24-3296-cv (L)
Sandra Yousefzadeh, et al., Newton's Pharmacy, Inc. v. Johnson & Johnson Consumer Inc., et al.

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

August Term 2025

(Argued: March 4, 2026 Decided: July 30, 2026)

Docket Nos. 24-3296 (L), 25-119 (CON)

SANDRA YOUSEFZADEH, ET AL.,
NEWTON'S PHARMACY, INC.,

Plaintiffs-Appellants,

GWEN THOMAS, RHONDA NITTO,

Plaintiffs,

- against -

JOHNSON & JOHNSON CONSUMER INC., RB HEALTH (US) LLC, TARGET CORPORATION, BAYER HEALTHCARE, LLC, A DELAWARE LIMITED LIABILITY CORPORATION, WALMART INC., A DELAWARE CORPORATION, CVS PHARMACY, INC., A DELAWARE CORPORATION, WALGREEN CO., AN ILLINOIS CORPORATION, THE PROCTER & GAMBLE COMPANY, HALEON US HOLDINGS LLC, PUBLIX SUPER MARKETS, INC., AMAZON.COM, INC., AMAZON.COM SERVICES LLC, KENVUE, INC., GLAXOSMITHKLINE LLC, RITE AID CORPORATION, ALBERTSONS COMPANIES, INC., COSTCO WHOLESALE CORP.,

Defendants-Appellees,

DOES 1-200, GLAXOSMITHKLINE CONSUMER HEALTHCARE HOLDINGS (US) LLC, RECKITT BENCKISER LLC, MERCK, MCNEIL CONSUMER HEALTHCARE, SANOFI-AVENTIS U.S. LLC, CHURCH & DWIGHT CO. INC., ASSOCIATED WHOLESALE GROCERS INC, VALU MERCHANDISERS CO., PFIZER INC., PERRIGO COMPANY PLC, HELEN OF TROY LIMITED, DIERBERGS MARKETS, INC., RECKITT BENCKISER PHARMACEUTICALS INC., THE KROGER CO., HARRIS TEETER, LLC, HARRIS TEETER SUPERMARKETS, INC., DOLGENCORP, INC. FAMILY DOLLAR, LLC.,

Defendants.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

Before:

RAGGI, CHIN, and PÉREZ, *Circuit Judges*.

Consolidated appeals from orders and final judgment of the United States District Court for the Eastern District of New York (Cogan, *J.*) dismissing all claims in nearly one hundred class actions against drug manufacturers and retailers. Plaintiffs, buyers of nasal decongestants, sued drug manufacturers for advertising and selling over-the-counter drugs allegedly known to be ineffective. Plaintiffs' cases were consolidated in this multidistrict litigation, after which plaintiffs filed a single representative complaint in the Eastern District of New

York raising state law claims and a federal claim under the Racketeer Influenced and Corrupt Organizations Act. The district court entered judgment for the defendant drug manufacturers, concluding that the Federal Food, Drug, and Cosmetic Act preempted plaintiffs' state law claims and that plaintiffs lacked statutory standing to bring their federal claim.

AFFIRMED in part, VACATED in part, and REMANDED for further proceedings consistent with this opinion.

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Christopher J. Walker, U.S. Chamber Litigation Center, Washington, D.C.; Robert E. Dunn, Isaac J. Weitzhandler, Eimer Stahl LLP, Campbell, CA, *for Amicus Curiae* Chamber of Commerce of the

United States of America, *in support of Defendants-Appellees.*

CHIN, *Circuit Judge*:

For decades, the Food and Drug Administration (the "FDA") and others recognized that oral phenylephrine ("oral PE") -- used in such popular products as Nyquil Severe Cold & Flu, Advil Sinus Congestion & Pain, and Mucinex Sinus Max -- was an effective nasal decongestant. Starting in 2007, however, scientific studies began casting doubt on that finding. Indeed, in 2016, some studies concluded that oral PE "[was] no more effective than [a] placebo" as a decongestant. App'x at 166-67. Yet, the FDA has continued to require manufacturers to adhere to its existing labeling requirements denoting oral PE as effective.

In this consolidated case, buyers of nasal decongestants contend that, in the past decade, drug manufacturers have sold some $12 billion's worth of purportedly ineffective nasal decongestants to consumers. After the scientific studies reported the nasal decongestants' alleged deficiency, consumers ("Consumer Plaintiffs") and other entities -- including retail pharmacy Newton's Pharmacy, Inc. ("NPI," and together with Consumer Plaintiffs, "Plaintiffs") -- filed

nearly one hundred class actions that were eventually consolidated in this multidistrict litigation. They allege, in sum, that the defendant drug manufacturers and retailers ("Defendant Manufacturers") produce, market, advertise, and sell nasal decongestants containing the active ingredient oral PE, despite having known since at least 2016 that oral PE does not, in fact, decongest.

In 2023, the Judicial Panel on Multidistrict Litigation consolidated Plaintiffs' putative class actions and transferred them to the Eastern District of New York. Plaintiffs then collectively filed an "initial streamlined" complaint (the "Complaint") raising claims representative of those brought in the underlying actions. App'x at 123-24. The Complaint alleged (1) New York state statutory and common-law claims against Defendant Manufacturers, *see* N.Y. Gen. Bus. Law §§ 349, 350; N.Y. U.C.C. Law. §§ 2-313, 2-314, and (2) a federal Racketeer Influenced and Corrupt Organizations Act ("RICO") claim against a subset of drug manufacturers ("RICO Defendants," and together with Defendant Manufacturers, "Defendants"), *see* 18 U.S.C. § 1962(c)-(d). In response, Defendants filed a motion to dismiss the Complaint for failure to state a claim.

After concluding that the Federal Food, Drug, and Cosmetic Act (the "FDCA") barred Plaintiffs' state law claims and that Plaintiffs lacked statutory

standing to bring their RICO claim, the United States District Court for the Eastern District of New York (Cogan, *J.*) granted Defendants' motion to dismiss.[1] It therefore entered judgment on November 12, 2024, dismissing all claims in all underlying cases in the multidistrict litigation, including NPI's Lanham Act claim, which the Complaint had not raised. *See In re Oral Phenylephrine Mktg. & Sales Pracs. Litig.*, 755 F. Supp. 3d 208 (E.D.N.Y. 2024). The district court also denied NPI's subsequent motion for reconsideration, which sought relief from the dismissal of its Lanham Act claim with prejudice. *In re Oral Phenylephrine Mktg. & Sales Pracs. Litig.*, No. 23-cv-9307, 2024 WL 5120039 (E.D.N.Y. Dec. 16, 2024). Plaintiffs now appeal the district court's orders and final judgment.

We hold that the FDCA expressly preempts the majority of Consumer Plaintiffs' state law claims and that Consumer Plaintiffs lack a cause of action to bring their RICO claim. Indeed, Defendant Manufacturers followed the FDA's prescribed labeling requirements by designating their decongestants'

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[1] Although the district court referred to its RICO analysis as a "statutory standing" inquiry, we have clarified that the "'statutory standing' appellation is 'misleading' and 'a misnomer.'" *Am. Psychiatric Ass'n v. Anthem Health Plans, Inc.*, 821 F.3d 352, 359 (2d Cir. 2016) (quoting *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 128 n.4 (2014)). Instead, "what has been called 'statutory standing' in fact is not a standing issue, but simply a question of whether the particular plaintiff 'has a cause of action under the statute.'" *Id.* (quoting *Lexmark Int'l, Inc.*, 572 U.S. at 128).

purpose as decongestion. Defendant Manufacturers cannot now be sued for complying with those FDA specifications. Therefore, the claim that Defendant Manufacturers mislabeled their products by indicating their use for decongestion fails. Accordingly, we AFFIRM the district court's entry of judgment for Defendant Manufacturers on the state law claims, with the exception that we VACATE as to (1) the "Maximum Strength" claims and (2) the claims regarding brand-name oral PE products approved through the FDCA's New Drug Application process. We also AFFIRM the district court's dismissal of Consumer Plaintiffs' civil RICO claim and the district court's denial of NPI's motion for reconsideration. Finally, we REMAND for further proceedings consistent with this opinion.

BACKGROUND

This case requires us to resolve three questions: first, whether the FDCA preempts Consumer Plaintiffs' state law claims; second, whether Consumer Plaintiffs have a cause of action to bring their RICO claim; and third, whether the district court abused its discretion in denying NPI's motion for reconsideration. Because answering the first question requires some familiarity with the "labyrinth" that is the FDCA, *see N.Y. State Rest. Ass'n v. N.Y.C. Bd. of*

Health, 556 F.3d 114, 117 (2d Cir. 2009), we begin with an overview of this statutory and regulatory regime. We then turn to the factual background and procedural history underlying this appeal.

I. *The FDCA*

We first describe the basics of the FDCA's over-the-counter ("OTC") drug regulation process. We then discuss each of the three FDCA labeling provisions upon which this appeal's preemption question hinges, namely: (1) the misbranding provision, 21 U.S.C. § 352(a)(1); (2) the "monograph" labeling requirements applicable to oral PE products, 21 C.F.R. § 330.1 and 21 C.F.R. § 341.80; and (3) the express preemption provision that ultimately dooms most of Consumer Plaintiffs' state law claims, 21 U.S.C. § 379r.

A. *The FDCA's OTC Drug Regulation and Approval Process*

Enacted in 1938, the FDCA, 21 U.S.C. § 301 *et seq.*, charges the FDA with ensuring the safety and efficacy of drugs, including by promulgating regulations. 21 U.S.C. § 393(b)(2)(B); *see id.* § 371(a).[2] Because the FDCA does not provide for a private right of action, individual plaintiffs may not sue directly

[2] While the statute vests "[t]he authority to promulgate regulations for the efficient enforcement of this chapter" in the Secretary of Health and Human Services, 21 U.S.C. § 371(a), the Secretary can delegate this authority to the FDA, pursuant to which the FDA Commissioner "may propose and promulgate regulations," 21 C.F.R. § 10.40.

under the FDCA to enforce the statute's provisions and regulations. *See* 21 U.S.C. § 337(a); *POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 109 (2014). Nevertheless, plaintiffs may bring state law misbranding claims that enforce "*state laws* imposing requirements identical to those contained in the FDCA." *Jackson-Mau v. Walgreen Co.*, 115 F.4th 121, 128 (2d Cir. 2024) (internal quotation marks omitted).

In accordance with the FDA's duties to regulate drugs, before a drug manufacturer may introduce a new drug into interstate commerce, the FDA must approve the drug and determine that it is "generally recognized as safe and effective," or "GRAS/E," for the use described in the drug's label. *Nat. Res. Def. Council, Inc. v. U.S. Food & Drug Admin.*, 710 F.3d 71, 75 (2d Cir. 2013); *see also* 21 U.S.C. §§ 321(p)(1), 355(a), 355h(a)(1). The FDCA establishes two mechanisms for evaluating whether OTC drugs -- such as the nasal decongestants at issue here -- are GRAS/E: (1) the New Drug Application ("NDA") process and (2) the monograph process. The NDA process governs select drugs at issue in this action, while the monograph process governs the rest.[3]

[3] The record is unclear as to which drugs involved in this lawsuit are regulated through the NDA process and which are regulated through the monograph process.

Under the NDA process, manufacturers seek, and the FDA may provide, premarket approval of a drug on an individualized basis. 21 U.S.C. § 355; 21 C.F.R. § 314. The manufacturer's NDA must contain proposed labeling. *Wyeth v. Levine*, 555 U.S. 555, 568 (2009); 21 U.S.C. § 355(b)(1)(A)(vi). The FDA will then approve the NDA only if it finds, *inter alia*, that the drug is "safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling," "substantial evidence [exists] that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling," and the proposed labeling is not "false or misleading in any particular." 21 U.S.C. § 355(d).

Meanwhile, under the monograph process, a manufacturer may sell an OTC drug *without* individualized FDA review if the drug and its label adhere to a "monograph" -- that is, a detailed regulation the FDA promulgates for certain therapeutic categories of drugs (with categories based on the purpose and uses of the drug). More specifically, a monograph establishes the FDA-approved active ingredients for a particular therapeutic class of drugs and identifies the conditions under which each active ingredient is GRAS/E. *Id.* § 355h; 21 C.F.R. § 330.10(a). If the drug and its label adhere to the appropriate monograph, the

FDA considers the drug to be GRAS/E. *See* 21 U.S.C. §§ 355, 355h; *see also Nat. Res. Def. Council, Inc.*, 710 F.3d at 75. If the drug and its label do not observe the monograph requirements, the drug is "liable to regulatory action" by the FDA. 21 C.F.R. § 330.1.

Notably, in 1994, the FDA published a final monograph determining that oral PE -- the active ingredient in the OTC drugs at issue in this case -- is GRAS/E as a nasal decongestant. 59 Fed. Reg. 43,386, 43,408 (Aug. 23, 1994). In March 2020, Congress converted the FDA's existing monographs for OTC drugs -- including the monograph covering oral PE -- to administrative orders, 21 U.S.C. § 355h(k)(2)(A), and affirmed that covered drugs must be "marketed in conformity with an administrative order," *id.* § 355h(b)(1)(B)(ii).

B. *The FDCA's Labeling Provisions and Regulations*

1. The FDCA's Misbranding Provision

To ensure the safety and efficacy of drugs on the market, the FDCA prohibits introducing into interstate commerce any drug "that is . . . misbranded." *Id.* § 331(a). Under the FDCA's misbranding provision, a drug "shall be deemed to be misbranded" if "its labeling is false or misleading in any particular." *Id.* § 352(a)(1). "All drugs, including those the Food and Drug Administration approves . . . , are subject to" the misbranding provision. 21 C.F.R. § 314.170. In

this case, as discussed below, the nasal decongestant monograph gives color to the meaning of "misbranded" as that term is used in the misbranding provision. *Id.* § 341.80 (nasal decongestant monograph clarifying that oral PE products are not misbranded if they adhere to certain requirements).

If a drug is alleged to be misbranded, "in determining whether the labeling or advertising is misleading there shall be taken into account (among other things)":

> not only *representations made or suggested by statement, word, design, device, or any combination thereof*, but also the extent to which the labeling or advertising *fails to reveal facts material in the light of such representations or material with respect to consequences which may result* from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.

21 U.S.C. § 321(n) (emphases added). The misbranding provision therefore prohibits not only affirmative misrepresentations but also failures to disclose material facts.

2. The Nasal Decongestant Monograph's Labeling Requirements

Under the FDCA regulations, oral PE is GRAS/E and an oral PE drug "*is not misbranded*" if it complies with (1) the requirements in the monograph for Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for

Over-the-Counter Human Use (the "nasal decongestant monograph"), 21 C.F.R. § 341.80, and (2) the general conditions established in 21 C.F.R. § 330.1. *See* 21 C.F.R. § 330.1 (emphasis added); *see also id.* § 341.1; 21 U.S.C. § 355h(a)(1)(A).

The nasal decongestant monograph mandates that an oral PE product's label set forth, in addition to certain warnings and directions, a Statement of Identity and Indications for use. *See* 21 C.F.R. § 341.80(a)-(b). The product's Statement of Identity must identify the product as a "nasal decongestant." *Id.* § 341.80(a). The product's Indications section must feature -- "as appropriate" -- the phrase "For the temporary relief of nasal congestion" or "Temporarily relieves nasal congestion." *Id.* § 341.80(b)(1). The label may additionally contain other phrases such as "Temporarily relieves nasal stuffiness" or "Decongests." *Id.* § 341.80(b)(2)(i)-(ii). The nasal decongestant monograph emphasizes that "[o]ther truthful and nonmisleading statements, describing only the indications for use . . . listed in . . . this section, may also be used . . . subject to the" misbranding provision. *Id.* § 341.80(b).

Meanwhile, 21 CFR § 330.1 establishes the general conditions by which oral PE products must abide. These conditions require the drug's label to include the Indications prescribed in the monograph "or alternative truthful and

nonmisleading statements" subject to the misbranding provision. *Id.* § 330.1(c)(2). Moreover, an OTC drug's advertising does not constitute misbranding if it "prescribes, recommends, or suggests [the drug's] use only under the conditions stated in the labeling." *Id.* § 330.1(d).

C. *The FDCA's Preemption Provision for Nonprescription Drugs*

Finally, the FDCA also features a preemption provision. Section 379r -- entitled "National uniformity for nonprescription drugs" -- states 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 and its regulations. 21 U.S.C. § 379r(a)(2). In relevant part, the preemption provision provides an exception for product liability claims. *Id.* § 379r(e).

As used in the preemption provision, the term "requirements" includes common-law duties. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 324 (2008); *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 443 (2005); *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 521 (1992). Thus, consumers may not sue under state law unless they are enforcing state law duties identical with a manufacturer's duties under the FDCA. *See Jackson-Mau v. Walgreen Co.*, 115 F.4th 121, 128 (2d Cir.

2024). The statute also specifies that preemptive effect extends to "any requirement relating to public information or any other form of public communication relating to a warning of any kind for a drug." 21 U.S.C. § 379r(c)(2).[4]

II. *Factual Background*[5]

In 1994, the FDA published a final monograph recognizing oral PE as effective for nasal decongestion. 59 Fed. Reg. 43,386, 43,408 (Aug. 23, 1994). Since then, for the past thirty years, the nasal decongestant monograph has required that manufacturers label their oral PE products as "decongestants" and indicate their use for decongestion. During that time, Defendant Manufacturers have produced and sold OTC nasal decongestants that utilize oral PE as an active ingredient. The products' labels have accordingly indicated their use for decongestion, as required.

By 2007, however, new scientific studies began to cast doubt on oral PE's efficacy as a nasal decongestant. These reports ignited a controversy that

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[4] This subsection is labeled "Safety or effectiveness," 21 U.S.C. § 379r(c)(2), and thus presumably extends to warnings about both safety and efficacy.

[5] We draw these facts, which we assume to be true for the purposes of this appeal, from Plaintiffs' Complaint. *See Galper v. JP Morgan Chase Bank, N.A.*, 802 F.3d 437, 443 (2d Cir. 2015).

continued to smolder for the next decade. Around this time, RICO Defendants began "[i]nfiltrat[ing]" the Consumer Health Products Association (the "CHPA"), a national trade association of manufacturers and marketers of consumer healthcare products. App'x at 153. The CHPA, steered by RICO Defendants, then hid the inefficacy of oral PE from consumers and delayed the FDA's review of oral PE's efficacy by issuing deceptive press releases and misrepresenting the available scientific evidence about oral PE. Consequently, in 2007, the FDA's Nonprescription Drugs Advisory Committee (the "NDAC") -- which provides the FDA with non-binding advice, *see* 21 C.F.R. §§ 14.40, 14.100(c)(15) -- declined to recommend changes to the FDA's original approval of oral PE as a nasal decongestant. The NDAC instead informed the FDA that, due to the limitations of the available data (which RICO Defendants had misconstrued through the CHPA), additional studies were required to evaluate the efficacy of oral PE. The final nasal decongestant monograph, classifying oral PE as GRAS/E, thus remained in effect.

Over the next ten years, scientific studies surrounding oral PE continued to emerge and develop. By 2016, the science had made "crystal clear" that oral PE "[was] no more effective than [a] placebo" for decongestion. App'x at

166-67. Yet the FDA did not reverse course or revoke oral PE's status as GRAS/E for decongestion, and Defendant Manufacturers continued to market, advertise, and label their oral PE products as effective nasal decongestants, in compliance with the nasal decongestant monograph.[6] Since becoming aware of oral PE's ineffectiveness by no later than 2016, Defendant Manufacturers have sold at least $12 billion in oral PE nasal decongestants.

In 2020, the FDA converted the nasal decongestant monograph into a final administrative order, again recognizing oral PE as GRAS/E when used as a nasal decongestant. *See* U.S. Food & Drug Admin., Final Administrative Order OTC000026: Over-the-Counter Monograph M012: Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use (effective Mar. 27, 2020). In September 2023, though, the FDA convened the NDAC panel of experts to again review oral PE's efficacy. At the end of the meeting, the NDAC concluded, by a unanimous vote of 16-0, that oral PE

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[6] Though of course Defendant Manufacturers were not required to sell their oral PE products in the first place, the Supreme Court has rejected the idea that manufacturers must pull their products from the market if they cannot otherwise comply with both federal and state law. *See Mut. Pharm. Co., Inc. v. Bartlett*, 570 U.S. 472, 475, 488 (2013) ("We reject this 'stop-selling' rationale as incompatible with our pre-emption jurisprudence. Our pre-emption cases presume that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability.").

products were ineffective as nasal decongestants. These lawsuits were filed shortly thereafter.

After the NDAC issued its conclusion, in November 2024, the FDA proposed an administrative order that would remove oral PE from the nasal decongestant monograph. The FDA explained that "an agency review of the available data [had] determined that oral phenylephrine is not effective for [temporary relief of nasal congestion]." *FDA Proposes Ending Use of Oral Phenylephrine as OTC Monograph Nasal Decongestant Active Ingredient After Extensive Review*, U.S. Food & Drug Admin. (Nov. 7, 2024), https://www.fda.gov/news-events/press-announcements/fda-proposes-ending-use-oral-phenylephrine-otc-monograph-nasal-decongestant-active-ingredient-after [https://perma.cc/ZM6X-5LTE]. The agency based its determination on a "comprehensive review of all available data on the safety and efficacy of oral phenylephrine." *Id.* Nonetheless, as oral PE is still considered GRAS/E until the administrative order becomes final, the FDA decreed that, "[f]or now, companies may continue to market OTC monograph drug products containing [oral PE] as a nasal decongestant." *Id.*

III. *Procedural Background*

In December 2023, the Judicial Panel on Multidistrict Litigation transferred Plaintiffs' nearly one hundred putative class actions to the Eastern District of New York for consolidated pretrial proceedings.[7] The district court then ordered the parties to engage in a "bellwether" process to test claims and defenses common across the consolidated cases. App'x at 131. Accordingly, Plaintiffs filed the Complaint alleging New York state law claims and a federal civil RICO claim. Plaintiffs' state law claims allege that Defendant Manufacturers misled them by falsely labeling and advertising their oral PE products as effective for nasal decongestion. The RICO claim alleges that RICO Defendants committed mail and wire fraud in furtherance of a scheme to defraud the public and fool the FDA into believing that oral PE works as a decongestant.

In October 2024, the district court granted Defendants' motion to dismiss the Complaint for failure to state a claim, holding that the FDCA preempts Consumer Plaintiffs' state law claims and that Consumer Plaintiffs

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[7] This consolidation included NPI's class action filed in the Southern District of Ohio, which alleged claims under state law and under the Lanham Act, 15 U.S.C. § 1125(a), for false advertising.

lacked standing to pursue their RICO claim. The district court accordingly entered judgment dismissing all claims in all underlying cases in the multidistrict litigation -- including NPI's Lanham Act claim, which the Complaint did not contain and which the district court's decision did not address. *See* 755 F. Supp. 3d at 219**.** Consumer Plaintiffs filed a timely notice of appeal from the district court's judgment. Meanwhile, NPI moved for partial relief from the final judgment under Federal Rules of Civil Procedure 60(b)(1) and 60(b)(6), requesting that the district court reconsider its dismissal of NPI's Lanham Act claim. After the district court denied the motion for reconsideration, *see* 2024 WL 5120039, at *2, NPI filed a timely notice of appeal from that order.

On appeal, Consumer Plaintiffs contend that this Court should (1) reverse the district court's dismissal of their state law claims on preemption grounds and (2) reverse the district court's dismissal of their RICO claim on "statutory standing" grounds. NPI asks this Court to reverse the district court's order denying its motion for partial relief from the final judgment on its Lanham Act claim.

DISCUSSION

We first discuss the FDCA's preemptive effect on Consumer Plaintiffs' state law claims. We next proceed to Consumer Plaintiffs' right to sue under civil RICO. Finally, we conclude by assessing NPI's challenge to the district court's denial of its motion for reconsideration.

I. *The FDCA's Express Preemption of State Law Claims*

Defendant Manufacturers contend, and the district court ruled, that the FDCA expressly preempts Consumer Plaintiffs' state law claims because those claims would impose on Defendant Manufacturers requirements that are "different from," "in addition to," or "otherwise not identical with" labeling requirements under the FDCA (and specifically, under the nasal decongestant monograph). *See* 21 U.S.C. § 379r(a)(2). Consumer Plaintiffs counter that the FDCA does not preempt their state law claims, as those claims would simply enforce Defendant Manufacturers' duty under the FDCA's misbranding provision not to falsely or misleadingly label their drugs. *See id.* § 352(a)(1). We conclude that, with two exceptions, the FDCA expressly preempts Consumer Plaintiffs' state law claims.

A. ***Standard of Review***

We review *de novo* a district court's grant of a motion to dismiss on preemption grounds. *DCC Propane, LLC v. KMT Enters., Inc.*, 147 F.4th 171, 174 (2d Cir. 2025).[8] At this stage, we accept a complaint's factual allegations as true and view them in the light most favorable to the plaintiff. *Galper v. JP Morgan Chase Bank, N.A.*, 802 F.3d 437, 443 (2d Cir. 2015). Accordingly, we "may find a claim preempted only if the facts alleged in the complaint do not plausibly give rise to a claim that is not preempted." *Id.* at 444.

B. ***Applicable Preemption Law***

The Supremacy Clause provides 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. Consequently, federal legislation may preempt state law. *Galper*, 802 F.3d at 443. Federal regulations, like federal statutes, can also preempt state law if validly promulgated and falling within the scope of the agency's congressionally delegated authority. *Hillsborough County v. Automated Med. Lab'ys, Inc.*, 471 U.S.

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[8] Preemption -- although an affirmative defense -- can support a motion to dismiss if the "barrier to suit is evident from the face of the complaint." *Glover v. Bausch & Lomb Inc.*, 6 F.4th 229, 236 n.3 (2d Cir. 2021) (quoting *Ricci v. Teamsters Union Loc. 456*, 781 F.3d 25, 28 (2d Cir. 2015)).

707, 713 (1985); *New York v. F.E.R.C.*, 535 U.S. 1, 18 (2002). Here, the FDCA authorizes the FDA to promulgate regulations, including labeling requirements, that govern OTC drugs; these regulations therefore fall within the scope of the FDA's authority and have preemptive effect. 21 U.S.C. § 393(b)(2)(B); *id.* § 355h(a)(1)(A).[9]

Congress may preempt state law either expressly, through a statute's text, or impliedly, "through [a statute's] structure and purpose." *Altria Grp., Inc. v. Good*, 555 U.S. 70, 76 (2008). When a federal law contains an *express* preemption clause -- as here -- "we focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' preemptive intent."

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[9] To the extent Consumer Plaintiffs contend that *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024), upends this rule by overturning *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), and ending the era of *Chevron* deference, that argument fails. Following *Loper Bright*, courts reviewing agency action must "exercise their *independent* judgment in" interpreting statutes and in "deciding whether an agency has acted within its statutory authority." 603 U.S. at 412 (emphasis added). A statute may nevertheless still authorize an agency to "give meaning to a particular statutory term," *id.* at 394, and to "prescribe rules to 'fill up the details' of a statutory scheme" through regulation, *id.* at 395 (quoting *Wayman v. Southard*, 10 Wheat. 1, 43 (1825)). Thus, *Loper Bright* does *not* subvert agencies' authority to promulgate preemptive regulations pursuant to the authority vested in them by statute -- authority the FDCA vests in the FDA here. Indeed, the Supreme Court has given preemptive effect to federal regulations since before *Chevron*. *See, e.g.*, *Fidelity Fed. Savs. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153-54 (1982); *United States v. Shimer*, 367 U.S. 374, 381-83 (1961).

Chamber of Com. of U.S. v. Whiting, 563 U.S. 582, 594 (2011) (internal quotation marks omitted). In other words, when an express preemption clause exists, the plain text of the statute begins and ends our analysis, and courts should not invoke the presumption against preemption. *Puerto Rico v. Franklin Cal. Tax-free Tr.*, 579 U.S. 115, 125 (2016); *DCC Propane*, 147 F.4th at 174. *But cf. Good*, 555 U.S. at 77 (noting that when "the text of a pre-emption clause is susceptible of more than one plausible reading," courts typically accept the interpretation disfavoring pre-emption).

The mere existence of an express preemption clause, however, "does not immediately end the inquiry"; the court must interpret the clause to determine "the *substance and scope* of Congress' displacement of state law." *Good*, 555 U.S. at 76 (emphasis added). "Our inquiry into the scope of a statute's pre-emptive effect is guided by the rule that '"[t]he purpose of Congress is the ultimate touchstone" in every pre-emption case.'" *Id.* (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)). To determine Congress's preemptive intent, we "begin . . . with the text of the provision in question, and move on, as need be, to the structure and purpose of the Act." *N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 655 (1995).

C. *Section 379r Expressly Preempts Consumer Plaintiffs' State Law Claims*

As explained above, the FDCA expressly preempts state law claims seeking to enforce state law duties "different from or in addition to, or . . . otherwise not identical with," requirements under federal law. 21 U.S.C. § 379r(a)(2). Accordingly, to decide whether the FDCA expressly preempts Consumer Plaintiffs' state law claims, we must answer two questions. First, we must determine whether the federal government has instituted requirements applicable to the oral PE nasal decongestants at issue. Looking to the FDA's monograph and NDA requirements, we easily answer this first question in the affirmative.

Second, we must resolve whether the Consumer Plaintiffs' state law claims are premised on state law requirements "different from or in addition to, or . . . otherwise not identical with" those federal requirements. *Id.* In other words, we ask if successful state law claims here would hold Defendant Manufacturers liable for labeling (or advertising) approved by the FDCA through the monograph or NDA process. This second question is the subject of our analysis below. Ultimately, we conclude that the answer to this question is also yes, except as to two sets of claims.

We therefore hold that the FDCA expressly preempts Consumer Plaintiffs' claims except as to the "Maximum Strength" claims and as to the claims concerning brand-name NDA drugs. To reach this conclusion, we first analyze the FDCA's express preemption of state law claims regarding oral PE drugs regulated through the *monograph* process -- including (a) Consumer Plaintiffs' labeling claims, (b) their failure-to-disclose marketing and advertising claims, and (c) their "Maximum Strength" claims. Second, we briefly discuss the FDCA's preemption of state law claims regarding oral PE drugs regulated through the *NDA* process.

1. Monograph Drugs

The crux of Consumer Plaintiffs' state law claims is that Defendant Manufacturers misled them by labeling, advertising, and marketing oral PE products as effective for nasal decongestion, thus deceiving Consumer Plaintiffs into purchasing products they would not have bought had they known the truth about oral PE's inefficacy.[10] Consumer Plaintiffs bring three main buckets of state law claims.

[10] Specifically, Consumer Plaintiffs challenge the "Indications" section of the products' labels, which states that the products decongest. They do not challenge the "Statement of Identity" section, which identifies the products as decongestants.

First, Consumer Plaintiffs contend that Defendant Manufacturers misbranded their drugs by adhering to the nasal decongestant monograph's Indications requirement, which instructs that oral PE products' labels must indicate the drug's use for nasal decongestion (the "labeling claims"). *Second*, Consumer Plaintiffs challenge Defendant Manufacturers' failure to disclose in their advertising and marketing that oral PE does not actually decongest (the "failure-to-disclose claims"). Finally, *third*, Consumer Plaintiffs bring claims based on Defendant Manufacturers' assertions -- on their oral PE products' packaging and elsewhere -- that their drugs are "Maximum Strength" (the "Maximum Strength claims"). We discuss each of these three buckets of claims in turn.

a. Labeling Claims

i. Section 379r Preempts Consumer Plaintiffs' Labeling Claims

If a drug's label satisfies the FDCA's and the appropriate monograph's labeling requirements, consumers generally may not challenge the drug's labeling under state law mislabeling theories. *See Jackson-Mau*, 115 F.4th at 128. Here, the nasal decongestant monograph requires that Defendant Manufacturers indicate their oral PE products' purpose as nasal decongestion;

Defendant Manufacturers' labels satisfy that federal requirement. Consumer Plaintiffs nevertheless claim that, under state law, oral PE products *cannot* be labeled as effective nasal decongestants (or must include disclaimers).

In other words, taking Consumer Plaintiffs' allegations as true, "[f]ederal law requires a very specific label for [oral PE products], and state law forbids the use of that label." *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 490 (2013). The upshot is that state law imposes requirements "different from or in addition to, or . . . otherwise not identical with," federal requirements. *See* 21 U.S.C. § 379r(a)(2). The FDCA's "expansive" express preemption provision, § 379r, therefore forecloses Consumer Plaintiffs' state law claims. *See Jackson-Mau*, 115 F.4th at 127-28; *see also Collaza v. Johnson & Johnson Consumer, Inc.*, No. 23-cv-6030, 2024 WL 3965933, at *5 (S.D.N.Y. Aug. 27, 2024) (holding that FDCA preempted state law claims in case challenging allegedly deceptive labeling, pricing, and marketing of Tylenol Extra Strength Rapid Release Gelcaps), *aff'd mem.*, No. 24-2568-cv, 2025 WL 2233746 (2d Cir. Aug. 6, 2025) (summary order).

Consumer Plaintiffs contend that the FDCA's misbranding provision compels a different result because it forbids labeling that "is false or misleading in any particular." 21 U.S.C. § 352(a)(1). Thus, according to Consumer Plaintiffs,

state law does not impose any requirements that differ from those the FDCA itself imposes -- both demand that drug manufacturers not mislabel or misbrand their products. We are not persuaded. Under the nasal decongestant monograph, an oral PE product cannot be considered "misbranded" by virtue of its compliance with the requirements established in 21 C.F.R. § 330.1 and the monograph -- including the condition that the product's label indicate its approved use as a nasal decongestant. *See* 21 C.F.R. § 341.80; *see also id.* § 341.1. Because Defendant Manufacturers' products fulfill these requirements, their drugs are not misbranded, as that term is used in the FDCA, and do not violate the misbranding provision.[11]

We reached the same conclusion under similar circumstances in *Critcher v. L'Oreal USA, Inc.*, 959 F.3d 31 (2d Cir. 2020). In *Critcher*, the plaintiffs claimed that L'Oreal had violated state law by selling liquid cosmetics whose labels "omitted certain critical information" about the amount of dispensable liquid within the container (as the containers prevented consumers from actually dispensing the full amount of liquid). *Id.* at 36. The cosmetics labels, however,

[11] We acknowledge that the FDCA's regulatory provisions "sometimes appear to conflict" and can seem "difficult to harmonize." *See N.Y. State Rest. Ass'n*, 556 F.3d at 117.

conformed to the FDCA regulations governing what product quantity to list on the label. *Id.* Nonetheless, as here, the plaintiffs asserted that compliance with this federal labeling regulation resulted in a violation of the FDCA's misbranding provision. *Id.*

In holding that the FDCA expressly preempted the plaintiffs' state law claims, this Court pointed to the FDCA's cosmetics preemption provision, which -- similar to the OTC preemption provision at issue here -- forbids any requirement "for labeling or packaging of a cosmetic that is different from or in addition to, or that is otherwise not identical with, a requirement" under the FDCA. *Id.* at 35 (quoting 21 U.S.C. § 379s(a)). The court explained that, under this express preemption provision, the general misbranding provision could not "be read to impose the particular labeling additions" the plaintiffs sought under state law theories. *Id.* at 38. Indeed, the court reasoned that if the plaintiffs were permitted to pursue their state law claims (by arguing that those claims were merely enforcing the misbranding provision), they would be "using state law to impose labeling requirements on top of those already mandated in the FDCA and the regulations promulgated thereunder. . . . This is exactly what the FDCA

does not permit." *Id.* at 36. So, too, here. The FDCA's misbranding provision does not unlatch an escape hatch for Consumer Plaintiffs' state law claims.[12]

This Court recently affirmed *Critcher*'s reasoning in *Jackson-Mau v. Walgreen Co.*, 115 F.4th 121 (2d Cir. 2024). There, we relied on *Critcher* to hold that the FDCA preempted the plaintiff's state law claims that a dietary supplement she purchased was "mislabeled." *Id.* at 123. As with OTC drugs, the FDCA includes a preemption provision for food -- including dietary supplements -- that renders ineffective any state requirement that is "not identical" to the FDCA's labeling requirements for that food. *Id.* at 126. Thus, if a dietary supplement satisfies the FDCA's labeling requirements, "consumers may not attack the supplement's labeling under similar state law mislabeling theories." *Id.* at 128 (internal quotation marks omitted). That same logic applies here in the OTC drug context. Thus, the FDCA preempts Consumer Plaintiffs'

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[12] The Ninth Circuit has gone the opposite route, holding under similar circumstances that the FDCA did not preempt consumer plaintiffs' claim that state law required a manufacturer to include supplemental statements on the label about product accessibility. *Ebner v. Fresh, Inc.*, 838 F.3d 958, 964 (9th Cir. 2016). The Ninth Circuit reasoned that the plaintiffs were enforcing the FDCA's cosmetics misbranding provision, which -- like state law -- prohibited the false or misleading labeling of a cosmetic. *Id.* Thus, in the Ninth Circuit's view, the state law duty was identical to the manufacturer's federal duty: "the duty to avoid false or misleading labeling." *Id.* at 965. For reasons explained in the text, we do not agree.

state law mislabeling claims because Defendant Manufacturers' products comply with the nasal decongestant monograph's labeling requirements.

ii. Monograph Drug Manufacturers Cannot Independently Change Their Drugs' Labels

Consumer Plaintiffs contend that, regardless of the monograph requirements, Defendant Manufacturers had a duty to independently update their labels without prior FDA approval, in light of new scientific evidence undermining the efficacy of oral PE as a nasal decongestant. Unlike for other drugs, however, the FDCA and its regulations do not allow Defendant Manufacturers to independently update the labels of their monograph drugs to reflect new information about a drug's efficacy.[13]

The lack of this option for monograph drugs is telling, particularly in light of the FDA's provision of just such a possibility for brand-name NDA

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[13] Consumer Plaintiffs point to a number of cases suggesting that manufacturers have a responsibility to update their drug labels based on new and scientifically significant information -- but those cases specifically evaluate the FDCA's provisions and regulations relating to the labels of *prescription* drugs, which are approved through the NDA (not monograph) process. *See Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S. 299, 303 (2019) ("The federal law that we consider is the statutory and regulatory scheme through which the FDA regulates the information that appears on *brand-name prescription drug labels*." (emphasis added)); *Bartlett*, 570 U.S. at 492-93 (emphasizing that the FDCA's treatment of *prescription* drugs lacks either an express preemption clause or an express non-preemption clause, unlike in the OTC drug context); *Wyeth*, 555 U.S. at 567 (highlighting that Congress declined to enact an express preemption provision for *prescription* drugs).

drugs. Under the FDA's "changes-being-effected" ("CBE") regulation, manufacturers of brand-name drugs (but not generic drugs) approved through the NDA process *can* unilaterally change their labels without prior FDA approval. *See* 21 C.F.R. § 314.70(c)(6)(iii) (the "CBE regulation"); *Wyeth*, 555 U.S. at 568. Manufacturers may do so if the change "reflect[s] newly acquired information" about the safety or efficacy of a drug approved through the NDA process. 21 C.F.R. § 314.70(c)(6)(iii). The Supreme Court has held that, if a brand-name NDA holder can update its label under the CBE process but does not do so, it may be held liable under state law mislabeling theories. *Wyeth*, 555 U.S. at 571.

It is also revealing that the FDCA defines a drug as "misbranded" if it poses a "danger[] to *health*" when used as "recommended[] or suggested in [its] labeling." 21 U.S.C. § 352(j) (emphasis added). Presumably, then, a monograph drug could be considered misbranded if it has a dangerous effect on the user, even when the drug's label conforms to the monograph requirements, thus allowing a manufacturer to add a safety disclaimer to the product's label. *See Rutledge v. Walgreen Co.*, No. 24-916-cv(L), 2026 WL 2015284, at *23 (2d Cir. July 13, 2026) (holding that the FDA's Pregnancy Warning Regulation "does not

prohibit manufacturers from adding supplemental warnings [to acetaminophen products] when additional, pregnancy-related risks become known"). The FDCA, however, does not define a monograph drug as automatically misbranded if it is simply *ineffective* when used as recommended or suggested in the label.

Thus, the FDA can and does impose additional labeling requirements in certain circumstances. Yet it has declined to do so for OTC monograph drugs alleged to be ineffective. *Cf. Bartlett*, 570 U.S. at 486 (holding that the FDCA prevents generic NDA holders from changing their labels, and thus the FDCA preempted alleged state law duty that would have required the generic drug manufacturer to change the drug's label "so as to render [it] not 'unreasonably dangerous'"). Because monograph drug manufacturers cannot utilize the CBE process to unilaterally change their labels' efficacy information, contrary to Consumer Plaintiffs' suggestion, their obligation is to conform to the applicable monograph, not to update their labels to reflect new scientific evidence. Therefore, § 379r bars Consumer Plaintiffs' claims as to monograph drugs. *See Gibbons v. Bristol-Myers Squibb Co.*, 919 F.3d 699, 707 (2d Cir. 2019) (emphasizing that although "'manufacturers, not the FDA, bear primary

responsibility for their drug labeling at all times,' . . . drug manufacturers are limited in their ability to unilaterally change the labels on their products" and must comply with the CBE regulation if they wish to do so (quoting *Wyeth*, 555 U.S. at 579)).

Consumer Plaintiffs also argue that federal law does not *prevent* Defendant Manufacturers from making additional disclosures or updates about the efficacy of oral PE, as evidenced by Johnson & Johnson's website disclosure acknowledging the NDAC's 2023 findings. That may be true. To *require* manufacturers to make those disclosures or updates, though, would be to impose an additional requirement beyond the FDCA's mandates.[14] Moreover, any such

[14] Our interpretation is consistent with the Supreme Court's recent decision in *Monsanto Co. v. Durnell*, 146 S. Ct. 2001 (2026), which addressed the scope of a similarly worded preemption provision in the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"). *See* 7 U.S.C. § 136v(b) (providing that states "shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required" under FIFRA). There, the Supreme Court resolved a circuit split "over whether FIFRA preempts a state tort claim based on [a pesticide's] lack of a cancer warning." *Durnell*, 146 S. Ct. at 2010. *Compare, e.g.*, *Schaffner v. Monsanto Corp.*, 113 F.4th 364, 399 (3d Cir. 2024) (holding that FIFRA preemption applies), *with Hardeman v. Monsanto Co.*, 997 F.3d 941, 954 (9th Cir. 2021) (reaching the opposite conclusion). The Supreme Court held that FIFRA's preemption clause expressly preempted the "failure-to-warn" claim under Missouri law, "which would require a cancer warning on the [pesticide] label" and "impose a labeling requirement that is 'in addition to or different from' federal labeling requirements imposed 'under' FIFRA." *Durnell*, 146 S. Ct. at 2010.

compulsory language would not be permissible if it was inconsistent with the statements required by the FDA.[15] Thus, the preemption provision renders null any such state law requirement. We accordingly affirm the district court's dismissal of these labeling claims.

b. Failure-to-Disclose Marketing and Advertising Claims

Consumer Plaintiffs further claim that Defendant Manufacturers failed to disclose their oral PE products' ineffectiveness in their marketing and advertising materials. They assert that the nasal decongestant monograph does not preempt these claims because the monograph only concerns labeling statements, not marketing and advertising statements. We conclude otherwise and hold that these failure-to-disclose claims are also preempted.

The express preemption provision voids state law marketing and advertising claims, not only labeling claims. *See* 21 U.S.C. § 379r(c)(2) (subsection

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The Supreme Court also noted that allowing the failure-to-warn claim "to overcome preemption would affect more than FIFRA." *Id.* at 2012 (citing 21 U.S.C. § 379r(a)(2) in acknowledging that "similar labeling preemption clauses reflect Congress's judgment that the ability to sell a product throughout the country with a single label can be important to maintaining an efficient nationwide market").

[15] Additionally, the FDCA's regulations do not permit on a label a "statement of differences of opinion with respect to the effectiveness of a drug unless each of the opinions expressed is supported by substantial evidence of effectiveness." 21 C.F.R. § 1.21(c)(2) (regulation under "General Enforcement Regulations" section).

of § 379r labeled "Safety or effectiveness," specifying that its preemptive effect extends to "any requirement relating to public information or any other form of public communication relating to a warning of any kind for a drug"). Indeed, the FDCA's regulations encompass marketing and advertising statements, not merely labeling statements; under the federal regulations, an OTC drug is not "misbranded" if, *inter alia*, the advertising for the drug "prescribes, recommends, or suggests its use only under the conditions stated in the labeling." 21 C.F.R. § 330.1(d). Thus, the oral PE products here are not misbranded if the advertising only recommends their use for decongestion.

The failure-to-disclose claims, however, would indeed premise Defendant Manufacturers' liability on their advertisements' recommendation that consumers use their oral PE products for decongestion. The failure-to-disclose claims would thus create an end-run around federal labeling regulations by essentially forcing Defendant Manufacturers to add language to their advertisements disclosing that their products are actually *not* effective nasal decongestants, when the nasal decongestant monograph requires them to label their oral PE products in precisely the opposite way. Such additional forced advertising disclosures would clearly conflict with the nasal decongestant

monograph, which already "state[s], with specificity, what information is necessary to avoid misleading consumers," such that "[i]f we were to impose [these] *additional* labeling requirements, we would be construing state law to impose many 'requirements' that are not contained in the federal statute." *Critcher*, 959 F.3d at 38; *see also Collaza*, 2024 WL 3965933, at *4-5 (holding that the FDCA preempted the plaintiff's similar claims for false and misleading advertising based on monograph-approved product descriptors). Accordingly, the failure-to-disclose claims would enforce state law requirements "in addition to" or "not identical" with the FDCA's requirements. The FDCA thus preempts the failure-to-disclose claims, and we affirm the district court's dismissal of them.[16]

[16] This approach mirrors one the Fourth, Fifth, Seventh, Ninth, and Eleventh Circuits have taken in addressing the scope of FIFRA's near-identical preemption provision. *See* 7 U.S.C. § 136v(b) (providing that states "shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required" under FIFRA). These Circuits have held that, under FIFRA, even claims regarding "off-label statements" are preempted if the basis for liability is a statement that "merely repeat[s]" information from the label. *See Andrus v. AgrEvo USA Co.*, 178 F.3d 395, 400 (5th Cir. 1999); *accord Lowe v. Sporicidin Int'l*, 47 F.3d 124, 130 (4th Cir. 1995); *Kuiper v. Am. Cyanamid Co.*, 131 F.3d 656, 662 (7th Cir. 1997); *Taylor AG Indus. v. Pure-Gro*, 54 F.3d 555, 561 (9th Cir. 1995); *Papas v. Upjohn Co.*, 985 F.2d 516, 519 (11th Cir. 1993).

c. "Maximum Strength" Claims[17]

Finally, Consumer Plaintiffs argue that, by placing the phrases "Maximum Strength" or "Max Strength" on certain products, Defendant Manufacturers falsely claim that their products work better than other oral nasal decongestants, such as pseudoephedrine.[18] These Maximum Strength claims

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[17] The "Maximum Strength" products are sold by companies such as Johnson & Johnson, Procter & Gamble Company ("P&G"), RB Health (US) LLC ("RB"), Walgreens, CVS, and Target. These drugs include, but are not limited to, Sudafed PE Sinus Pressure + Pain Maximum Strength (Johnson & Johnson), Vicks NyQuil Severe Maximum Strength Cold & Flu Berry Flavored Liquid Medicine (P&G), Mucinex Maximum Strength Sinus-Max Day & Night (RB), Walgreens Daytime Severe Cold & Flu Maximum Strength (Walgreens), CVS Health Non-Drowsy Nasal Decongestant PE Maximum Strength (CVS), and Acetaminophen Day/Night Time Vapor Ice Cold and Flu Relief Caplets (Target). While multiple other lawsuits bring Maximum Strength claims, the Panel on Multidistrict Litigation excluded those actions from this MDL. *See* NPI Sp. App'x at 2-3.

[18] Defendant Manufacturers contend that Consumer Plaintiffs forfeited this theory by failing to raise it before the district court. Specifically, Defendant Manufacturers argue that, in the Complaint and briefing below, Consumer Plaintiffs' Maximum Strength challenge "was derivative of their ineffectiveness theory," rather than on a theory that "maximum strength" is a claim of *comparative* strength. Appellees' Br. at 38. The district court appears to have concluded similarly, writing in a footnote that the descriptors "maximum strength" or "[suited for] severe symptoms" "are only false and misleading if PE is ineffective." Consumer Pls. Sp. App'x at 9 & n.2. We disagree that Consumer Plaintiffs did not pursue this theory below. *See* App'x at 152 n.19 ("*[O]ther* non-prescription pseudoephedrine oral decongestants exist . . . that unequivocally *work better*." (emphases added)); *id.* at 151 (Defendant "goes so far as to call its product 'Maximum Strength,' despite the product having been proven by multiple studies . . . to have no efficacy greater than placebo (*much less [products containing] pseudoephedrine*)." (emphasis added)). While Plaintiffs properly raised their comparative strength claims as to the "Maximum Strength" statements, however, we agree with the district court that the "severe symptoms" statements do not amount to comparative strength assertions.

stand on different footing than the labeling and failure-to-disclose claims and are not preempted.

Defendant Manufacturers point to no FDCA provision or regulation that addresses phrases such as "Maximum Strength" or claims of comparative strength. Thus, we conclude that the FDCA does not require, nor has it blessed, Defendant Manufacturers' inclusion of these phrases on their oral PE products' labels. Defendant Manufacturers therefore *voluntarily* and on their own accord placed these Maximum Strength statements on their products; they were not obligated to do so. Consequently, these additional statements are subject to the misbranding provision's requirements and cannot be rescued by the monograph or approved NDAs. *See* 21 C.F.R. § 341.80(b) ("Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed . . . , may also be used . . . *subject to the provisions of [the misbranding provision].*" (emphasis added)); *id.* § 330.1(c)(2) ("The '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*

[the misbranding provision.]" (emphasis added)). Holding Defendant Manufacturers liable for their purportedly false Maximum Strength promises therefore would not impose state law requirements that diverge from federal requirements, as long as the state law requirements are identical to the misbranding provision's requirements. *See Astiana v. Hain Celestial Grp.*, 783 F.3d 753, 758 (9th Cir. 2015) (holding that FDCA did not preempt plaintiffs' state law claims -- alleging that statements "All Natural" and "Pure Natural" were false, deceptive, and misleading -- because FDA regulations did not require defendant to label its products with those terms).[19]

Our precedents support this conclusion. In *Bates v. Dow Agrosciences LLC*, for example, the Supreme Court concluded that the Federal Insecticide,

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[19] Our breach-of-express-warranty caselaw offers support for this logic, and particularly for Consumer Plaintiffs' breach-of-express-warranty Maximum Strength claims. After all, express promises, unless required by law, are "undertaken by the manufacturer itself," *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 526 (1992), and are not required by state law, *see Bates*, 544 U.S. at 444-45. Indeed, state law express warranty rules do not require manufacturers to "label . . . their products in any *particular* way"; they require only that, if a manufacturer *does* promise a particular quality in their product, that promise be accurate. *Id.* (emphasis added). Consequently, a manufacturer's state law liability for breach of express warranty arises from the *terms of the warranty* the *manufacturer* voluntarily undertook -- and therefore the *manufacturer*, not state law, imposes the warranty requirement. *See Cipollone*, 505 U.S. at 525. Thus, although state law may impose a general duty not to breach warranties, the *particular* requirements imposed on the manufacturer in an express warranty claim arise from the manufacturer's own voluntary statements. *Id.*

Fungicide, and Rodenticide Act's similarly worded preemption clause -- which expressly preempted state labeling requirements that differed from federal labeling requirements -- did *not* bar the plaintiffs' state law claims that were based on the defendant manufacturers' breach of voluntarily undertaken warranties placed on their products' labels. 544 U.S. at 448-49. The *Bates* court underscored that the preemption provision voided only state law requirements "*in addition to or different from*" federal requirements -- not *all* requirements related to labeling or packaging. *Id.* (emphasis added). The court cautioned against "reading those words out of the statute, which would leave the following: 'Such State shall not impose or continue in effect *any* requirements for labeling or packaging.'" *Id.* (emphasis added).

Here, too, reading the words "different from or in addition to, or . . . otherwise not identical with" out of § 379r would violate the canon against surplusage. Because the nasal decongestant monograph and FDCA are silent on claims of comparative strength, allowing the Maximum Strength claims to proceed would not enforce state law requirements "different from or in addition to, or . . . otherwise not identical with" federal requirements. 21 U.S.C. § 379r(a)(2). Allowing the claims to proceed may instead merely invoke state law

requirements that are compatible with the monograph and that are identical to, or "equivalent" with, the misbranding provision's ban on "false or misleading" statements. *Bates*, 544 U.S. at 449.

We therefore vacate and remand to the district court as to the Maximum Strength claims, to determine (1) whether the state law duties here are identical to those under the FDCA misbranding provision, and are thus not expressly preempted, (2) whether the Maximum Strength claims are impliedly preempted, and (3) for such other proceedings as the district court may deem appropriate.

2. NDA Drugs

Our preemption discussion so far has focused on drugs regulated through the FDA's monograph process. Consumer Plaintiffs have also raised state law claims against Defendant Manufacturers who have obtained FDA approval of their oral PE products through the NDA process.[20] Consumer Plaintiffs argue that manufacturers of NDA drugs have an independent duty to update their drugs' labels through the CBE process, even without FDA approval,

[20] The record is unclear as to which drugs at issue here are monograph drugs and which are NDA drugs. It appears that Defendant Manufacturer Haleon, at least, which manufactures Advil Sinus Congestion and Pain among other oral PE drugs, is an NDA holder.

to reflect newly acquired information bearing on a drug's efficacy. Here, Consumer Plaintiffs contend, NDA holders violated this duty by failing to update their labels in light of new scientific evidence undercutting oral PE's efficacy as a nasal decongestant.

While, as discussed, the CBE process is unavailable for monograph drugs, it *is* available for brand-name NDA drugs, thus providing a potential pathway for brand-name NDA holders to independently update their drugs' labels. *See* 21 C.F.R. § 314.70(c)(6)(iii) (stating that manufacturers of brand-name NDA drugs may unilaterally update their labels to "reflect newly acquired information" if the change "delete[s] false, misleading, or unsupported indications for use or claims for effectiveness"); *see also Wyeth*, 555 U.S. at 570 (holding that FDCA did not impliedly preempt plaintiffs' state law claims when CBE process was available, as the "FDCA does not provide that a drug is misbranded simply because the manufacturer has altered an FDA-approved label"). The district court did not consider the availability of this CBE process for brand-name NDA drugs. We accordingly vacate the judgment dismissing the plaintiffs' state law claims as to brand-name NDA drugs, and we remand for the

district court to consider the CBE regulation's effect on the express and implied preemption of Consumer Plaintiffs' state law claims regarding these drugs.[21]

D. *Section 379r(e)'s Savings Clause Does Not Apply to Consumer Plaintiffs' State Law Claims*

Section 379r(e) states that "[n]othing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State." 21 U.S.C. § 379r(e). This exception for product liability claims does not save Consumer Plaintiffs' state law claims because none constitutes a product liability claim.

Plaintiffs bring six New York state law claims in their Complaint: (1) violation of the New York Deceptive Acts and Practices Act, (2) violation of the New York False Advertising Act, (3) breach of express warranty, (4) breach of implied warranty of merchantability, (5) unjust enrichment, and (6) fraudulent concealment. Under the "economic loss rule," New York's product liability law excludes claims for pure economic loss. *See IKB Int'l, S.A. v. Wells Fargo Bank, N.A.*, 220 N.E.3d 646, 656 (N.Y. 2023); *532 Madison Ave. Gourmet Foods, Inc. v.*

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[21] We note that the leading cases to consider the CBE regulation's effect on preemption have involved *prescription* drugs -- which, unlike OTC drugs, are not covered by an express preemption provision. *See Albrecht*, 587 U.S. at 303; *Bartlett*, 570 U.S. at 492-93; *Wyeth*, 555 U.S. at 567 (highlighting that Congress declined to enact an express preemption provision for prescription drugs).

Finlandia Ctr., Inc., 750 N.E.2d 1097, 1101 n.1 (N.Y. 2001); *Hydro Investors, Inc. v. Trafalgar Power Inc.*, 227 F.3d 8, 16 (2d Cir. 2000); *Goldstein v. Walmart, Inc.*, 637 F. Supp. 3d 95, 113 n.7 (S.D.N.Y. 2022). *But see Voss v. Black & Decker Mfg. Co.*, 450 N.E.2d 204, 207-08 (N.Y. 1983) (describing breach of express warranty as one way to bring a product liability claim -- but seemingly only when the plaintiff is *injured* by the defective product). Because Consumer Plaintiffs premise their claims on pure economic losses, Section 379r(e) does not save their claims from preemption.[22]

* * *

We conclude that the FDCA expressly preempts most of Consumer Plaintiffs' state law claims; but we vacate and remand as to their Maximum

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[22] Some district courts have held that courts must look to federal law -- not state law -- to define the phrase "product liability law" as used in 21 U.S.C. § 379r(e). *See, e.g.*, *In re Zantac (Ranitidine) Prods. Liab. Litig.*, 512 F. Supp. 3d 1278, 1299 (S.D. Fla. 2021). Even assuming that to be correct, Consumer Plaintiffs' argument still fails. When Congress borrows a term of art that carries a certain meaning under the common law, courts presume that Congress adopted the common-law meaning of that term. *See Morissette v. United States*, 342 U.S. 246, 263 (1952). Here, when the preemption clause became law in 1997, the consensus common-law understanding was that product liability law did not extend to claims for pure economic loss. *See* Restatement (Third) of Torts: Prods. Liab. § 21 cmt. a (A.L.I. 1998) (providing that recovery under product liability law requires more than pure economic losses); *Home Warranty Corp. v. Caldwell*, 777 F.2d 1455, 1486 (11th Cir. 1985); *In re Zantac (Ranitidine) Prods. Liability Litig.*, 512 F. Supp. 3d at 1299-1300; Restatement (Third) of Torts: Prods. Liab. -- Economic Loss, 1 Owen & Davis on Prod. Liab. § 6:36 (4th ed.).

Strength claims and their brand-name NDA drug claims. We acknowledge that the limitations on Consumer Plaintiffs' state law remedies may appear unfair, particularly when the FDA's own agency review has confirmed that oral PE does not work as a decongestant and when studies have impugned oral PE's efficacy for twenty years. The fix, however, must flow not from litigation but from the FDA, which indeed has proposed an administrative order that would remove oral PE from the nasal decongestant monograph. *See FDA Proposes Ending Use of Oral Phenylephrine as OTC Monograph Nasal Decongestant Active Ingredient After Extensive Review*, U.S. Food & Drug Admin. (Nov. 7, 2024), https://www.fda.gov/news-events/press-announcements/fda-proposes-ending-use-oral-phenylephrine-otc-monograph-nasal-decongestant-active-ingredient-after [https://perma.cc/ZM6X-5LTE]. Unless and until the FDA changes its requirements for OTC monograph oral PE products, however, manufacturers must still comply with the existing labeling regime and cannot be sued under state law for doing so.[23]

[23] To be clear, Consumer Plaintiffs do not argue that agency corruption or capture caused the FDA's failure to change the labeling requirements despite new scientific evidence. As this case does not confront such allegations, we are not called to explore what, if any, claims or recourse would be available to plaintiffs making such allegations.

II. *Consumer Plaintiffs' Right to Sue Under RICO*

Consumer Plaintiffs also allege that RICO Defendants violated RICO by committing mail and wire fraud in furtherance of a scheme to defraud the public and the FDA as to oral PE's efficacy. The district court dismissed this claim, applying the "indirect purchaser" rule applicable in antitrust law to hold that Consumer Plaintiffs lack statutory standing to sue. Consumer Plaintiffs do not dispute that, if the rule applies, they lack a cause of action under RICO because they are indirect, rather than direct, purchasers. We hold that the indirect purchaser rule applies to civil RICO actions and, therefore, affirm the district court's dismissal of Consumer Plaintiffs' RICO claim.

A. *Standard of Review*

RICO Defendants' cause-of-action argument presents a question of law, which we review *de novo*. *See Rojas v. Cigna Health & Life Ins. Co.*, 793 F.3d 253, 256 (2d Cir. 2015).

B. *Applicable Law*

1. RICO

The RICO statute, 18 U.S.C. §§ 1961-68, makes it "unlawful for any person employed by or associated with any enterprise engaged in . . . interstate . . . commerce, to conduct or participate, directly or indirectly, in the conduct of

such enterprise's affairs through a pattern of racketeering activity" and for any person "to conspire to" engage in such activity. *Id.* § 1962(c)-(d). To succeed on a civil RICO claim, therefore, four elements are required: (1) conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity. *Sedima, S.P.R.L. v. Imrex Co.*, 473 U.S. 479, 496 (1985). "Racketeering activity" includes, *inter alia*, "any act which is indictable" under the federal mail and wire fraud statutes. 18 U.S.C. § 1961(1). Under RICO's private-right-of-action provision, "[a]ny person injured in his business or property by reason of" a RICO violation "may sue therefor" and receive treble damages. *Id.* § 1964(c).

2. The Indirect Purchaser Rule

RICO Defendants contend that antitrust law's "indirect purchaser" rule also applies in the civil RICO context. Under the indirect purchaser rule, only "immediate buyers" have a cause of action to sue a product seller for injuries, while "indirect purchasers who are two or more steps removed from" the seller lack standing to sue. *Apple Inc. v. Pepper*, 587 U.S. 273, 279 (2019). The Supreme Court first implemented the indirect purchaser rule in the antitrust context in 1977 in *Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977), when interpreting § 4 of the Clayton Act. The *Illinois Brick* Court listed several policy rationales for adopting the rule, which we discuss below. *Pepper*, 587 U.S. at 285.

All three federal courts of appeals that have explicitly considered whether the indirect purchaser rule applies to civil RICO have held that it does. *See McCarthy v. Recordex Serv., Inc.*, 80 F.3d 842, 855 (3d Cir. 1996); *Counts v. Gen. Motors, LLC*, 139 F.4th 576, 583 (6th Cir. 2025); *Carter v. Berger*, 777 F.2d 1173, 1176 (7th Cir. 1985); *see also Mendoza v. Zirkle Fruit Co.*, 301 F.3d 1163, 1168-69 (9th Cir. 2002) (observing in non-indirect purchaser case that "potential plaintiffs who have suffered 'passed-on' injury -- that is, injury derived from a third party's direct injury -- lack [civil RICO] standing"). *But cf. Fenner v. Gen. Motors, LLC*, 113 F.4th 585, 604-05 & n.6 (6th Cir. 2024) (applying indirect purchaser rule to civil RICO claim but suggesting that a bright-line rule "does not necessarily reflect economic reality today" and "is . . . unsupported by sensible principles").[24]

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[24] The First, Fourth, and Eighth Circuits have expressly declined to weigh in. *See Humana Inc. v. Biogen, Inc.*, 126 F.4th 94, 98 (1st Cir. 2025); *MSP Recovery Claims, Series LLC v. Lundbeck LLC*, 130 F.4th 91, 110 n.11 (4th Cir. 2025); *Newton v. Tyson Foods, Inc.*, 207 F.3d 444, 447 (8th Cir. 2000). Meanwhile, the Eleventh Circuit, though it has not directly considered the issue, has held that proximate cause principles govern civil RICO standing. *See Bivens Gardens Off. v. Barnett Banks of Fla.*, 140 F.3d 898, 906 (11th Cir. 1998). Thus, under Eleventh Circuit precedent, if a RICO violation has proximately caused a plaintiff's injury, the plaintiff has standing. *Id.* That interpretation, though, is outdated as it conflates the issues of standing and proximate cause, which we have since explained are analytically distinct inquiries. *See D'Addario v. D'Addario*, 901 F.3d 80, 96 n.8 (2d Cir. 2018) (explaining that, although the Second Circuit has sometimes described proximate cause as necessary to support "statutory standing," proximate

While this RICO indirect purchaser issue is one of first impression for our Court, we have previously observed while conducting a RICO proximate cause analysis that "*consumers . . . further removed* from the racketeer . . . probably cannot recover under RICO, *just as they cannot recover under the anti-trust laws*," because "[e]xtending liability to everyone to whom an illegal price is passed would *extend the chain of liability indefinitely*." *Sperber v. Boesky*, 849 F.2d 60, 65 (2d Cir. 1988) (emphases added). This language suggests that the *Sperber* Court was concerned not only with causation principles but also with *who* in the consumer chain has a right to sue under civil RICO -- that is, who has a cause of action. Moreover, in support of this proposition, the *Sperber* Court cited *Illinois Brick*, the foundational indirect purchaser case. *See id.* We have thus signaled that the indirect purchaser rule may apply to civil RICO cases.

C. *The Indirect Purchaser Rule Bars Consumer Plaintiffs' Civil RICO Claim*

We now hold that the indirect purchaser rule indeed applies to civil RICO claims. We begin with a brief textual analysis. We then discuss whether

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cause is better understood not as a standing requirement but as an "element essential to the viability of a plaintiff's claim"); *see also Am. Psychiatric Ass'n, Inc.*, 821 F.3d at 359 (disclaiming the term "statutory standing" based on developing Supreme Court guidance (citing *Lexmark Int'l, Inc.*, 572 U.S. at 128 & n.4)); *Trollinger v. Tyson Foods, Inc.*, 370 F.3d 602, 616 (6th Cir. 2004).

Illinois Brick's policy rationales apply to civil RICO cases. Finally, we address why Consumer Plaintiffs' arguments to the contrary are unavailing.

1. Textual Overlap Between Civil RICO and Antitrust Laws

We start, of course, with the text. *Illinois Brick* located the indirect purchaser rule in § 4 of the Clayton Act, an antitrust law providing for threefold damages to "any person who shall be injured in his business or property by reason of anything forbidden in the antitrust laws." 15 U.S.C. § 15(a). RICO's private-right-of-action provision, 18 U.S.C. § 1964(c), mirrors this language almost exactly. S*ee* 18 U.S.C. § 1964(c) (providing for threefold damages to "[a]ny person injured in his business or property by reason of a violation of [this law]," with an exception for "fraud in the purchase or sale of securities"); *Holmes v. Sec. Inv. Prot. Corp.*, 503 U.S. 258, 268 (1992) (explaining that Congress modeled RICO's enforcement provision on § 7 of the Sherman Act and § 4 of the Clayton Act). Because of these textual similarities, courts -- including the Supreme Court -- often interpret civil RICO in parallel with the major antitrust statutes. *See, e.g.*, *Holmes*, 503 U.S. at 268 (applying antitrust principle of proximate cause from the Clayton Act and Sherman Act in the civil RICO context).

Congress passed RICO in 1970 -- seven years before *Illinois Brick* -- and thus it could not have had *Illinois Brick*'s indirect purchaser rule in mind

when drafting or enacting RICO. *Cf. id.* (incorporating antitrust proximate cause principles into civil RICO because "[w]e may fairly credit the 91st Congress, which enacted RICO, with knowing the interpretation federal courts *had given* the words earlier Congresses had used . . . . It used the same words, and we can only assume *it intended them to have the same meaning [in RICO] that courts had already given them [in the antitrust laws]*." (emphases added)). Nonetheless, because of our longstanding practice of interpreting civil RICO in parallel, if not lockstep, with the antitrust laws, we must consider whether *Illinois Brick*'s reasoning supports importing the indirect purchaser rule into civil RICO as well.

Consumer Plaintiffs point out that the text of § 1964(c) does not, on its face, limit civil RICO standing to direct purchasers. That is true. Because the Supreme Court has nevertheless recognized the indirect purchaser rule in the near-identical Clayton Act provision, however, we do not see civil RICO's text as a barrier to importing the rule here, either. Indeed, while "RICO is to be read broadly," *Sedima*, 473 U.S. at 497, like the Clayton Act it should not be read so "expansive[ly]" as to "allow *all* factually injured plaintiffs to recover," *Holmes*, 503 U.S. at 266 (emphasis added).

2. The *Illinois Brick* Rationales

The *Illinois Brick* Court listed three policy rationales for adopting the indirect purchaser rule: "(1) facilitating more effective enforcement of antitrust laws; (2) avoiding complicated damages calculations; and (3) eliminating duplicative damages against antitrust defendants." *Pepper*, 587 U.S. at 285. Thus, to determine whether the indirect purchaser rule extends to § 1964(c), we consider the applicability of the three *Illinois Brick* policy rationales to civil RICO claims. We analyze each rationale in turn.

First, placing the right to damages exclusively in the hands of direct purchasers may best promote deterrence and the efficient enforcement of civil RICO. *See Hanover Shoe, Inc. v. United Shoe Mach. Corp.*, 392 U.S. 481, 494 (1968); *Illinois Brick*, 431 U.S. at 734-37. Indeed, concentrating the *full* amount of recovery in direct purchasers -- rather than allowing each indirect purchaser down the line to sue for a relatively lower amount of damages -- provides direct purchasers with financial incentives to bring enforcement actions. *See Carter*, 777 F.2d at 1176. Meanwhile, indirect purchasers who stand to recover fewer damages lack this incentive. This rationale applies with as much strength in civil RICO cases as in antitrust cases.

Second, as the Supreme Court indicated in *Illinois Brick*, calculating the amount of inflated cost (or "overcharge") that is "passed on" by direct buyers to indirect buyers can be highly challenging and costly. 431 U.S. at 731-32. Thus, permitting indirect purchasers to sue for damages could "transform [civil RICO] actions into massive efforts to apportion the recovery among all potential plaintiffs that could have absorbed part of the overcharge -- from direct purchasers to middlemen to ultimate consumers." *Id.* at 737, 740-41.[25] The need to avoid these complex calculations and to preserve judicial economy exists no less in civil RICO actions than in antitrust litigation.

Third, and finally, if direct purchasers may recover the full amount of overcharge from a defendant, even after passing on part of that overcharge to indirect purchasers, then allowing indirect purchasers also to recover for all or part of that same overcharge would impose double liability upon the defendant. *Id.* at 730. Again, this principle against double liability carries no less force in the civil RICO context than in the antitrust context.

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[25] These complicated damages calculations would "seriously undermine the[] effectiveness" and effective enforcement, *Illinois Brick*, 431 U.S. at 737, 740-41, of civil RICO by "add[ing] whole new dimensions of complexity to treble-damages suits," *id.*

Consumer Plaintiffs argue that these policies have little relevance to the facts at issue here. While that argument carries some weight, in the antitrust context, the Supreme Court has rejected attempts to carve out exceptions to the indirect purchaser rule for particular types of markets and circumstances. *Id.* at 744. It has instead called the indirect purchaser rule a "bright-line" requirement that applies even when a policy rationale does not map neatly onto the facts of a particular case. *Pepper*, 587 U.S. at 279.[26] For example, even when the full cost of a product has been passed on to an indirect purchaser, meaning that the direct purchaser has suffered *no* damage and the indirect purchaser has incurred *all* the damage, the Supreme Court has applied the indirect purchaser rule for consistency. *Illinois Brick*, 431 U.S. at 730; *Kansas v. UtiliCorp United, Inc.*, 497 U.S. 199, 208 (1990). We therefore follow the Supreme Court's example and apply the rule, even on these facts.

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[26] The Supreme Court has recognized exceptions to the indirect purchaser rule when (1) "the direct purchaser and the indirect purchaser have entered into pre-existing cost-plus contracts" and (2) "the direct purchaser is owned or controlled by the indirect purchaser." *California v. ARC Am. Corp.*, 490 U.S. 93, 97 n.2 (1989). Neither exception applies here.

3. Consumer Plaintiffs' Arguments Are Unavailing

It is true, as Consumer Plaintiffs contend, that the Supreme Court has cautioned against automatically importing every antitrust standing rule into the civil RICO context. *Sedima*, 473 U.S. at 498-99. For example, the Supreme Court has held that the "antitrust injury" standing rule does not apply to RICO. *Id*. at 481, 485. But where, as here, an antitrust requirement is "[]intelligible" in the civil RICO context, the requirement has been applied to civil RICO cases as well. *Cf. Carte*r, 777 F.2d at 1176 (explaining that *Sedima* did not apply the "antitrust injury" rule to civil RICO because a "RICO injury" "would be an unintelligible requirement, not because there is no parallel between the two statutes"). Thus, because the logic underpinning the indirect purchaser rule is intelligible and applies in the civil RICO context, we import the rule.

Consumer Plaintiffs also posit that the "direct-relation" proximate cause standard in civil RICO actions -- which requires that the injury asserted have a direct relationship with the injurious conduct alleged, *Bridge v. Phoenix Bond & Indem. Co.*, 553 U.S. 639, 654 (2008) -- already does much of the same work as the indirect purchaser rule. Thus, in Consumer Plaintiffs' view, civil RICO's proximate cause rules leave no room for an indirect purchaser rule. To the contrary, the indirect purchaser rule is *consistent* with civil RICO's proximate

cause principles. *See Pepper*, 587 U.S. at 279 (noting that the indirect purchaser rule reflects "principles of proximate cause"). Indeed, the Supreme Court derived civil RICO's proximate cause standard from the proximate cause requirement in antitrust statutes, where the indirect purchaser rule applies. *Holmes*, 503 U.S. at 267-68.

Finally, we note that Consumer Plaintiffs raise fair concerns about applying the indirect purchaser rule to RICO cases, including whether the rule actually enhances the efficient enforcement of RICO. We acknowledge that resolving which way the policy considerations point is a close call. The Sixth Circuit, too, has articulated -- with some force -- the rule's drawbacks in our present-day economy (even while holding that the indirect purchaser rule applies to civil RICO cases). *See Fenner*, 113 F.4th at 604-05 & n.6 (calling the bright-line rule "unsupported by sensible principles"). Indeed, it has not only remarked on the rule's logical incoherence but has also criticized its effect of allowing "major manufacturers [to] insulate themselves from all antitrust and RICO liability, simply by selling their products through intermediaries." *Id.* Still, the Sixth Circuit nonetheless adhered to the indirect purchaser rule, noting that because the bright-line rule applied, it would "not engage in an unwarranted and

counterproductive exercise to litigate a series of exceptions." *Id.* at 604-05 (internal quotation marks omitted) (quoting *Pepper*, 587 U.S. at 285); *see also UtiliCorp United, Inc.*, 497 U.S. at 217.

Many of the same arguments could have been and were raised in *Illinois Brick*, where the Supreme Court still ruled as it did. *See Illinois Brick*, 431 U.S. at 748-65 (Brennan, J., dissenting) (emphasizing the "broad objectives" of the Clayton Act and pointing out that the indirect purchaser rule "undermines the effectiveness" of antitrust enforcement because, "in many instances, the brunt of antitrust injuries is borne by indirect purchasers," whereas middlemen "have little incentive to sue suppliers"). While economic conditions have changed in the fifty years since *Illinois Brick*, the Supreme Court continues to apply the indirect purchaser rule as a "bright-line" standing criterion in antitrust cases. *Pepper*, 587 U.S. at 279. Even if the indirect purchaser rule has shortcomings, those shortcomings are no more potent in the RICO context than in the antitrust context. Thus, because *Illinois Brick* remains good law, because of our inclination toward interpreting civil RICO in parallel with antitrust law, and for the other reasons set forth above, we join our sister circuits in holding that the indirect purchaser rule applies to civil RICO actions.

III. NPI's Motion for Relief from Final Judgment

Finally, we turn to NPI's appeal from the district court's denial of its motion for partial relief from final judgment under Federal Rules of Civil Procedure 60(b)(1) and 60(b)(6). NPI's motion requested reconsideration of the dismissal of its Lanham Act claim.

A. *Standard of Review*

We review a district court's order denying a motion for relief from final judgment for abuse of discretion. *See Transaero, Inc. v. La Fuerza Aerea Boliviana*, 162 F.3d 724, 729 (2d Cir. 1998), *cert. denied*, 526 U.S. 1146 (1999). A district court abuses its discretion if it bases its ruling on an erroneous view of the law or clearly erroneous assessment of the evidence or if it renders a decision that "cannot be located within the range of permissible decisions." *Gomez v. City of New York*, 805 F.3d 419, 423 (2d Cir. 2015) (per curiam).

B. *Applicable Law*

Under Federal Rule of Civil Procedure 60(b)(1), a district court may relieve a party from a final judgment for mistake, inadvertence, surprise, or excusable neglect. Fed. R. Civ. P. 60(b)(1). Under Federal Rule of Civil Procedure 60(b)(6), a district court may also relieve a party from a final judgment

for "any other reason that justifies relief." *Id.* 60(b)(6). Rule 60(b)(6) "grants federal courts broad authority to relieve a party from a final judgment upon such terms as are just, provided that the motion . . . is not premised on one of the grounds for relief enumerated in clauses (b)(1) through (b)(5)." *Liljeberg v. Health Servs. Acquisition Corp.*, 486 U.S. 847, 863 (1988) (internal quotation marks omitted). Relief under Rule 60(b)(6) is appropriate "where there are extraordinary circumstances, or where the judgment may work an extreme and undue hardship, and should be liberally construed when substantial justice will thus be served." *Matarese v. LaFevre*, 801 F.2d 98, 106 (2d Cir. 1986) (internal citations and quotation marks omitted).

A court deciding a Rule 60(b) motion must "balance the policy in favor of hearing a litigant's claims on the merits against the policy in favor of finality." *Kotlicky v. U.S. Fid. & Guar. Co.*, 817 F.2d 6, 9 (2d Cir. 1987). As a general matter, however, Rule 60(b) motions are "not favored." *United States v. Int'l Bhd. Of Teamsters*, 247 F.3d 370, 391 (2d Cir. 2001). Courts typically deny Rule 60(b) motions for reconsideration "unless the moving party can point to controlling decisions or data that the court overlooked" and that "might

reasonably be expected to alter the conclusion reached by the court." *Shrader v. CSX Transp., Inc.*, 70 F.3d 255, 257 (2d Cir. 1995).

C. ***Application***

NPI does not point to controlling decisions or data that the district court overlooked, much less to ones that might alter the district court's decision. *Cf. id.* It instead argues that the district court abused its discretion in denying the motion because, in sum and substance, the district court did not afford NPI an opportunity to assert its Lanham Act claim, and Plaintiffs' Complaint, Defendants' motion to dismiss, and the district court's order dismissing all underlying class actions do not address NPI's Lanham Act claim. We reject NPI's contentions and conclude that the district court did not abuse its discretion.

NPI had many opportunities, through Plaintiffs' Executive Committee and interim class counsel, to preserve or raise its Lanham Act claim -- but it chose not to do so.[27] First, Plaintiffs did not include a Lanham Act claim in their Complaint, which they agreed would contain claims representative of those

[27] After the district court initiated these MDL proceedings, Plaintiffs submitted a "consensus" motion to appoint an Executive Committee and interim class counsel for all plaintiffs and absent class members. The district court granted the motion, bestowing upon the Executive Committee the authority to, for instance, "[e]nter[] into stipulations with Defendants' counsel." NPI Supp. App'x at 65. NPI did not challenge this structure or the Executive Committee's authority.

in their underlying class actions. Plaintiffs themselves proposed the order directing that they submit the Complaint (the "Streamlined Complaint Order"), in the hopes that Defendants' responsive motion to dismiss would resolve *all* preemption issues.[28] NPI did not seek to amend the Complaint to include the Lanham Act claim.

Second, after the district court issued the Streamlined Complaint Order, Interim Class Counsel (on behalf of Plaintiffs, including NPI) represented that a motion to dismiss on preemption or primary jurisdiction grounds -- if granted -- would "*resolve this litigation in its entirety*, regardless of additional specific examples of wrongful conduct, additional products named, additional Plaintiff-related allegations, or additional state-law claims that are pled or could be pled in a future Full Master Consolidated Complaint." NPI Sp. App'x at 11 (emphasis added); *see also id.* at 13. Plaintiffs also agreed that "to the extent the Court grants or denies Defendants' motion to dismiss based on preemption and/or primary jurisdiction, the order will apply to *all* cases in this Multidistrict

[28] Although preemption doctrine only applies to situations where a federal law or regulation bars *state* law claims, preclusion doctrine serves an analogous function for situations where a federal law or regulation potentially bars other *federal* law claims -- such as those under civil RICO or the Lanham Act. *See Church & Dwight Co. v. SPD Swiss Precision Diagnostics, GmBH*, 843 F.3d 48, 65 (2d Cir. 2016).

Litigation or otherwise subject to transfer into this Multidistrict Litigation." NPI Supp. App'x at 90 (emphasis added); *see also* NPI Sp. App'x at 11, 34. NPI did not attempt to exclude its Lanham Act claim from this representation that a successful motion to dismiss would "resolve this litigation in its entirety." NPI Sp. App'x at 11.

Third, after Plaintiffs filed the Complaint containing not only state law claims but also asserting a federal civil RICO claim for the first time, the district court issued an amended order allowing Defendants to raise in their motion to dismiss any arguments responsive to the RICO claim. The fact that Plaintiffs successfully added this federal claim underscores that NPI could have also added their Lanham Act claim to the Complaint. But NPI did not do so. Indeed, it neither objected to the amended order nor otherwise attempted to preserve its Lanham Act claim. Instead, Plaintiffs *again* stipulated that if the motion to dismiss were successful, it would "resolve this litigation in its entirety." NPI Sp. App'x at 11, 34.

Finally, the record is also replete with other indications that the order on the motion to dismiss could resolve the case in its entirety, including NPI's Lanham Act claim. For example, in a hearing on the motion to dismiss, the

district court proposed setting a deadline for a master consolidated complaint containing all claims in all underlying cases, "*in the event* I do not *totally dismiss*." NPI Supp. App'x at 231 (emphases added). This statement clearly indicated that the district court could, in fact, dismiss all claims in all underlying cases in the multidistrict litigation. Nevertheless, NPI did not object or take steps to preserve its Lanham Act claim.

If that were not enough, following the district court's grant of Defendants' motion to dismiss, Plaintiffs consented to a proposed judgment that "*all claims* in the complaints transferred into the above-captioned master docket *are dismissed with prejudice*." NPI Supp. App'x at 250-51 (emphases added). Yet again, NPI did not raise an objection to the proposed order. NPI may not now wield Rules 60(b)(1) and 60(b)(6) to "undo[]" the "legal consequences of [its] stipulation [that was] incorporated in a court order . . . simply because, with the benefit of hindsight, stipulating turns out to have been an unfortunate tactic." *Nemaizer v. Baker*, 793 F.2d 58, 59-60 (2d Cir. 1986).

The district court thus did not abuse its discretion in denying the motion for partial reconsideration because, as it explained, NPI "had numerous opportunities to object, to seek a carve-out for its claim, or to at least attempt to

reserve its rights to assert that claim." NPI Sp. App'x at 39. NPI elected not to do so. Under these circumstances, "[m]ere dissatisfaction in hindsight with choices deliberately made by counsel is not grounds for finding the mistake, inadvertence, surprise or excusable neglect necessary to justify Rule 60(b)(1) relief." *Nemaizer*, 793 F.2d at 62. Nor is NPI's "failure to evaluate carefully the legal consequences of a chosen course of action" a "basis for relief from [the] judgment" under either Rule 60(b)(1) or Rule 60(b)(6). *Id.* at 62-63. Accordingly, we affirm the district court's denial of NPI's motion for reconsideration.

CONCLUSION

For the foregoing reasons, we AFFIRM the district court's entry of judgment for Defendant Manufacturers on all state law claims except for the Maximum Strength claims and the brand-name NDA drug claims, VACATE the district court's dismissal of the Maximum Strength claims and the brand-name NDA drug claims, AFFIRM the district court's entry of judgment for Defendant Manufacturers on the civil RICO claim, AFFIRM the district court's denial of NPI's motion for reconsideration, and REMAND for further proceedings consistent with this opinion.