UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

BARBARA GAYLE, *et al.*, Plaintiffs, -against- PFIZER INC., *et al.*, Defendants.	19cv3451 OPINION & ORDER

WILLIAM H. PAULEY III, Senior United States District Judge:

Barbara Gayle and twenty-three additional individual plaintiffs (collectively, "Plaintiffs") allege that Lipitor—a cholesterol management drug manufactured by defendant Pfizer—caused their type 2 diabetes. Plaintiffs claim that had the Lipitor label warned their doctors of the risks of type 2 diabetes, their doctors would not have prescribed Lipitor for them.

Pfizer moves for judgment on the pleadings under Federal Rule of Civil Procedure 12(c). (ECF No. 21.) While Plaintiffs do not allege when their claims arose, Pfizer argues that: (1) if their claims arose after the 2012 Lipitor label change, they are preempted; and (2) if their claims arose before April 2016, they are untimely. For the reasons that follow, Pfizer's motion is granted.

BACKGROUND

I. Lipitor

Lipitor is an FDA-approved statin prescribed for the prevention of cardiovascular disease and treatment of high cholesterol. (Compl., ECF No. 1-1 ("Compl."), ¶ 39.) In 1996, the FDA approved Lipitor for marketing and sale. (Compl. ¶ 40.) In 2009, the FDA approved updated labeling for Lipitor in response to a clinical trial titled "Stroke Prevention by Aggressive

Reduction in Cholesterol Levels" ("SPARCL"). (2009 Lipitor Packaging Insert, available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2009/020702Orig1s056.pdf (the "2009 Label").) The 2009 Label included a description of the SPARCL trial, stating in pertinent part, "[d]iabetes was reported as an adverse reaction in 144 subjects (6.1%) in the atorvastatin group and 89 subjects (3.8%) in the placebo group." (2009 Label, at 16.)

In February 2012, the FDA issued a drug safety announcement directed at doctors and patients. (FDA Drug Safety Communication: Important Safety Label Changes to Cholesterol-Lowering Statin Drugs (Feb. 28, 2012), available at https://www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-important-safety-label-changes-cholesterol-lowering-statin-drugs#sa (the "2012 Safety Announcement").) The announcement addressed, in part, "clinical trial meta-analyses and epidemiological data from the published literature, information concerning an effect of statins on incident diabetes and increases in HbA1c and/or fasting plasma glucose was added to statin labels." (2012 Safety Announcement.) However, despite this risk, the FDA concluded that it "continues to believe that the cardiovascular benefits of statins outweigh these small increased risks." (2012 Safety Announcement.)

Accompanying the 2012 Safety Announcement, the FDA again approved an update to the Lipitor label. (2012 Lipitor Packaging Insert, ECF No. 30-1 ("2012 Label").) The updated label added the following language to its Warnings and Precautions section: "Increases in HbAlc and fasting serum glucose levels have been reported with HMG-CoA reductase inhibitors, including LIPITOR." (2012 Label, at 78.) However, despite updating disclosures regarding risks relating to increases in HbA1c, the FDA did not alter the description of the diabetes risk contained in the SPARCL trial section. (2012 Label, at 42–43.)

II. Procedural History

On April 15, 2019, twenty-four individual plaintiffs filed this action in New York County Supreme Court. (Compl., at 1.) Pfizer removed the action on April 18, 2019, (see ECF No. 1), and answered the complaint the following day, (ECF No. 5). On September 16, 2019, Pfizer moved for judgment on the pleadings. (ECF No. 21.)

First, Plaintiffs seek to amend their complaint and attach a Proposed Amended Complaint as an exhibit to their opposition brief. (ECF No. 27-1.) However, the Proposed Amended Complaint fails to cure any of the fatal deficiencies described below. Second, Plaintiffs request that Pfizer's motion be converted into one for summary judgment and that they be allowed to conduct discovery. However, this is not warranted as no amount of discovery will cure the deficiencies in Plaintiffs' claims. Finally, Plaintiffs request more time to respond. But Plaintiffs already received additional time to respond. For these reasons, Pfizer's motion for judgment on the pleadings dismissing this action is granted.

DISCUSSION

I. Legal Standard

"The standards to be applied for a motion for judgment on the pleadings pursuant to [Federal Rule of Civil Procedure] 12(c) are the same as those applied to a motion to dismiss pursuant to Rule 12(b)." Estate of Smith v. Cash Money Records, Inc., 2018 WL 2224993, at *2 (S.D.N.Y. May 15, 2018) (quotation marks omitted); accord Hayden v. Paterson, 594 F.3d 150, 160 (2d Cir. 2010). Thus, to survive a motion for judgment on the pleadings, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 677 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). A court must accept the complaint's allegations as true and draw all

reasonable inferences in the plaintiff's favor. Kirkendall v. Halliburton, Inc., 707 F.3d 173, 178 (2d Cir. 2013). A judgment under Rule 12(c) is proper if, from the pleadings, the moving party is entitled to judgment as a matter of law. See United States v. Watts, 786 F.3d 152, 176 (2d Cir. 2015); Burns Int'l Sec. Servs., Inc. v. Int'l Union, 47 F.3d 14, 16 (2d Cir. 1995).

II. Preemption

Pfizer argues that to the extent Plaintiffs' claims arose after February 2012, they are preempted by federal law. This Court agrees.

A. FDA Approval of Drug Labels

Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq., the FDA closely controls the label for all FDA-approved drugs and therapies. During a drug's initial application, the FDA must approve the label. See 21 U.S.C. § 355; 21 C.F.R. § 314.105(b). Relevant here, the label includes risks that the FDA determines are necessary to warn patients. The label must:

> describe clinically significant adverse reactions (including any that are potentially fatal, are serious even if infrequent, or can be prevented or mitigated through appropriate use of the drug), other potential safety hazards (including those that are expected for the pharmacological class or those resulting from drug/drug interactions), limitations in use imposed by them (e.g., avoiding certain concomitant therapy), and steps that should be taken if they occur (e.g., dosage modification).

21 C.F.R. § 201.57(c)(6)(i). To warn of potential adverse reactions caused by the drug, the label must also:

> describe the overall adverse reaction profile of the drug based on the entire safety database. For purposes of prescription drug labeling, an adverse reaction is an undesirable effect, reasonably associated with use of a drug, that may occur as part of the pharmacological action of the drug or may be unpredictable in its occurrence. This definition does not include all adverse events observed during use of a drug, only those adverse events for which there is some basis to

> believe there is a causal relationship between the drug and the occurrence of the adverse event.

21 C.F.R. § 201.57(c)(7). Notably, this disclosure "does not include all adverse events observed during use of a drug, only those adverse events for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event." 21 C.F.R. § 201.57(c)(7) (emphasis added). This is a backstop to prevent manufacturers from warning of every possible adverse reaction in an effort to insulate themselves from any conceivable liability. Over-disclosure dilutes warnings of more significant adverse reactions both by likelihood and severity of the reaction and can unjustifiably deter patients from a helpful drug or therapy. See, e.g., Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 2848, 2851 (Jan. 16, 2008).

However, the FDCA and FDA regulations contemplate the inevitable advancement of scientific knowledge. Even after receiving approval, various constituencies—including the manufacturers—continue to conduct studies on FDA-approved drugs. As a result, labels may need to be updated periodically to recognize advancements in scientific knowledge. Label updates can reflect new adverse reactions, remove previously disclosed adverse reactions, or note changes in efficacy.

Two avenues exist for manufacturers to update their drug labels. First, manufacturers may update a label with FDA approval, similar to the approval process for the initial label. See 21 C.F.R. § 314.70(b). Second, manufacturers may update a label—without prior FDA approval—through the "changes being effected" ("CBE") regulation. See 21 C.F.R. § 314.70(c).

The CBE regulation allows a manufacturer to change its label unilaterally to "add or strengthen a contraindication, warning, precaution, or adverse reaction," 21 C.F.R.

§ 314.70(c)(6)(iii)(A), as soon as there is "reasonable evidence of a causal association," 21 C.F.R. § 201.57(c)(6)(i). However, "a causal relationship need not have been definitely established." 21 C.F.R. § 201.57(c)(6)(i). Further, the CBE regulation allows manufacturers to "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product," 21 C.F.R. § 314.70(c)(6)(iii)(C), or "delete false, misleading, or unsupported indications for use or claims for effectiveness," 21 C.F.R. § 314.70(c)(6)(iii)(D).

However, labeling changes pursuant to the CBE regulation may only be made on the basis of "newly-acquired information." 21 C.F.R. § 314.70(c)(6)(iii). The regulations define "newly-acquired information" as:

> [D]ata, analyses, or other information not previously submitted to the [FDA], which may include (but is not limited to) data derived from new clinical studies, reports of adverse events, or new analyses of previously submitted data (e.g., meta-analyses) if the studies, events, or analyses reveal risks of a different type or greater severity or frequency than previously included in submissions to FDA.

21 C.F.R. § 314.3(b). As with the initial labeling, speculative or exaggerated risks do not warrant a labeling update. The label may be "revised to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug." 21 C.F.R. § 201.57(c)(6)(i). However, "a causal relationship need not have been definitely established." 21 C.F.R. § 201.57(c)(6)(i).

B. Preemption Generally

The doctrine of preemption reflects the Supremacy Clause's core mandate that federal law prevails where it conflicts with state law. U.S. Const. art. VI, cl. 2; see Murphy v. Nat'l Collegiate Athletic Ass'n, 138 S. Ct. 1461, 1479–80 (2018) (holding that when "Congress enacts a law that imposes restrictions or confers rights on private actors" and "a state law confers rights or imposes restrictions that conflict with the federal law[,] . . . the federal law takes

precedence and the state law is preempted"). In general, three types of preemption exist: "(1) express preemption, where Congress has expressly preempted local law; (2) field preemption, where Congress has legislated so comprehensively that federal law occupies an entire field of regulation and leaves no room for state law; and (3) conflict preemption, where local law conflicts with federal law such that it is impossible for a party to comply with both or the local law is an obstacle to the achievement of federal objectives." Figueroa v. Foster, 864 F.3d 222, 227–28 (2d Cir. 2017) (quotation marks omitted). Preemption is "ultimately a question of statutory construction," and courts "look to the intent of Congress to determine the preemptive force of a statute" and the agency's intent "in evaluating preemption by a regulation." N.Y. Pet Welfare Ass'n, Inc. v. City of New York, 850 F.3d 79, 87 (2d Cir. 2017) (quotation marks omitted). Finally, the "same ordinary pre-emption principles [apply] whether the relevant federal law is a statute or a regulation." N.Y. Pet Welfare Ass'n, 850 F.3d at 87.

The party "asserting that federal law preempts state law bears the burden of establishing preemption." In re Methyl Tertiary Butyl Ether (MTBE) Prod. Liab. Litig., 725 F.3d 65, 96 (2d Cir. 2013). Here, Pfizer predicates its preemption arguments on conflict preemption. The burden to establish conflict preemption is a demanding one and requires a showing that "compliance with federal and state law is an impossibility." In re MTBE, 725 F.3d at 97 (quotation marks omitted). This occurs, for example, when state law "penalizes what federal law requires," or when state law claims "directly conflict[] with federal law." In re MTBE, 725 F.3d at 97 (quotation marks omitted) (collecting Supreme Court cases). Demonstrating that state law poses an "obstacle to the accomplishment and execution of the full purposes and objectives of Congress" is also a heavy burden. In re MTBE, 725 F.3d at 101. It requires a showing of "actual conflict with the overriding federal purpose and objective" and a

"repugnance or conflict [to be] so direct and positive that the two acts cannot be reconciled." In re MTBE, 725 F.3d at 101–02 (quotation marks omitted). In analyzing preemption, "the purpose of Congress is the ultimate touchstone." Wyeth v. Levine, 555 U.S. 555, 565 (2009) (quotation marks omitted).

Finally, while the Second Circuit disfavors preemption in areas traditionally entrusted to the states, that presumption generally does not apply to a sphere "where there has been a history of significant federal presence." N.Y. SMSA Ltd. P'ship v. Town of Clarkstown, 612 F.3d 97, 104 (2d Cir. 2010).

C. Preemption by the FDCA and FDA Regulations

Since the FDCA and FDA regulations require that the FDA approve a drug's initial label and significantly limit manufacturers' ability to update that label, state law failure-to-warn claims can be preempted. However, "[b]ecause manufacturers may unilaterally update a drug's label if the change complies with the CBE regulation, a state law failure-to-warn claim that depends on newly acquired information—information that Defendants could have added to their label without FDA approval—is not preempted." Gibbons v. Bristol-Myers Squibb Co., 919 F.3d 699, 708 (2d Cir. 2019). Thus, the Second Circuit has established a test to determine when failure to warn claims are preempted. "[T]o state a claim for failure-to-warn that is not preempted by the FDCA, a plaintiff must plead a labeling deficiency that [Defendants] could have corrected using the CBE regulation." Gibbons, 919 F.3d at 708 (second alteration in original) (quotation marks omitted). "If the plaintiff meets that standard, the burden shifts to the party asserting a preemption defense to demonstrate that there is clear evidence that the FDA would not have approved a change to the [prescription drug's] label." Gibbons, 919 F.3d at 708 (alteration in original) (quotation marks omitted).

The issue of what constitutes "clear evidence" such that the FDA would not have approved the change is a "critical question not as a matter of fact for a jury but as a matter of law for the judge to decide." Merck Sharp & Dohme Corp. v. Albrecht, 139 S. Ct. 1668, 1679 (2019). "In sum, if the plaintiff can point to the existence of 'newly acquired information' to support a labeling change under the CBE regulation, the burden then shifts to the manufacturer to show by 'clear evidence' that the FDA would not have approved the labeling change made on the basis of this newly acquired information." Utts v. Bristol-Myers Squibb Co., 251 F. Supp. 3d 644, 661 (S.D.N.Y. 2017), aff'd sub nom. Gibbons v. Bristol-Myers Squibb Co., 919 F.3d 699 (2d Cir. 2019).

D. Application of Preemption to Plaintiffs' Claims

Plaintiffs do not specify when their claims arose. However, as Pfizer argues, to the extent that Plaintiffs' claims arose after the 2012 Lipitor label change, they would be preempted.

"Plaintiffs' claims here fail at the first step because . . . they consist of conclusory and vague allegations and do not plausibly allege the existence of newly acquired information that could have justified Defendants' revising the [Lipitor] label through the CBE regulation." Gibbons, 919 F.3d at 708 (quotation marks omitted). Plaintiffs' complaint does not identify any "newly acquired information" on which Pfizer could have altered the Lipitor label. Plaintiffs begin with conclusory allegations that Pfizer knew that Lipitor causes type 2 diabetes. (Compl. ¶¶ 41, 50, 57 60, 74.) But this falls short of alleging "newly acquired information" on which Pfizer could have updated the label through the CBE regulations.

In their briefing and Proposed Amended Complaint, Plaintiffs offer a new theory: some 6,000 adverse event reports relating to diabetes sent from Pfizer to the FDA constitute

"newly acquired information." (Prop. Am. Compl. ¶ 87.) Pfizer forwarded these reports to the FDA between July 2012 and June 2015. (Prop. Am. Compl. ¶ 87.) FDA regulations require pharmaceutical companies to submits reports for "[a]ny adverse event associated with the use of a drug in humans, whether or not considered drug related." 21 C.F.R. § 314.80(a). Importantly, the regulation contains a disclaimer that "[a] report or information submitted by an applicant under this section (and any release by FDA of that report or information) does not necessarily reflect a conclusion by the applicant or FDA that the report or information constitutes an admission that the drug caused or contributed to an adverse effect." 21 C.F.R. § 314.80(l).

These adverse event reports do not constitute "newly acquired information." In order to qualify as "newly acquired information," the information must demonstrate "reasonable evidence of a causal association with a drug . . . ." 21 C.F.R. § 201.57. But "[t]he fact that a user of a drug has suffered an adverse event, standing alone, does not mean that the drug caused that event." Matrixx Initiatives, Inc. v. Siracusano, 563 U.S. 27, 44 (2011). The reports describe instances where patients taking Lipitor were diagnosed with type 2 diabetes but do not reach any conclusions regarding a causal association. Under a plain reading of the regulations, adverse event reports, without any analysis indicating causality, cannot constitute "newly acquired information."

Courts have also rejected the notion that analyses based on adverse event reports—much less the reports standing alone—can constitute "newly acquired information." See, e.g., Utts, 251 F. Supp. 3d at 663; McGrath v. Bayer HealthCare Pharm. Inc., 393 F. Supp. 3d 161, 169 (E.D.N.Y. 2019) (holding that "[r]eports and studies that discuss" adverse events do not constitute "newly acquired information"). In Utts, the plaintiffs offered a study that provided an analysis of adverse event reports. Utts, 251 F. Supp. 3d at 663. There, the court declined to

characterize the study as "newly acquired information," noting that the study itself "acknowledge[d] the limitations of its analysis of adverse event report data." Utts, 251 F. Supp. 3d at 664. Here, Plaintiffs offer no analysis on the adverse event reports. Instead, they merely proffer the adverse event reports by themselves to conclude that Pfizer could have updated the Lipitor label. Under the applicable regulations and case law, Plaintiffs' argument misses the mark.

Plaintiffs also argue that Pfizer could have analyzed the adverse event reports and that Pfizer's alleged failure to do that amounts to "newly acquired evidence." From there, Plaintiffs argue that the burden shifts to Pfizer to present clear evidence that the FDA would have rejected a Lipitor label change. This argument is also unavailing. To shift the burden to Pfizer, Plaintiffs must demonstrate the existence of "newly acquired information." See Gibbons, 919 F.3d at 708. Plaintiffs' attempt to shift the burden to Pfizer upends the framework set forth in Gibbons. Under Plaintiffs' theory, any litigant could circumvent Gibbons by merely alleging that a manufacturer should have created the "newly acquired information."

Finally, Plaintiffs argue that Lipitor's label warning of potential HbA1c increases is distinct from any warning of type 2 diabetes risk. Plaintiffs' highlight the distinction by alleging that "[w]hile increases in HbA1c are a symptom of diabetes, not every increase in HbA1c means the patient has diabetes." (Prop. Am. Compl. ¶ 94.) Accordingly, Plaintiffs assert that the Lipitor Label did not adequately warn of type 2 diabetes risk. But this argument is belied by the 2012 Label. Despite an additional warning of potential HbA1c increase, the FDA chose not to include any warning of type 2 diabetes and declined to disturb the description of diabetes risk contained in the SPARCL trial. Therefore, to the extent Plaintiffs' claims arose after the February 2012 label change, they are preempted by federal law.

III. Timeliness

While Plaintiffs do not allege when their claims accrued, to the extent those claims accrued before April 2016, they are untimely. New York personal injury claims have a three-year statute of limitations. N.Y. C.P.L.R. § 214(5). New York's borrowing statute applies the shorter of New York or the state where the claims accrued. N.Y. C.P.L.R. § 202. While Plaintiffs reside in other states and their claims could be subject to other states' statutes of limitations, other state statutes of limitations could only be shorter. Since Plaintiffs brought this action in April 2019, any claims that accrued prior to April 2016 would be untimely. Because any post-February 2012 claims are barred by preemption, the New York statute of limitations bars any surviving claims arising before that time. Thus, any analysis of the timeliness of Plaintiffs' claims under other states' statutes of limitations is moot.

New York provides an exception allowing plaintiffs to bring a claim one year after the discovery of the cause of the injury, so long as the cause is discovered within five years of the injury. N.Y. C.P.L.R. § 214-c(4). At best, this rule extends the statute of limitations to six years. Therefore, if Plaintiffs can utilize N.Y. C.P.L.R. § 214-c(4), any claims which accrued after April 2013 would be timely. However, Plaintiffs would still be caught in the preemption trap. Further, to fall into this exception, Plaintiffs would need to "allege and prove that technical, scientific or medical knowledge and information sufficient to ascertain the cause of his injury had not been discovered, identified or determined prior to the expiration of the period within which the action or claim would have been authorized." N.Y. C.P.L.R. § 214-c(4). Plaintiffs make no such allegations.

Plaintiffs contend Pfizer fraudulently concealed the information, thereby equitably tolling the statute of limitations. In order to take refuge in equitable tolling, Plaintiffs

would need to plead "with particularity (1) wrongful concealment by the defendant; (2) which prevented the plaintiff's discovery of the nature of the claim within the limitations period; and (3) due diligence in pursuing discovery of the claim." In re Crude Oil Commodity Futures Litig., 913 F. Supp. 2d 41, 59 (S.D.N.Y. 2012) (emphasis in original). Plaintiffs' conclusory allegation that Pfizer is "estopped from asserting a statute of limitations defense because they fraudulently concealed from Plaintiffs the nature of Plaintiffs' injuries and the connection between the injury and LIPITOR" falls short of pleading with particularity.[1] (Compl. ¶ 77.)

Since there is no possible overlap here where a claim could be timely and not federally preempted, Plaintiffs cannot state an actionable claim.

IV. Other Relief Requested

As an alternative to dismissal, Plaintiffs request (1) leave to amend their complaint, (2) conversion of Pfizer's motion for judgment on the pleadings to one for summary judgment, and (3) additional time to respond to Pfizer's motion. Because Plaintiffs' claims are futile, none of these avenues for relief are warranted.

A. Leave to Amend

Plaintiffs seek leave to amend, arguing that the complaint was drafted for New York State court. Pfizer removed this action and promptly answered the complaint. Plaintiffs did not amend their pleading within 21 days after Pfizer interposed its answer, which Plaintiffs could have done as a matter of course. Fed. R. Civ. P. 15(a)(1)(B). Plaintiffs did not—until their opposition to a clearly meritorious motion for judgment on the pleadings—seek leave to amend. Fed. R. Civ. P. 15(a)(2). But here, Plaintiffs went one step further and attached their Proposed Amended Complaint as an exhibit to their opposition papers. (ECF No. 27-1.) Thus this Court

[1] The Proposed Amended Complaint does not elaborate on Plaintiffs' fraud allegations.

addresses Plaintiffs' application for leave to amend with the benefit of their Proposed Amended Complaint.

Plaintiffs assert leave to amend is warranted because Pfizer's answer vaguely referenced preemption and did not provide Plaintiffs with an understanding of the deficiencies in their complaint. However, Pfizer's fifteenth defense provided a detailed argument that Plaintiffs' claims were preempted by FDA labeling regulations. (ECF No. 5, at 19.) Further, Pfizer's sixteenth and eighteenth affirmative defenses reference preemption as a defense to the allegations. (ECF No. 5, at 19–20.) It is hard to imagine a defendant giving more notice of a pleading's deficiencies.

"[L]eave to amend a complaint may be denied if the proposed amendment would be futile." Tocker v. Philip Morris Cos., 470 F.3d 481, 491 (2d Cir. 2006). An amendment is futile if it fails to cure prior deficiencies. Panther Partners, Inc. v. Ikanos Commc'ns, Inc., 681 F.3d 114, 119 (2d Cir. 2012).

Plaintiffs' Proposed Amended Complaint fails to cure the deficiencies Pfizer notes in its motion. Absent from the Proposed Amended Complaint is any mention of when Plaintiffs' claims accrued. While the Proposed Amended Complaint adds the allegations regarding adverse event reports, this does not enable Plaintiffs to circumvent preemption. The Proposed Amended Complaint also fails to demonstrate how Plaintiffs' claims could be timely. Accordingly, Plaintiffs' request to amend would be futile.

B. Conversion to Summary Judgment

Alternatively, Plaintiffs argue that this Court should convert Pfizer's Rule 12(c) motion to one for summary judgment under Rule 12(d).

Plaintiffs argue that Pfizer relies on documents outside of the complaint. "[A] court may convert a motion to dismiss into a motion for summary judgment, and . . . consider . . . external exhibits and affidavits, when it is satisfied that the parties are not taken by surprise or deprived of a reasonable opportunity to contest facts averred outside the pleadings and the issues involved are discrete and dispositive." Access 4 All, Inc. v. Trump Int'l Hotel and Tower Condo., 458 F. Supp. 2d 160, 165 (S.D.N.Y. 2006) (quotation marks omitted); accord Kennedy v. Empire Blue Cross & Blue Shield, 989 F.2d 588, 592 (2d Cir. 1993). However, this Court may rely on documents "the plaintiff has actual notice of . . . and relied upon . . . in framing the complaint." Cortec Indus., Inc. v. Sum Holding L.P., 949 F.2d 42, 48 (2d Cir. 1991). Here, the Lipitor label changes are publicly available and referenced in Plaintiffs' complaint. (Compl. ¶¶ 47–49.) It is clear that the label changes are integral to Plaintiffs' complaint. See Utts, 251 F. Supp. 3d at 657 (holding "[t]he court may also consider 'documents upon which the complaint relies and which are integral to the complaint'" and that "[t]he . . . labeling is integral to the [complaint]") (quoting Subaru Distribs. Corp. v. Subaru of Am., Inc., 425 F.3d 119, 122 (2d Cir. 2005)). Thus, this Court may rely on the label change in deciding the motion for judgment on the pleadings, and conversion to summary judgment is not warranted.

Plaintiffs also seek to conduct discovery. But Plaintiffs cannot breeze past Rule 12(c) when they have failed to state a claim upon which relief can be granted. No amount of discovery will remedy the deficiencies in the Proposed Amended Complaint.

C. Additional Time to Respond

Finally, in their opposition papers, Plaintiffs request additional time to respond to Pfizer's motion. Previously, this Court previously granted Plaintiffs' request for a fourteen-day extension to file their opposition papers. (ECF No. 26.) Plaintiffs made no further requests

before filing their opposition. Now, instead of responding to Pfizer's timeliness arguments in their opposition, Plaintiffs ask for the opportunity to file a second opposition brief. However, Plaintiffs fail to articulate why any further extension is warranted or how an extension would cure the deficiencies of their claims. Plaintiffs relinquished the opportunity to counter Pfizer's timeliness arguments in their Proposed Amended Complaint, which is bereft of any allegations concerning when Plaintiffs' claims arose.

This Court does not see how Plaintiffs can remedy their claims. Because claims that arose after 2012 are preempted and claims that arose before 2016 are time-barred, no circumstance exists that would allow Plaintiffs' claims to survive.

CONCLUSION

For the foregoing reasons, Pfizer's motion for judgment on the pleadings dismissing this action is granted and the case is dismissed with prejudice. The Clerk of Court is directed to terminate the motion pending at ECF No. 21 and mark this case closed.

Dated: April 7, 2020
New York, New York

SO ORDERED:

WILLIAM H. PAULEY III
U.S.D.J.