law. PLIVA, Inc. v. Mensing, 564 U.S. 604, 617 (2011). The Supreme Court has recognized various types of preemption, but "all of them work in the same way: Congress enacts a law that imposes restrictions or confers rights on private actors; a state law confers rights or imposes restrictions that conflict with the federal law; and therefore the federal law takes precedence and the state law is preempted." N.J. Thoroughbred Horsemen's Ass'n v. Nat'l Collegiate Athletic Ass'n, 584 U.S. 453, 477 (2018).

Whether a federal law preempts a state law is a question of Congressional intent. If Congress is silent, courts presume that Congress did not intend to displace state law, and litigants can rebut that presumption in only limited circumstances. Wyeth v. Levine, 555 U.S. 555, 575 (575). For instance, a litigant can demonstrate "impossibility" preemption by showing that it is impossible to comply with both state and federal law. See PLIVA, 564 U.S. at 617. Sometimes, though, Congress explicitly states its intention for certain federal law to preempt state law. In these cases of "express preemption," there is no presumption against preemption because Congress has spoken clearly. Puerto Rico v. Franklin Cal. Tax-Free Tr., 579 U.S. 115, 125 (2016). An express preemption clause often preempts state law that extends beyond federal law in any respect, meaning that federal law acts as a floor and a ceiling for state requirements. See Riegel v. Medtronic, 552 U.S. 312, 316 (2008).

The FDCA selectively employs this form of express preemption. Generally, state law may supplement the FDCA so long as there is no direct conflict between the state and federal regulations. But, in certain areas, Congress sought to create a "uniform – and federally-led – regulatory scheme." Critcher v. L'Oreal USA, Inc., 959 F.3d 31, 38 (2d Cir. 2020). To do so, it inserted various preemption clauses throughout the statute. See, e.g., Riegel, 552 U.S. at 316.

OTC drug labeling is one such area. The applicable preemption clause, aptly titled "National uniformity for nonprescription drugs," provides that "no State or political subdivision of a State may establish or continue in effect any requirement . . . that is different from or in addition to, or that is otherwise not identical with, a requirement under" the FDCA's OTC drug provisions. 21 U.S.C. § 379r. The parties do not dispute the import of § 379r: that outside of some enumerated exceptions, a state OTC drug labeling requirement is preempted if it expands upon or dilutes federal law – or, in short, that state law must parallel federal law. Plaintiffs also do not argue that their claims fall within § 379r's "savings clause," which exempts from the express preemption "any action or the liability of any person under the product liability law of any State." Id. § 379r(e). Whether the state claims are preempted therefore turns on whether they would enforce a requirement different the federal OTC drug labelling requirements.

ii. Federal OTC Drug Regulations

Congress enacted the FDCA in the early twentieth century to address "concern[s] about unsafe drugs and fraudulent marketing." Wyeth v. Levine, 555 U.S. 555, 556 (2009). The FDCA empowers the FDA to carry out this task, requiring that "[n]o drug can enter interstate commerce 'unless [the] FDA determines that it is generally recognized as safe and effective . . . for the particular use described in its product labeling.'" In re Acetaminophen - ASD-ADHD Prod. Liab. Litig., No. 22-md-3042, 2022 WL 17348351, at *3 (S.D.N.Y. Nov. 14, 2022) (quoting Nat. Res. Def. Council, Inc. v. FDA, 710 F.3d 71, 75 (2d Cir. 2013)).

The FDA uses two systems to determine whether OTC drugs are safe and effective: the New Drug Application ("NDA") system, and the monograph system. The NDA system operates precisely how it sounds. A drug manufacturer submits an NDA to the FDA; the FDA reviews

the application; and if the FDA is satisfied that the new drug is safe and effective for the uses on the label, it approves the drug.

The monograph system provides a more streamlined route. For certain OTC drugs, the FDA issues a regulation – a monograph – detailing "the FDA-approved active ingredients . . . and . . . the conditions under which each active ingredient is" safe and effective. Nat. Res. Def. Council, 710 F.3d at 75. A manufacturer can sell an OTC drug without individualized FDA review when the drug and its label conform to the monograph. An OTC drug distributed under a monograph "is generally recognized as safe and effective and is not misbranded if it meets each of the conditions contained" in the general regulation applicable to all OTC drug monographs, 21 C.F.R. § 330.1, "and each of the conditions contained in any applicable monograph." Id. Each monograph regulates four types of information – the statement of identity, which describes "the general pharmacological category(ies) of the drug or the principal intended action(s) of the drug," id. § 201.61(b); indications for use, which explain the effects of the drug; warnings; and directions – and provides sample language for each.

B. Mislabeling Claims

To determine whether plaintiffs' claims are preempted, I must first determine the scope of the state duties plaintiffs seek to enforce. See Mut. Pharm. Co. v. Bartlett, 570 U.S. 472, 480 (2013). I begin with the claims plaintiffs admit are predicated entirely on defendants' labels before addressing what remains.

The complaint contains broad allegations that defendants misled consumers by labelling their PE products as nasal decongestants despite knowing that PE was no more than a placebo, but plaintiffs' brief drastically cabins their labeling claims. Plaintiffs target only the "indications" section of the labels, which state that PE was an effective nasal decongestant.

They argue that defendants should have updated their indications to "truthfully describ[e] PE products' efficacy," although they never clarify whether that means simply removing the indications, or updating the indications to state that PE is an ineffective decongestant. Regardless, this circumscribed duty has no coordinate in federal law.

Both the PE monograph and the general monograph regulation give manufacturers some flexibility in describing the indications of a PE product. The PE monograph allows manufacturers to use a "phrase listed in paragraph (b)(1) of this section," – either "For the temporary relief of nasal congestion" or "Temporarily relieves nasal congestion." – "as appropriate."[1] Id. § 341.80(b). But it also allows manufacturers to use alternative language instead:

> Other truthful and nonmisleading statements, *describing only the indications for use that have been established and listed in paragraphs (b)(1) and (b)(2) of this section*, may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

Id. § 341.80(b) (emphasis added). The general monograph regulation is structured similarly. In addition to requiring that "[t]he product is labeled in compliance with chapter V" of the FDCA, id. § 330.1(c)(1), it provides that

> [t]he "Uses" section of the label and labeling of the product shall contain the labeling describing the "Indications" that have been established in an applicable OTC drug monograph *or alternative truthful and nonmisleading statements describing only those indications for use that have been established in an applicable monograph*, subject to the provisions of section 502 of the act relating to misbranding . . . .

Id. § 330.1(c)(2) (emphasis added).

[1] Manufacturers may add additional phrases listed in subsection (b)(2), such as "for the temporary relief of nasal stuffiness." Id. 341.80(b)(2).

The text's plain meaning is clear that manufacturers must include "indications" on their labels, and they may do so in one of two ways: either by using the monograph language or using truthful and non-misleading statements describing the monograph language. Nothing in the PE monograph or the general monograph suggests that manufacturers have a freestanding duty to update their indications in response to new scientific information. Indeed, it's unclear if manufacturers could do so here without misbranding the product: if they updated the "Uses" section to indicate that PE is not an effective nasal decongestant, they would be using "alternative language describing" exactly the opposite of "those indications for use that have been established in the applicable OTC drug monograph."

If the text was not enough, this interpretation is confirmed by the 1986 Final Rule adding the relevant sections of the general monograph regulation. Before the Rule, the FDA followed an "exclusivity policy" for OTC drug labeling, under which "any OTC drug product containing labeling with claims or representations other than those established in the monograph, or using differing terminology, would have been a new drug and/or misbranded." Labeling of Drug Products for Over-the-Counter Human Use, 51 Fed. Reg. 16258-01, 16258. The 1986 amendments discarded this practice in favor of the current "flexibility policy." Id. The new policy, the Rule stated, "allow[s] manufacturers the opportunity to change label information without complying with unnecessary FDA procedures; . . . provide[s] for regional differences in the way people refer to the same condition, e.g., acid stomach versus upset stomach; and . . . provide[s] greater flexibility." Id.

The Rule does not suggest that the new language imposes some *obligation* on manufacturers to update efficacy claims on OTC drug labels; instead, the FDA merely touted the efficiency gained by allowing manufacturers to tweak the monograph language. And the Rule

even sheds light on the phrase "subject to section 502 of the act relating to misbranding." Throughout the notice-and-comment process, many interested parties criticized the flexibility policy as "a license for manufacturers of OTC drug products to use words that are misleading and confusing." Id. at 16259. The FDA seemingly included the "subject to . . ." proviso to allay these fears, not to impose on manufacturers a duty to update their drugs' indications.

As they must, plaintiffs oppose this reading of the text. They first point out that, crediting their allegations, PE is no more effective than a placebo. Thus, to the extent that defendants used alternative language describing the monograph indications, they violated the monograph because that language was not "truthful and nonmisleading." 21 C.F.R. 330.1(c)(2). Plaintiffs even claim that labels using the monograph language itself were misbranded because the FDCA's misbranding provision prohibits labels that are "false or misleading in any particular," 21 U.S.C. § 352(a), and the general monograph regulation requires that a label comply with chapter V of the FDCA, which includes § 352. See 21 C.F.R. § 330.1(c)(1).

This interpretation is strained. Most obviously, whether a drug is "effective" is a term of art under the FDCA, and the statute empowers the FDA, not manufacturers, to make that determination. See Nat. Res. Def. Council, 710 F.3d at 75. So, even taking plaintiffs' allegations as true, nothing on the labels was false or misleading – unless and until the FDA amends the monograph in response to the NDAC's findings, it is not misleading to state that PE is an effective nasal decongestant.[2] Plaintiffs also do not explain why federal law would require defendants to update only the indications section. Indeed, such a result would be nonsensical. As plaintiffs recognize, the FDA regulations straightforwardly require a manufacturer to use the "statement of identity" listed in the monograph, meaning a manufacturer must label a PE product

[2] The same applies to the statements on some labels that the products were "maximum strength" or suited for "severe" symptoms. Those statements are only false and misleading if PE is ineffective.

as a "nasal decongestant." 21 C.F.R. § 341.80(a) ("The labeling of the product . . . identifies the product as a 'nasal decongestant.'"); see also id. § 330.1 ("[T]he statement of identity of the product *shall* be the term or phrase used in the applicable OTC drug monograph established in this part." (emphasis added)). Under plaintiffs' reading of the regulations, PE manufacturers would still be allowed to sell products labelled as "nasal decongestants," so long as the products' labels do not state that the products are effective.

Further still, the Second Circuit already rejected a near-identical argument in Critcher v L'Oreal USA Inc., 959 F.3d 31 (2d Cir. 2020). The court there dismissed state claims alleging that a manufacturer mislabeled one of its liquid cosmetics products by failing to disclose that consumers could not dispense all the liquid. The plaintiffs admitted that an express preemption clause applied and that the cosmetic's label complied with the FDA's specific labelling requirements, but they argued that the manufacturer violated § 352(a) because the net weight on the label was misleading. The Second Circuit rejected the proposition that § 352 was a vehicle through which states could impose additional labeling requirements on products regulated by the FDCA. It recognized that because "[t]he [FDA] regulations have . . . stated, with specificity, what information is necessary to avoid misleading consumers," a cosmetic in compliance with the FDA labeling regulations cannot be misbranded.

Critcher rests on a straightforward application of administrative law. The FDCA generally commands that a drug's label cannot be false or misleading and, in turn, vests authority in the FDA to determine whether a label is false or misleading. And, so long as there is an applicable preemption clause, that authority is exclusive. Here, by promulgating the monograph regulation, the FDA determined that it is neither false nor misleading to represent that PE is an effective decongestant. Cf. Booker v. E.T. Browne Drug Co., No. 20-cv-03166, 2021 WL

4340489, at *7 (S.D.N.Y. Sept. 23, 2021) (finding no preemption where the drugs were not deemed effective by the FDA).

Yet plaintiffs attempt to do exactly what Critcher prohibited. They attempt to circumvent the Second Circuit's holding by arguing that, unlike the labeling regulations in Critcher, the PE monograph expressly incorporates the rule they seek to enforce. But, as explained above, their argument is completely divorced from the text of the regulations, which does not reference any duty to revise indications based on newly discovered scientific information. And for good reason. The FDCA empowers the FDA, not drug manufacturers, to determine whether a drug is effective.[3]

Of course, the FDCA imposes some duties on drug manufacturers that depend on newly acquired scientific information. For instance, the misbranding statute requires a manufacturer to "pull even an FDA-approved drug" from the market when the drug "is 'dangerous to health' even if 'used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.'" Bartlett, 570 U.S. at 477 n.4 (quoting 21 U.S.C. § 352(j)). There is no similar provision in § 352 for ineffective drugs.

Similarly, the savings clause in § 379r(e) imposes limited state labeling obligations on manufacturers. For this reason, the cases cited by plaintiff that allow state law challenges to OTC drug labels are inapposite. See, e.g., Wyeth v. Levine, 555 U.S. 555 (2009); In re Acetaminophen, 2022 WL 17348351. In both cases, the plaintiffs alleged that the label misrepresented whether a drug was safe for use and asserted state tort claims against the manufacturers. Because § 379r(e) exempts product liability law from the preemption clause, the

[3] This same rationale applies to drugs approved under an NDA, like Haleon's PE product. The FDA determined that the drug was not misbranded, and there is no apparent federal duty to update labels. Indeed, plaintiffs even admit that Haleon "can," not must, update its products' indications through the Changes Being Effected regulation. See 21 C.F.R. § 314.70(c)(6)(iii)(D).

plaintiffs' claims were preempted only if compliance with both state and federal law was impossible. Wyeth, 555 U.S. at 563; In re Acetaminophen, 2022 WL 1734835, at *6-7. And it was not – the FDCA contains many provisions allowing manufacturers to "strengthen" the warnings on their label. See, e.g., 21 C.F.R. §§ 314.70(c)(6)(iii)(A), (C) (applicable to the OTC drugs approved under an NDA in Wyeth) and § 201.63 (applicable to the OTC drugs approved under a monograph in In re Acetaminophen).[4] This distinction between safety- and efficacy-focused state law was an intentional legislative choice. By excepting state product-liability law from express preemption in § 379r(e), Congress allowed states to layer additional state protections atop federal ones, but only when those protections relate to safety; whether a drug is effective remains within the exclusive purview of the FDA. This division reflects a balance between twin aims of the FDCA: safety and uniformity.

Plaintiffs' final alternative argument fails for this same reason. Plaintiffs argue that, even if defendants' drugs were otherwise properly labeled, the FDCA imposes "an independent obligation to update their labels to reflect new scientific information." In support, they cite passages from three Supreme Court cases – Wyeth, Albrecht, and Bartlett. See Merck Sharp & Dohme Corp. v. Albrecht, 587 U.S. 299, 303 (2019); Bartlett, 570 U.S. at 487; Wyeth, 555 U.S. at 571. In those cases, the Court dealt with safety challenges, not efficacy challenges, and therefore was determining whether a manufacturer *could* update their labels to reflect new scientific information under federal law, not whether they *had to* update their labels. Indeed,

[4] Nor do I find merit in plaintiffs' appeal to In re Zantac (Ranitidine) Prod. Liab. Litig., 546 F. Supp. 3d 1284 (S.D. Fla. 2021). To plaintiffs' credit, the court in In re Zantac, unlike in Wyeth and In re Acetaminophen, held that certain misbranding claims were parallel to federal law not preempted by § 379r. Id. at 1305. But the claims there were focused on the warnings of an OTC drug, not the indications, and therefore do not run into the same structural and textual problems as plaintiffs' claims. See id. Further, the ruling was preliminary – the court held that defendants could later demonstrate preemption after argument on "state-specific matters." Id. at 1309. Perhaps most importantly, though, the court did not have to grapple with circuit precedent like Critcher; if it did, I do not see how it could have reached the same conclusion.

plaintiffs reveal their hand by cobbling together quotations from Wyeth to argue that a manufacturer must update its label to reflect new scientific information so the drug's labelling "remain[s] adequate as long as the drug is on the market." Wyeth, 555 U.S. at 571. Wyeth in fact says that the FDCA charges manufacturers "both with crafting an adequate label and ensuring that its *warnings* remain adequate as long as the drug is on the market." Id. (emphasis added). The full passage reaffirms the key flaw with plaintiffs' claims: because the state claims focus on efficacy, not safety, they run headlong into § 379r.

C. Remaining Claims

Plaintiffs attempt to save their false-advertising, false-concealment, and express-warranty claims claims from § 379r by arguing that they do not implicate federal labeling requirements. Like with the mislabeling claims, I must first determine the scope of the state duties plaintiffs seek to enforce. See Bartlett, 570 U.S. at 480. Because each duty would have required defendants to update the labels of their PE products or stop selling the products altogether, the claims are preempted.

Crediting plaintiffs' allegations, defendants could not have advertised their products truthfully without updating the labels to disclaim PE's effectiveness. See Smith v. GlaxoSmithKline Consumer Healthcare Holdings (US) LLC, 660 F. Supp. 3d 863, 873-74 (N.D. Cal. 2023); Kuiper v. American Cyanamid Co., 131 F.3d 656, 662 (7th Cir. 1997). The same is true for the false-concealment and express-warranty claims. Although plaintiffs point to omissions outside of the label which they claim constitute false concealments and statements outside of the label which they claim constitute express warranties, defendants would have had to update their label to avoid liability under either theory. And, despite plaintiffs' arguments to the contrary, New York considers purely economic express-warranty claims to arise out of

contract law, not product-liability law. See Goldstein v. Walmart, Inc., 637 F. Supp. 3d 95, 113 n.7 (S.D.N.Y. 2022); Restatement (Third) of Torts: Prod. Liab. § 21 (1998). Accordingly, plaintiffs' state claims are preempted in their entirety.

III. RICO Claim

In addition to their state law claims, plaintiffs allege that the RICO defendants violated RICO by engaging in numerous acts of mail and wire fraud in furtherance of a scheme to defraud the public and mislead the FDA into believing that PE is an effective decongestant. Defendants move to dismiss plaintiffs' civil RICO claim for lack of statutory standing and preclusion by the FDCA.

"Courts have described civil RICO as an unusually potent weapon – the litigation equivalent of a thermonuclear device." Moss v. BMO Harris Bank, N.A., 258 F. Supp. 3d 289, 297 (E.D.N.Y. 2017) (internal quotation marks and quotation omitted). The "mere assertion of a RICO claim has an almost inevitable stigmatizing effect on those named as defendants," yet "plaintiffs wielding RICO almost always miss the mark." Id. (cleaned up). Plaintiffs here are no exception. As indirect purchasers of the PE products, they lack standing to bring a RICO claim.[5]

The Supreme Court, in interpreting federal antitrust law, has applied a "direct purchaser" rule: a standing doctrine that bars downstream indirect purchasers from bringing an antitrust claim. See Ill. Brick Co. v. Illinois, 431 U.S. 720 (1977). "[I]ndirect purchasers who are two or more steps removed from the antitrust violator in a distribution chain may not sue. By contrast, direct purchasers – that is, those who are 'the immediate buyers from the alleged antitrust violators' – may sue." Apple Inc. v. Pepper, 587 U.S. 273, 280 (2019) (quoting Kansas v. UtiliCorp United Inc., 497 U.S. 199, 207 (1990)). Plaintiffs do not dispute that they are indirect

[5] Because plaintiffs lack standing, I need not reach preclusion.

purchasers; the question for this Court is whether the direct-purchaser rule applies to civil RICO claims.

Although the Supreme Court and Second Circuit have not directly addressed the issue, the Supreme Court has explained that Congress, in enacting the RICO statute with the same language used in antitrust legislation, "intended [the words in the RICO statute] to have the same meaning that courts had already given them" in the antitrust context. Holmes v. Sec. Inv. Prot. Corp., 503 U.S. 258, 268 (1992). Thus, the same standing requirements established in antitrust cases apply to RICO cases. See id.; McCarthy v. Recordex Serv., Inc., 80 F.3d 842, 855 (3d Cir. 1996) ("[A]ntitrust standing principles apply equally to allegations of RICO violations." (citing Holmes, 503 U.S. at 270)). This is no less true for the direct-purchaser requirement. The direct-purchaser requirement applies in the civil RICO context and bars plaintiffs' RICO claim.[6]

The Supreme Court's analysis in Sedima, S.P.R.L. v. Imrex Co., 473 U.S. 479 (1985), does not change the application of the direct-purchaser requirement in the context of civil RICO claims. Sedima did not apply the "antitrust injury" rule to a civil RICO case, but that was "because 'RICO injury' would be an unintelligible requirement, not because there is no parallel between the two statutes." Carter, 777 F.2d at 1176 (citing Sedima, 473 U.S. at 489 & n.8). Where an antitrust standing requirement is easily intelligible in the civil RICO context, such as

[6] "Every circuit to have considered the issue has held that the [direct purchaser] rule also applies to civil RICO actions, and that indirect purchasers therefore do not have standing to assert RICO claims." Humana, Inc. v. Biogen, Inc., 666 F. Supp. 3d 135, 141 (D. Mass. 2023), reconsideration denied, No. 21-cv-11578, 2023 WL 8374584 (D. Mass. Dec. 4, 2023). The Sixth, Third, and Seventh Circuit Courts of Appeals have all applied the direct-purchaser rule to civil RICO claims. See Trollinger v. Tyson Foods, Inc., 370 F.3d 602, 616 (6th Cir. 2004) ("[I]ndirect purchasers lack standing under RICO and the antitrust laws to sue for overcharges passed on to them by middlemen." (citations omitted)); McCarthy, 80 F.3d at 855 (3d Cir. 1996) ("The precepts taught by Illinois Brick and Utilicorp apply to RICO claims, thereby denying RICO standing to indirect victims." (citations omitted)); Carter v. Berger, 777 F.2d 1173 (7th Cir. 1985) ("The Hanover Shoe-Illinois Brick [direct purchaser] rule promotes enforcement and therefore applies to RICO, too.").

with the bright-line rule at issue here, the identical language of the statutes dictates that courts apply the same requirement in both contexts.

The proximate-cause requirement for a plaintiff to proceed with a civil RICO claim, recognized by the Supreme Court and the Second Circuit, does not conflict with the direct-purchaser requirement. These requirements "address two analytically distinct aspects" of standing. McCarthy, 80 F.3d at 851 n.14.[7] Proximate-cause analysis concerns whether a plaintiff's injury is too far removed from the defendant's violation of the statute at issue to warrant a remedy. Id. By contrast, the direct-purchaser rule concerns whether a plaintiff, having satisfied the proximate-cause requirement, "falls within the group of private attorneys general that Congress created to enforce" the statute. Id. (internal quotation marks and quotation omitted). Many cases only address the proximate-cause requirement, and not the direct-purchaser requirement, because there is no purchasing relationship at issue between the parties. See, e.g., Bridge v. Phoenix Bond & Indem. Co., 553 U.S. 639 (2008) (competitors sued petitioner for violating the rules of an auction; no buyer-seller relationship); Empire Merchs., LLC v. Reliable Churchill LLLP, 902 F.3d 132 (2d Cir. 2018) (alcohol distributor sued other distributors for conspiring with retail liquor stores to smuggle liquor from Maryland to New York; no buyer-seller relationship). Other cases do not address the direct-purchaser requirement because the plaintiff is clearly a direct purchaser, vitiating the need for such analysis. See, e.g., Horn v. Med. Marijuana, Inc., 80 F. 4th 130, 133 (2d Cir. 2023) (plaintiff purchased a product undisputably "produced, marketed, and sold by [defendants]"), cert. granted, 144 S. Ct. 1454

[7] Alternatively, some courts have explained that proximate cause analysis is completely separate from the question of standing. See, e.g., Trollinger, 370 F.3d at 612 (6th Cir. 2004) ("Like the antitrust laws, RICO's civil-suit provision imposes two distinct but overlapping limitations on claimants – standing and proximate cause. . . . Proximate cause poses a merits question involving common-law and prudential limitations on the consequences for which the law will hold a defendant accountable, regardless of the plaintiff's standing to sue." (citation omitted)). The role of proximate cause in relation to the question of standing does not affect the analysis here.

(2024). Plaintiffs' argument that the direct-purchaser requirement would usurp the proximate cause standard is not supported by the caselaw. Applying the direct-purchaser rule to plaintiffs' civil RICO claim, I dismiss plaintiffs' claim for lack of standing.

CONCLUSION

For the foregoing reasons, defendants' motion to dismiss the streamlined complaint is GRANTED.

SO ORDERED.

Brian M. Cogan

U.S.D.J.

Dated: Brooklyn, New York
October 29, 2024