UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

SUMMARY ORDER

At a stated term of the United States Court of Appeals for the Second Circuit, held at the Thurgood Marshall United States Courthouse, 40 Foley Square, in the City of New York, on the 6th day of August, two thousand twenty-five.

PRESENT:

JOSEPH F. BIANCO,
SARAH A. L. MERRIAM,
MARIA ARAÚJO KAHN,
Circuit Judges.

EVIE COLLAZA, on behalf of herself and all others similarly situated,

Plaintiff-Appellant,

v. 24-2568-cv

JOHNSON & JOHNSON CONSUMER INC.,

Defendant-Appellee.

FOR PLAINTIFF-APPELLANT: MITCHELL BREIT, Milberg Coleman Bryson Phillips Grossman, PLLC, New York, New York.

FOR DEFENDANT-APPELLEE: MARK A. NEUBAUER (Joseph H. Lang, Jr., Carlton Fields, P.A., Tampa, Florida, *on the brief*), Carlton Fields LLP, Los Angeles, California.

Appeal from a judgment of the United States District Court for the Southern District of New York (Andrew L. Carter, *Judge*).

UPON DUE CONSIDERATION, IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that the judgment of the district court, entered on August 28, 2024, is **AFFIRMED**.

Plaintiff-Appellant Evie Collaza appeals from the district court's order granting Defendant-Appellee Johnson & Johnson Consumer Inc.'s ("JJCI") motion to dismiss, pursuant to Federal Rule of Civil Procedure 12(b)(6), on preemption grounds. We assume the parties' familiarity with the underlying facts, procedural history, and issues on appeal, to which we refer only as necessary to explain our decision to affirm.

This is a dispute regarding the alleged deceptive labeling, pricing, and marketing of Tylenol Extra Strength Rapid Release Gelcaps (the "Gelcaps"). JJCI manufactures and sells Gelcaps that have laser-drilled holes to allow for the release of medicine in a manner different from its other, non-rapid release acetaminophen tablets. Collaza asserts that, beginning in 2005, JJCI deceptively marketed its Gelcaps as being more effective and providing faster relief than its other acetaminophen products. For example, Collaza contends that JJCI published various advertisements claiming that the Gelcaps "work[] at the speed of life," and emphasizing that "only Tylenol® Rapid Release Gels have laser-drilled holes" that "release medicine fast for fast pain relief." App'x at 19. The Gelcaps are also allegedly priced higher than JJCI's non-rapid release products. According to Collaza, "[c]onsumers have been willing to and continue to pay this premium because, as a result of [JJCI's] false, misleading, unfair, and/or deceptive labeling and other advertising, they believe the [Gelcaps] work faster than other, cheaper acetaminophen products when in fact they do not." *Id*. at 16. Collaza supports this allegation by pointing to, *inter alia*, a 2018 study which found that JJCI's Gelcaps reached 80% dissolution in 3.94 minutes, while

their Tylenol tablets reached 80% dissolution in 3.56 minutes. *Id.* at 24.

On July 13, 2023, Collaza initiated the instant action against JJCI, alleging in a putative class action complaint that the company's false and misleading conduct in connection with the labeling, advertisements, and pricing of the Gelcaps violates New York General Business Law §§ 349 and 350. The complaint also asserts an unjust enrichment claim under the same theory. The complaint seeks declaratory, monetary and injunctive relief, including "[a]n order requiring [JJCI] to adequately represent the true nature, quality, and capability of the Class Rapid Release Gelcaps" and "[a]n order . . . immediately discontinuing any false, misleading, unfair, and/or deceptive advertising, marketing, or other representations described herein." *Id*. at 39–40.

On December 12, 2023, JJCI moved to dismiss the complaint, pursuant to Rule 12(b)(6), arguing that Collaza's claims were preempted under 21 U.S.C. § 379r(a). Specifically, JJCI asserted that 21 U.S.C. § 379r(a) explicitly preempts "any requirement" set by a state for over-the-counter drugs that "is different from or in addition to, or that is otherwise not identical with" those prescribed by the Federal Food, Drug, & Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* ("FDCA"). Dist. Ct. Dkt. No. 38 at 7 (quoting 21 U.S.C. § 379r(a)). Therefore, according to JJCI, each of the claims in the complaint is expressly preempted because each relies on state laws that would, in effect, result in additional requirements for the labeling of their products beyond those established by the FDCA. On August 27, 2024, the district court granted JJCI's motion to dismiss, concluding that all of Collaza's claims were preempted by the FDCA. *See generally Collaza v. Johnson & Johnson Consumer, Inc.*, 23-cv-6030 (ALC), 2024 WL 3965933 (S.D.N.Y. Aug. 27, 2024). This appeal followed.

For purposes of this appeal, Collaza concedes that her labeling claim is preempted under Section 379r(a), and thus, she has abandoned it. Collaza therefore seeks review of only her

marketing and pricing claims. Accordingly, the sole issues on appeal are whether the district court properly determined that Collaza's marketing and pricing claims are preempted under Section 379r(a).

"We review de novo the grant of a Rule 12(b)(6) motion to dismiss for failure to state a claim, accepting all factual allegations as true and drawing all reasonable inferences in favor of the plaintiff." *Sierra Club v. Con-Strux, LLC*, 911 F.3d 85, 88 (2d Cir. 2018) (internal citation omitted).

It is well settled that "state law that conflicts with federal law is without effect." *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992) (internal quotation marks and citation omitted). "The question of whether federal law preempts state law is fundamentally a matter of Congress's intent." *Jackson-Mau v. Walgreen Co.*, 115 F.4th 121, 125 (2d Cir. 2024) (internal quotation marks and citation omitted). Thus, "we are to begin as we do in any exercise of statutory construction, with the text of the provision in question." *In re WTC Disaster Site*, 414 F.3d 352, 371 (2d Cir. 2005) (alteration adopted) (internal quotation marks and citation omitted).

The FDCA gives the Food and Drug Administration ("FDA") the power to regulate the labeling and marketing of over-the-counter ("OTC") drugs. *See* 21 U.S.C. § 393(b)(2)(A). The FDCA contains an express preemption provision for nonprescription drugs, which provides, with some exceptions not relevant to this appeal, that:

> no State or political subdivision of a State may establish or continue in effect any requirement – (1) that relates to the regulation of a drug [including an OTC drug] that is not subject to the requirements of section 353(b)(1) or 353(f)(1)(A) of this title; and (2) that is different from or in addition to, or that is otherwise not identical with, a requirement under this chapter.

21 U.S.C. § 379r(a). We have emphasized, when analyzing near-identical language in an FDCA preemption provision for cosmetic drugs, that "the FDCA preempts not only those state laws that

are in conflict with it (*i.e.*, any law that is 'different from' the FDCA), but also *any* state law that provides for [] requirements that are not *exactly the same* as those set forth in the FDCA and its regulations (*i.e.*, any law that is 'in addition to' the FDCA)." *Critcher v. L'Oreal USA, Inc.*, 959 F.3d 31, 35–36 (2d Cir. 2020) (quoting 21 U.S.C. § 379s(a)). The statute defines "requirement" to include "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).

In 1988, the FDA published a tentative final monograph ("TFM") on acetaminophen that set forth the conditions under which acetaminophen products "are generally recognized as safe and effective and not misbranded." 21 C.F.R. § 330.10(a)(7)(i). The TFM also set the dissolution standards needed for acetaminophen tablets to lawfully be referred to as "immediate release," establishing that such acetaminophen tablets must dissolve by at least 80% after 30 minutes. The TFM became a final administrative order in 2020, upon the enactment of the Coronavirus Aid, Relief, and Economic Security ("CARES") Act, Pub. L. No. 116-136, 134 Stat. 281 (2020).

Additionally, the FDA has published two non-binding guidance documents regarding acetaminophen dissolution rates. One of these guidance documents states that "immediate release solid oral drug products" have a "dissolution criterion [of] Q=80% in 30 minutes." App'x at 78. The other guidance document states that an immediate release solid oral drug is "considered rapidly dissolving when a mean of 85 percent or more of the labeled amount of the drug substance dissolves within 30 minutes," and "considered very rapidly dissolving when a mean of 85 percent or more of the labeled amount of the drug substance dissolves within 15 minutes." *Id*. at 85 (emphases omitted).[1]

[1] Collaza does not challenge the district court's reliance on non-binding FDA guidance for purposes of the preemption inquiry. In any event, the analysis would be the same using only the TFM, which has the force of law under the CARES Act.

Here, Collaza concedes that the Gelcaps are properly labeled as "Rapid Release," pursuant to the FDA's TFM and guidance on the dissolution standards for acetaminophen OTC tablets. Moreover, Collaza's counsel acknowledged during oral argument that, as other courts have found, Section 379r preempts any state law claim regarding the Gelcaps that would effectively require additional or different information on the federally-approved labels for that product. For example, in *Morgan v. Albertsons Companies*, No. 22-cv-02948-JST, 2023 WL 3607275 (N.D. Cal. Mar. 13, 2023), the plaintiffs alleged that the defendants deceptively labeled and marketed their acetaminophen gelcaps as "rapid release" and charged a premium for them, despite the fact that these products did not work any faster than the non-rapid release versions of the same product. *Id*. at *1. In dismissing the claims, the court held that "regardless of whether the alleged misrepresentation appears in the label, on the packaging, or in advertisements elsewhere [for acetaminophen], Section 379r preempts state law claims to the extent that those claims would effectively require a manufacturer to include additional or different information on a federally approved label." *Id*. at *5 (internal quotation marks and citation omitted).

Similarly, in *Sapienza v. Albertsons Companies*, No. 22-cv-10968-RGS, 2022 WL 17404919 (D. Mass. Dec. 2, 2022), the plaintiffs alleged that the defendants misrepresented their "rapid release" acetaminophen gelcap tablets while advertising, marketing, and selling the tablets because in actuality they dissolve more slowly than the company's cheaper non-rapid-release acetaminophen products. *Id*. at *1. The court held that the gelcaps at issue were governed by – and met – the standards set forth in the TFM and other FDA guidance, and therefore, the plaintiffs' claims were preempted because they were "attempt[ing] to augment the existing approved labeling requirement[s]." *Id*. at *3. In reaching that determination, the court explained that the gelcaps "are advertised as rapidly dissolving, which is, by any FDA guidance, accurate" and "[t]hat similar

[] products may dissolve just as (or even more) rapidly is no more relevant as a comparison than is a bag of ice labeled 'frozen' as opposed to one simply branded as 'ice.'" *Id*.; *see also Bischoff v. Albertsons Cos.*, 678 F. Supp. 3d 518, 527 (S.D.N.Y. 2023) ("Because the FDA regulates the subject of dissolution standards, and because the TFM does not require any specific disclaimers concerning the comparative rate of dissolution among products, Plaintiff's claims are preempted because she seeks to impose additional obligations on Defendant not imposed by the TFM." (alterations adopted) (internal quotation marks and citation omitted)); *Muskiar-Rosner v. Johnson & Johnson Consumer Inc.*, No. 23-cv-11746-ADB, 2024 WL 3596897, at *7 (D. Mass. July 31, 2024) (holding that claims of false and misleading statements about rapid release gelcaps in advertisements were preempted); *but see Edwards v. Walmart, Inc.*, No. 2:18-cv-09655-GW, 2019 U.S. Dist. LEXIS 230993 at *8 (C.D. Cal. Apr. 18, 2019) (unpublished decision) (attached as an addendum to Appellant's Brief) (holding that claims of false and misleading statements about rapid release gelcaps in advertisements were not preempted because, *inter alia*, the TFM and FDA guidance do not govern the issue).

Notwithstanding these decisions by other courts dismissing analogous claims as preempted, Collaza argues that her marketing and pricing claims are separate from the abandoned labeling claim and are not preempted under Section 379r(a) because they do not implicate JJCI's labeling of its Gelcaps. We disagree.

The gravamen of Collaza's claims is that JJCI uses certain false and misleading terms in its marketing—such as "[t]out[ing] on its website that the rapid release gelcaps are specially designed with 'laser-drilled holes to release medicine quickly'" and statements in advertisements that the Gelcaps provide "[r]apid release" and "rapid relief"—and this "[f]alse, misleading, and deceptive marketing campaign has been successful in getting the public to believe that the rapid

release gelcaps are faster acting than other Tylenol® products, when in fact they are *slower*." App'x at 16–17, 20–21 (citations omitted). However, as noted above, Collaza does not dispute that the Gelcaps meet the criteria established by the FDA to be labeled as a "rapid release" product. Therefore, if Collaza were to prevail on her claim that the use of that "rapid release" term or similar terms or phrases (such as "release[s] medicine fast") is misleading, JJCI would be unable to market its product using its federally-approved labeling and would effectively be required to place a disclaimer on the label and in advertising stating that the "rapid release" Gelcaps are not faster than the non-rapid release products. App'x at 10. Similarly, if marketing the Gelcaps at a higher price than other products were the basis for a successful deceptive practices claim, the same disclaimer about comparative dissolution rates would be necessary on the label of the Gelcap product, as well as any advertisements, to avoid such liability. Thus, contrary to Collaza's assertion otherwise, the district court correctly determined that her marketing and pricing claims were preempted under Section 379r(a) because, if Collaza were to prevail on such claims, it would impose additional labeling requirements beyond those required by the FDA. As the district court explained, "[t]o hold that the FDA's regulation of acetaminophen dissolution rates ought not control simply because a drug producer markets or prices several of its qualifying 'immediate release' products in varying manners would be to create an end-run around the FDCA's express preemption clause." *Collaza*, 2024 WL 3965933, at *5.

Accordingly, because the marketing and pricing claims are preempted under Section 379r(a), the district court properly dismissed the complaint.[2]

[2] To the extent Collaza argues that the complaint includes allegations of affirmative false and misleading advertising statements that go beyond FDA-approved terms related to the rapid or immediate nature of the release of the medicine, and thus, her marketing and pricing claims are not preempted because such allegations do not implicate a disclaimer, we find no allegation of that nature in the complaint. Collaza contends that the complaint alleges that JJCI has affirmatively and falsely claimed in advertisements that

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We have considered the remaining arguments on appeal and conclude that they are without merit. Accordingly, we **AFFIRM** the judgment of the district court.

FOR THE COURT:
Catherine O'Hagan Wolfe, Clerk of Court

its Gelcaps release medicine faster than its non-rapid release tablets. At oral argument, Collaza's counsel attempted to support that contention by pointing to an advertisement stating that the Gelcaps allow "the release [of] powerful medicine even faster than before," suggesting that the Gelcaps release medicine faster than traditional Tylenol tablets. App'x at 17. However, claims under GBL §§ 349 and 350 are subject to a three-year statute of limitations period, *see Lucker v. Bayside Cemetery*, 979 N.Y.S.2d 8, 18 (1st Dep't 2013) (citing *Corsello v. Verizon N.Y., Inc.*, 18 N.Y.3d 777, 789 (2012)), and the complaint does not allege that any advertisement contained such a statement after 2009. Indeed, the complaint does not provide a link to the Tylenol website for that alleged statement, but rather cites to another website with an undated photo of an advertisement. Thus, even assuming *arguendo* that the marketing claim based on this alleged statement was not preempted, Collaza still has failed to allege that any such statement was contained in an advertisement that existed within the limitations period.