# APPENDIX

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**[ENTERED: April 20, 2021]**

20-1208
*Frei, et al. v. Taro Pharmaceutical U.S.A., Inc.*

**UNITED STATES COURT OF APPEALS**
**FOR THE SECOND CIRCUIT**

**SUMMARY ORDER**

**RULINGS BY SUMMARY ORDER DO NOT HAVE PRECEDENTIAL EFFECT. CITATION TO A SUMMARY ORDER FILED ON OR AFTER JANUARY 1, 2007, IS PERMITTED AND IS GOVERNED BY FEDERAL RULE OF APPELLATE PROCEDURE 32.1 AND THIS COURT'S LOCAL RULE 32.1.1. WHEN CITING A SUMMARY ORDER IN A DOCUMENT FILED WITH THIS COURT, A PARTY MUST CITE EITHER THE FEDERAL APPENDIX OR AN ELECTRONIC DATABASE (WITH THE NOTATION "SUMMARY ORDER"). A PARTY CITING TO A SUMMARY ORDER MUST SERVE A COPY OF IT ON ANY PARTY NOT REPRESENTED BY COUNSEL.**

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 20th day of April, two thousand twenty-one.

PRESENT:

DEBRA ANN LIVINGSTON,
*Chief Judge*,
RICHARD C. WESLEY,
SUSAN L. CARNEY,
*Circuit Judges*.

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JUDITH FREI, SANDRA RHODES, CHARLES RHODES, SHIRLEY HART, WILLIAM MURPHY, BONNIE MURPHY, JAMES WALTZ, MARY BETH WALZ, TRIO CALDWELL, BEVERLY CALDWELL, ALBERT DELSANTRO, CHARLOTTE DELSANTRO, ANNA THOMAS, CHARLES DAVID SMEDLEY, EDWARD FRISCO, LARRY E. ROBINSON, CECIL BARKLEY, NANCY MILLER, LARRY JUNKIN, ARTHUR L. CHURCH, MABLE CHURCH, JACQUELINE BOYD, CORTIS BOYD, BRIAN SUKENIK, SANDRA WHITE, ROGER WHITE, MARY WATERS, KEVIN HILTON, CLINTON HUMPHREY, TENNA HUMPHREY, BONNIE GREENE, MICHAEL HESS, SANDRA BONEKEMPER, NANCY HAGERMAN, GARY MELTON, CHRISTOPHER FREEMAN, JUDITH FREEMAN, CAROLYN SUE BEAN, MARK THOMPSON, ADA DUFFY, JEFFRIE HARRISON, CHRISTEN HARRISON, RANIERE CASERTA, COUCHITA CASERTA, DON AMBURGEY, JOYCE AMBURGEY, MONA SIMMONS, TRINA OWEN, RUBIE HODA, BILLY WEST, MONA WINDHAM, RONNIE WINDHAM, JEANNE COLBORNE, TRACIE SHOLLENBARGER, WILLIAM SHELTON, PINK JONES, ANNIE JONES, CYNTHIA SKILES, RAYMOND SKILES, EARL HINES, DAVID WHITLOCK, JACQUELINE WHITLOCK, CONNIE LUTE, JANICE SHELTON, JAMES SKINNER, DIXIE MELTON, DIANA HINES,

*Plaintiffs-Appellants*,

RAY HUBLER, MARIE HUBLER, REBECCA FRISCO, DEBRA HINES,

*Plaintiffs*,

v. No. 20-1208

TARO PHARMACEUTICAL U.S.A., INC.,

*Defendant-Appellee*,

ABC CORPORATIONS OR ENTITIES 1-50, JOHN AND JANE DOES 1-50, DOES 1-10,

*Defendants*.*

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FOR PLAINTIFFS-APPELLANTS: SAMUEL C. COLE, Cole Legal Services, PLLC, Richardson, TX (Joseph P. Guglielmo, Scott+Scott Attorneys at Law LLP, New York, NY; Alan M. Mansfield, Consumer Law Group of California, San Diego, CA; Edward K. Wood, Jr., Wood Law Firm LLC, Birmingham, AL, *on the brief*).

FOR DEFENDANT-APPELLEE: ARTHUR J. LIEDERMAN (Nicole Battisti, *on the brief*), Morrison Mahoney LLP, New York, NY.

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* Although Judith Frei was dismissed as a plaintiff, the parties have retained her name in the caption for consistency, because she was the "first listed Plaintiff" for much of the litigation. *See* App'x at 22 n.1.

Appeal from a judgment of the United States District Court for the Southern District of New York (Briccetti, *J.*).

**UPON DUE CONSIDERATION WHEREOF, IT IS HEREBY ORDERED, ADJUDGED, AND DECREED** that the judgment entered on March 11, 2020, is **AFFIRMED**.

Plaintiffs-Appellants appeal from the dismissal of their First Amended Complaint (the "Complaint"), alleging that they suffered injuries from taking Amiodarone, a generic drug manufactured by Taro Pharmaceutical U.S.A., Inc., for the off-label treatment of atrial fibrillation. The Complaint pleads seven claims against Taro: strict liability and negligent failure to warn (Counts I-II), negligent marketing and sale (Count III), negligence *per se* (Count IV), violation of New York General Business Law §§ 349 & 350 (Count V), fraud (Count VI), and wrongful death (Count VII).[1] The District Court dismissed the entire Complaint, finding that the failure-to-warn and negligent marketing and sale claims were preempted under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, and that the remaining claims were not plausibly pled. We assume the parties' familiarity with the underlying facts, the procedural history of the case, and the issues on

[1] The parties suggest that the state law of each Plaintiff's domicile, where the respective injuries occurred, may apply to each Plaintiff's claims. At this stage of the litigation, however, the parties cite only to New York law as an exemplar, on the assumption that "Plaintiff's home states all have equivalent common law." Appellants' Br. at 15 n.4.

appeal, to which we refer only as necessary to explain our decision to affirm.

"We review a district court's grant of a motion to dismiss de novo." *In re Synchrony Fin. Sec. Litig.*, 988 F.3d 157, 166 (2d Cir. 2021).[2] This Court is "free to affirm on any ground that finds support in the record, even if it was not the ground upon which the trial court relied." *Wells Fargo Advisors, LLC v. Sappington*, 884 F.3d 392, 396 n.2 (2d Cir. 2018).

We affirm the dismissal of the Complaint under Federal Rule of Civil Procedure 12(b)(6) because none of the claims are plausibly pled under Rule 8 and, in the case of the fraud claim, Rule 9. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) ("To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.' A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007))). Accordingly, we do not reach the questions whether, as Taro argues, certain claims are federally preempted or are barred by the state-law learned intermediary doctrine.

The thrust of the allegations is that Plaintiffs were seriously harmed when they took Amiodarone for the "off-label" treatment of atrial fibrillation, a heart condition for which the U.S. Food and Drug Administration (the "FDA") has not officially

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[2] Unless otherwise noted, in quotations from caselaw, this Order omits all alterations, brackets, citations, emphases, and internal quotation marks.

approved the drug. Manufacturers—in particular, Wyeth Pharmaceuticals Inc., which produced the original brand-name version of Amiodarone—allegedly encouraged this off-label use.

The Complaint pleads that Taro, as a subsequent generic manufacturer of Amiodarone, also bears responsibility. Underlying all seven claims against Taro are three basic factual theories: (1) Taro failed to make available to patients "Medication Guides" on the proper use and risks of Amiodarone as mandated in 21 C.F.R. § 208.24; (2) Taro failed to ensure the accuracy of information regarding Amiodarone in prescribing reference materials relied on by physicians, like the Physicians' Desk Reference and Epocrates; and (3) Taro concealed information in its exclusive possession regarding adverse events that occurred from the use of Amiodarone to treat atrial fibrillation. Each of these three theories—and in turn, the seven claims they support—is fatally flawed because the Complaint does not plausibly allege Taro's own involvement in wrongdoing.

First, the Complaint conclusorily asserts that Taro failed to make Medication Guides available to patients "in the manner required by law." App'x at 200. But the Complaint offers no supporting allegations other than that Plaintiffs did not receive Medication Guides at the point of sale for Amiodarone. That this was the end result does not support a plausible inference that Taro committed wrongdoing. To the extent the theory is that Taro failed to ensure availability of the Medication Guides in accordance with 21 C.F.R. § 208.24, that regulation is minimally satisfied so long as Taro maintained "the *means to produce* Medication Guides." *Id.* (b)(2)

(emphasis added). It does not require that Taro distribute Medication Guides, let alone to patients at the point of sale, notwithstanding the Complaint's suggestion otherwise. The Complaint lacks any allegation that Taro violated the minimal requirements of § 208.24. To the extent the theory is that Taro had a duty to provide Medication Guides beyond the manner set out in § 208.24, the Complaint does not say so or plead how Taro violated this hypothetical enhanced duty. *See* App'x at 200 (the allegations framing Taro's "failure to provide each patient a Medication Guide" only in terms of a "violation of the FDA's mandate" in § 208.24).

Nor is the theory that Taro failed to ensure the accuracy of the prescribing reference materials viable. The Complaint alleges that "[i]n connection with Defendants' unlawful promotion and/or sale of Amiodarone . . . they either directly or indirectly provided . . . to the distributor of the Physician[s'] Desk Reference ("PDR") and the developer of Epocrates" "indications and usage information regarding Amiodarone" that was misleading. App'x at 171. But the Complaint does not allege what that misleading information was or adduce any examples, beyond vaguely asserting that the effect of the reference materials was to "deceive[] physicians into believing" that Amiodarone safely treated atrial fibrillation. App'x at 172. More critically, these allegations are not tailored to Taro. The Complaint suggests that the content of the reference materials is "considered 'labeling'" subject to FDA approval, App'x at 173, but Taro, as a generic manufacturer, does not have control over this labeling. *See PLIVA, Inc. v. Mensing*, 564 U.S. 604, 613 (2011) (explaining that only brand-name manufacturers are "responsible for

the accuracy and adequacy" of drug labeling and a generic manufacturer must "ensur[e] that its warning label is the same as the brand name's"). The Complaint does not explain what Taro's contribution to or authority to correct the reference materials was. Indeed, the allegations are not framed in terms of Taro's misconduct, but rather that of "Defendants" generally, presumably referring to the numerous unidentified Doe Defendants not parties to this appeal. The only allegation specific to Taro is that images of Amiodarone pills that it manufactured appear in Epocrates, but we cannot plausibly infer from this fact that Taro controlled the medical content of the reference materials.

Finally, the theory that Taro did not report adverse events from the use of Amiodarone is not plausibly pled. As Plaintiffs' counsel conceded at oral argument, this theory is based on a broad statistical allegation, and is not specifically tied to Taro's conduct. The Complaint alleges that:

> There are millions or [sic] persons who are diagnosed with A-fib annually. Amiodarone over the years has become the number one prescribed drug for the treatment of A-fib. Based on the percentages of persons diagnosed just with pulmonary toxicity, there would be tens of thousands or [sic] adverse event reports submitted each year. Yet that does not appear to be even close to the number of these reports submitted to the FDA in connection with Amiodarone.

App'x at 191. This allegation merely posits that all entities in the Amiodarone market should have collectively reported more adverse events of pulmonary toxicity in light of the frequency of these events in the general population. We cannot draw from this allegation an inference that Taro itself concealed information in its possession.

Because none of the three theories on which all the claims depend is viable, the Complaint fails to state a plausible claim for relief under Rules 12(b)(6), 8, and 9.

* * *

For the foregoing reasons, the District Court's judgment dismissing the Complaint is **AFFIRMED**.

FOR THE COURT:

Catherine O'Hagan Wolfe, Clerk of Court

**[ENTERED: March 10, 2020]**

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

| | | |
|---|---|---|
| JUDITH FREI; SANDRA RHODES; CHARLES RHODES; SHIRLEY HART; WILLIAM MURPHY; BONNIE MURPHY; JAMES WALZ; MARY BETH WALZ; TRIO CALDWELL; BEVERLY CALDWELL; ALBERT DELSANTRO; CHARLOTTE DELSANTRO; ANNA THOMAS; CHARLES DAVID SMEDLEY; EDWARD FRISCO; LARRY E. ROBINSON; CECIL BARKLEY; NANCY MILLER; LARRY JUNKIN; ARTHUR L. CHURCH; MABLE CHURCH; JACQUELINE BOYD; CORTIS BOYD; BRIAN SUKENIK; SANDRA WHITE; ROGER WHITE; MARY WATERS; KEVIN HILTON; CLINTON HUMPHREY; TENNA HUMPHREY; BONNIE GREEN; MICHAEL HESS; SANDRA BONEKEMPER; NANCY HAGERMAN; GARY MELTON; DIXIE MELTON; CHRISTOPHER FREEMAN; JUDITH FREEMAN; CAROLYN SUE BEAN; MARK THOMPSON; ADA DUFFY; JEFFERIE HARRISON; | : | **OPINION AND ORDER**<br><br>19 CV 2939 (VB) |

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| CHRISTEN HARRISON; RANIERE CASERTA; COUCHITA CASERTA; DON AMBURGEY; JOYCE AMBURGEY; MONA SIMMONS; TRINA OWEN; RUBIE HODA; BILLY WEST; MONA WINDHAM; RONNIE WINDHAM; JEANNE COLBORNE; TRACIE SHOLLENBARGER; WILLIAM SHELTON; JANICE SHELTON; PINK JONES; ANNIE JONES; CYNTHIA SKILES; RAYMOND SKILES; JAMES SKINNER; DAVID WHITLOCK; JACQUELINE WHITLOCK; CONNIE LUYE; EARL HINES; and DIANA HINES, | : |
| Plaintiffs, | : |
| v. | : |
| TARO PHARMACEUTICALS U.S.A., INC., and DOES 1-10, inclusive, | : |
| Defendants. | : |

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Briccetti, J.:

Plaintiffs Judith Frei, Sandra Rhodes, Charles Rhodes, Shirley Hart, William Murphy, Bonnie Murphy, James Walz, Mary Beth Walz, Trio Caldwell, Beverly Caldwell, Albert Delsantro,

Charlotte Delsantro, Anna Thomas, Charles David Smedley, Edward Frisco, Larry E. Robinson, Cecil Barkley, Nancy Miller, Larry Junkin, Arthur L. Church, Mable Church, Jacqueline Boyd, Cortis Boyd, Brian Sukenik, Sandra White, Roger White, Mary Waters, Kevin Hilton, Clinton Humphrey, Tenna Humphrey, Bonnie Green, Michael Hess, Sandra Bonekemper, Nancy Hagerman, Gary Melton, Dixie Melton, Christopher Freeman, Judith Freeman, Carolyn Sue Bean, Mark Thompson, Ada Duffy, Jefferie Harrison, Christen Harrison, Raniere Caserta, Couchita Caserta, Don Amburgey, Joyce Amburgey, Mona Simmons, Trina Owen, Rubie Hoda, Billy West, Mona Windham, Ronnie Windham, Jeanne Colborne, Tracie Shollenbarger, William Shelton, Janice Shelton, Pink Jones, Annie Jones, Cynthia Skiles, Raymond Skiles, James Skinner, David Whitlock, Jacqueline Whitlock, Connie Luye, Earl Hines, and Diana Hines, bring claims against defendants Taro Pharmaceuticals U.S.A., Inc., and Does 1-10 (collectively, "Taro"), relating to Taro's manufacture, sale, and promotion of the generic prescription drug amiodarone hydrochloride ("amiodarone"), an anti-arrhythmic heart medication.

Now pending is Taro's motion to dismiss plaintiffs' first amended complaint (the "amended complaint") under Rule 12(b)(6). (Doc. #27).

For the following reasons, the motion is GRANTED.

The Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1367.

## BACKGROUND

For the purpose of ruling on the motion to dismiss, the Court accepts as true all well-pleaded allegations in the amended complaint and draws all reasonable inferences in plaintiffs' favor, as summarized below.

Taro manufactures and sells amiodarone, which is the generic form of Cordarone, a brand-name drug manufactured by Wyeth Pharmaceuticals, Inc. ("Wyeth").

In 1985, Wyeth received approval from the Food and Drug Administration ("FDA") to market and sell Cordarone. The FDA approved the use of Cordarone/amiodarone for the treatment of "ventricular fibrillation and ventricular tachycardia"— life-threating heartbeat irregularities. (Doc. #21 ("Am. Compl.") ¶ 60). However, the FDA approved the use of amiodarone only when other treatment options have been unsuccessful or were otherwise not appropriate for a particular patient. (Id.). In other words, the FDA approved amiodarone as a "drug of last resort." (Id. ¶ 61).

Under federal law, generic pharmaceutical manufacturers are not required to repeat the FDA approval process undertaken by brand-name manufacturers, often called "innovators." Rather, pursuant to the Hatch-Waxman Act of 1984, which amended the Food, Drug, and Cosmetic Act ("FDCA"), a generic manufacturer must submit to the FDA an Abbreviated New Drug Application ("ANDA") to obtain approval to manufacture a generic pharmaceutical following the FDA's approval of its brand-name equivalent. In 2001, the FDA approved

Taro's ANDA, permitting Taro to manufacture and sell amiodarone.[1]

According to the amended complaint, Wyeth aggressively and successfully marketed Cordarone for inappropriate "off label" use as a first-line anti-arrhythmic therapy, even though it was approved for use only as a drug of last resort. "Off-label" use of a pharmaceutical occurs when the medication is used in a manner that has not been approved by the FDA. According to plaintiffs, the FDA repeatedly warned Wyeth to stop marketing Cordarone in a manner which downplayed safety risks and promoted off-label use. Further, the FDA promulgated a regulation requiring manufacturers of amiodarone to make available to distributors a medication guide—a handout explaining drug safety information, which distributors must then provide to patients when dispensing prescriptions—setting forth in plain terms the drug's medical uses and health risks. See 21 C.F.R. § 208.24.

Plaintiffs allege that as a result of Wyeth's pervasive marketing activities, which benefitted generic manufactures such as Taro, physicians—not appreciating the safety risks associated with amiodarone—began to prescribe the drug as a first-line therapy for atrial fibrillation.

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[1] Although plaintiffs do not allege that the FDA approved Taro's ANDA in 2001, the Court takes judicial notice of Taro's publicly available ANDA, approved by the FDA on March 30, 2001. See FDA, ANDA 75-424 (Mar. 30, 2001), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2001/75424ltr.pdf (last visited Feb. 29, 2020).

Plaintiffs are sixty-seven individuals across twenty-one states, who allege that they, or their spouses, or their related decedents, were injured as a result of being prescribed, and ingesting amiodarone manufactured by Taro, to treat atrial fibrillation. According to plaintiffs, Taro failed to provide, or make available for distribution, medication guides to both distributors and patients. Plaintiffs further allege Taro took advantage of Wyeth's promotional marketing of the drug for off-label use, and failed to inform physicians, distributors, or patients of the many potential dangers of amiodarone, including that it was not intended for use as a first-line therapy for atrial fibrillation.

Plaintiffs assert claims for strict products liability, negligence in promoting amiodarone for off-label use and failing to inform of the dangers thereof, negligence per se, failing to provide a medication guide to distributors and patients, misrepresentation and deception, fraud, and wrongful death.

## DISCUSSION

### I. Standard of Review

In deciding a Rule 12(b)(6) motion, the Court evaluates the sufficiency of the operative complaint under the "two-pronged approach" articulated by the Supreme Court in Ashcroft v. Iqbal, 556 U.S. 662, 679 (2009).[2] First, a plaintiff's legal conclusions and "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements," are not entitled to the assumption of truth and are thus

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[2] Unless otherwise indicated, case quotations omit all internal citations, quotations, footnotes, and alterations.

not sufficient to withstand a motion to dismiss. Id. at 678; Hayden v. Paterson, 594 F.3d 150, 161 (2d Cir. 2010). Second, "[w]hen there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." Ashcroft v. Iqbal, 556 U.S. at 679.

To survive a Rule 12(b)(6) motion, the complaint's allegations must meet a standard of "plausibility." Ashcroft v. Iqbal, 556 U.S. at 678; Bell Atl. Corp. v. Twombly, 550 U.S. 544, 564 (2007). A claim is facially plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Ashcroft v. Iqbal, 556 U.S. at 678. "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." Id. (quoting Bell Atl. Corp. v. Twombly, 550 U.S. at 556).

In considering a motion to dismiss pursuant to Rule 12(b)(6), courts "may consider the facts alleged in the complaint, documents attached to the complaint as exhibits, and documents incorporated by reference in the complaint." DiFolco v. MSNBC Cable L.L.C., 622 F.3d 104, 111 (2d Cir. 2010). Courts may also consider matter of which judicial notice may be taken, including public documents and records. Chambers v. Time Warner, Inc., 282 F.3d 147, 153 (2d Cir. 2002).

II. Warning and Labeling

Plaintiffs plead two separate failure to warn claims, one for strict liability, and the other for

negligence. Under New York law, failure to warn claims "are identical under strict liability and negligence theories of recovery." DiBartolo v. Abbott Labs., 914 F. Supp. 2d 601, 611 (S.D.N.Y. 2012).

"[A] pharmaceutical manufacturer has a duty to warn of all potential dangers in its prescription drugs that it knew, or, in the exercise of reasonable care, should have known to exist." DiBartolo v. Abbott Labs., 914 F. Supp. 2d at 611 (citing Martin v. Hacker, 83 N.Y.2d 1, 8 (1993)). To state a prima facie claim for failure to warn under New York law, a plaintiff "must demonstrate (1) that the warning was inadequate and (2) that the failure to adequately warn of the dangers of the drug was a proximate cause of his or her injuries." Id. at 611–12.

Taro argues that plaintiffs' strict liability and negligence causes of action for failure to warn are preempted by federal law. Taro contends federal law requires generic manufacturers, like Taro, to ensure that its product and labeling are the same as those of its brand-name equivalent approved by the FDA. Thus, Taro argues that any state law failure to warn claims that would have required Taro to alter its product or labeling are preempted.

The Court agrees.

"A fundamental principle of the Constitution is that Congress has the power to preempt state law." Crosby v. Nat'l Foreign Trade Council, 530 U.S. 363, 372 (2000). Thus, "[w]here state and federal law directly conflict, state law must give way." PLIVA, Inc. v. Mensing, 564 U.S. 604, 617–18 (2011). In determining whether federal preemption applies, "[c]ourts must 'start with the assumption that the

historic police powers of the States were not to be superseded by the Federal Act.'" Utts v. Bristol-Myers Squibb Co., 251 F. Supp. 3d 644, 660 (S.D.N.Y. 2017) (quoting Wyeth v. Levine, 555 U.S. 555, 565 (2009).

"Express preemption is present when Congress's intent to preempt state law is explicitly stated in the statute's language." In re PepsiCo., Inc., Bottled Water Mktg. & Sales Practices Litig., 588 F. Supp. 2d 527, 530 (S.D.N.Y. 2008). "Implied preemption arises when, in the absence of explicit statutory language, . . . Congress intended the Federal Government to occupy a field exclusively, or when state law actually conflicts with federal law." Air Trans. Ass'n of Am., Inc. v. Cuomo, 520 F.3d 218, 220 (2d Cir. 2008) (citing English v. Gen. Elec. Co., 496 U.S. 72, 79 (1990)).

The latter type of implied preemption, called "conflict preemption," "comes in two forms—impossibility preemption and obstacle preemption." McDaniel v. Upsher-Smith Labs., Inc., 893 F.3d 941, 944 (6th Cir. 2018). The first, impossibility preemption, arises as its title suggests: when compliance with both federal and state law is impossible. Gade v. Nat'l Solid Wastes Mgmt. Ass'n, 505 U.S. 88, 98 (1992). "The proper question for impossibility analysis is whether the private party could independently do under federal law what state law requires of it." PLIVA, Inc. v. Mensing, 564 U.S. at 620. The second form, obstacle preemption, exists "when a state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Wis. Pub. Intervenor v. Mortier, 501 U.S. 597, 605 (1991).

Here, plaintiffs' failure to warn claims are not expressly preempted by federal law. "The required clear statement of legislative intent to preempt is lacking." In re Zyprexa Prods. Liab. Litig., 489 F. Supp. 2d 230, 275 (E.D.N.Y. 2007).

However, plaintiff's failure to warn claims are impliedly preempted, as they rely principally on Taro violating its federal duty of sameness, as well as plaintiffs' attempt to enforce FDA regulations.

Although the Supreme Court has held, with respect to brand-name, or "innovator," manufacturers, that state law failure to warn claims are not preempted by federal law, Wyeth v. Levine, 555 U.S. at 568–69, it has also held that "such suits could not go forward against generic drug manufacturers, as it is impossible for them to comply simultaneously with their state duty to adequately warn and their federal duty of sameness." Fulgenzi v. PLIVA, Inc., 711 F.3d 578, 580 (6th Cir. 2013) (citing PLIVA, Inc. v. Mensing, 564 U.S. at 616). It is well-settled that a generic manufacturer has an ongoing duty of sameness—the generic's ingredients, safety, efficacy, and warning labels must remain identical to its branded equivalent. PLIVA, Inc. v. Mensing, 564 U.S. at 613.

Indeed, when "the FDA has made a conclusive determination, positive or negative, as to the existence of a link between the drug at issue and some adverse health consequence, state law cannot mandate that a manufacturer include additional warnings beyond those that the FDA has determined to be appropriate to the risk." In re Zypreza Prods. Liab. Litig., 489 F. Supp. 2d at 276.

Plaintiffs argue Fulgenzi v. PLIVA, Inc., a Sixth Circuit case, demonstrates that plaintiffs' failure to warn claims are not federally preempted pursuant to Mensing. (Doc. #35 ("Pls. Mem.") at 5). In Fulgenzi, a branded-name manufacturer strengthened certain warnings in its product labeling, as allowed, but the generic manufacturer failed to update its labeling as required by federal law. Fulgenzi v. PLIVA, Inc., 711 F.3d at 580. Fulgenzi sued the generic manufacturer on a state law theory of failure to warn. The Sixth Circuit concluded that compliance with both federal law and state law was no longer impossible, as the manufacturer could have complied with the law of both jurisdictions by appropriately strengthening its labeling, as required. Id. at 588–89. Here, however, plaintiffs' arguments respecting Fulgenzi are inapposite, as plaintiffs suggest Taro, a generic manufacturer, should have strengthened its warnings beyond those of the branded manufacturer and approved by the FDA.

Plaintiffs further argue their failure to warn claims are not preempted under Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001). Again, the Court disagrees. In Buckman, the Supreme Court considered whether the FDCA preempted "fraud-on-the-FDA" state claims. Id. at 348. There, the plaintiffs contended a medical device manufacturer obtained FDA approval for a product, but made fraudulent misrepresentations to the FDA to obtain its approval. Id. at 343. Plaintiffs sued the manufacturer on a theory of state law fraudulent misrepresentation. Id. The Court concluded fraud-on-the-FDA claims conflicted with, and therefore were preempted by, federal law. Id. at 348. "The conflict stems from the fact that the federal statutory scheme amply

empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives." Id. "In other words, policing fraud on the FDA through a tort action could interfere with how the FDA might wish to police that kind of fraud itself." Desiano v. Warner-Lambert & Co., 467 F.3d 85, 93 (2d Cir. 2006) (discussing Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341). Here, plaintiffs seek to police Taro's alleged failure to warn the FDA of the health risks of amiodarone. Such claims are preempted.

Plaintiffs also contend Taro could have complied with federal and state law by seeking the FDA's assistance in convincing the branded manufacturer, Wyeth, to adopt a stronger label, thereby allowing Taro to utilize a stronger label as well. However, even if Taro had asked the FDA for such assistance, it would not have satisfied any requirement under state law. See PLIVA, Inc. v. Mensing, 564 U.S. at 618. Indeed, "requesting FDA assistance . . . would not have satisfied [Taro's] state tort-law duty to provide adequate labeling," as state law does not instruct manufacturers to communicate with the FDA about a possibly safer label. See id. at 619.

Accordingly, because Taro could not have disseminated post-marketing warnings inconsistent with Wyeth's warnings and labeling—approved by the FDA—without violating federal law, and also could not have disseminated alternative post-marketing warnings without violating federal law, plaintiffs' claims are preempted in these respects.

Moreover, plaintiffs' failure to warn claims against Taro are also preempted inasmuch as they concern Taro's alleged failure to provide medication guides to amiodarone distributors and patients.

The FDA regulation titled "Distributing and dispensing a Medication Guide," provides in pertinent part:

> Each manufacturer who ships a container of drug product for which a Medication Guide is required . . . is responsible for ensuring that Medication Guides are available for distribution to patients by either:
>
> (1) Providing Medication Guides in sufficient numbers to distributors, packers, or authorized dispensers to permit the authorized dispenser to provide a Medication Guide to each patient receiving a prescription for the drug product; or
>
> (2) Providing the means to produce Medication Guides in sufficient numbers to distributors, packers, or authorized dispensers to permit the authorized dispenser to provide a Medication Guide to each patient by receiving a prescription for the drug product.

21 C.F.R. § 208.24(b). The regulation states further:

> Each authorized dispenser of a prescription drug product for which a Medication Guide is required . . . shall,

> when the product is dispensed to a patient (or to a patient's agent), provide a Medication Guide direct to each patient (or to the patient's agent).

21 C.F.R. § 208.24(e).

Accordingly, the regulatory text obligates manufacturers to provide medication guides in sufficient numbers, or the means to produce them in sufficient numbers, to distributors, so that such distributors could in turn provide the medication guides to patients. Critically, the regulation does not obligate a manufacturer to provide medication guides directly to patients or their agents.

"Except in circumstances not relevant here, 'all such proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States.'" McDaniel v. Upsher-Smith Labs., Inc., 893 F.3d at 944 (quoting 21 U.S.C. § 337(a)). "The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance." Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. at 349 n.4. Indeed, the FDCA does not provide a private right of action for a defendant's violation of its provisions. Merrell Dow Pharm. Inc. v. Thompson, 478 U.S. 804, 810 (1986).

Although plaintiffs couch their failure to warn claims in traditional state tort law, it is clear the existence of the FDA's medication guide regulation is the gravamen of these claims. There is no question Taro's amiodarone medication guide is a "critical element" in this case. See McDaniel v. Upsher-Smith Labs., Inc., 893 F.3d at 944. By the Court's count, the

amended complaint references Taro's medication guide over 400 times. Moreover, plaintiffs do not identify a parallel state law requiring Taro to make available to distributors an amiodarone medication guide. And when a plaintiff's claims "exist solely by virtue of the FDCA . . . requirements," state law claims are impliedly preempted. Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. at 352.

Finally, as an additional matter, the Court notes "the majority of district courts to consider this very issue have found identical claims preempted." See McDaniel v. Upsher-Smith Labs., Inc., 893 F.3d at 946 (collecting cases).

For these reasons, plaintiffs' failure to warn claims are preempted and must be dismissed.

III. Off-Label Promotion

Taro next argues any claims respecting its alleged promotion of amiodarone for off-label use must be dismissed.

The Court agrees.

The bases for plaintiffs' off-label promotion claims are that Taro: (i) benefitted from, and did nothing to counteract, Wyeth's pervasive marketing of Cordarone/amiodarone as a first-line therapy for atrial fibrillation; (ii) failed to correct promotional information appearing in third-party applications and reference materials, upon which many doctors allegedly rely; and (iii) failed to petition the FDA to alter the medication guide and strengthen product labeling.

These claims, like those discussed above, are preempted under PLIVA, Inc. v. Mensing. "Because each alleged cause of action requires [Taro] to either change the labeling for amiodarone, change its design or formation, exit the market, or accept state tort liability," each claim is impliedly preempted. Bean v. Upsher-Smith Pharm., Inc., 2017 WL 4348330, at *6 (D.S.C. Sept. 29, 2017) (citing PLIVA, Inc. v. Mensing, 564 U.S. at 620).

In addition, these claims respecting off-label use and promotion are subject to preemption under Buckman as well "because the duties [plaintiffs allege Taro] breached regarding off-label promotion exist solely under the FDCA." Bean v. Upsher-Smith Pharm., Inc., 2017 WL 4348330, at *7 (D.S.C. Sept. 29, 2017); see also Perdue v. Wyeth Pharms., Inc., 209 F.; Supp. 3d 847, 852 (E.D.N.A. July 20, 2016) (dismissing claim for negligent off-label promotion because the claim was not premised on conduct that would give rise to recovery under state law in the absence of federal law).

IV. Negligence Per Se

Taro argues plaintiff's negligence per se claim must be dismissed.

The Court agrees.

In New York, "the unexcused omission or violation of a duty imposed by statute for the benefit of a particular class is negligence itself." Timperio v. Bronx-Lebanon Hosp. Ctr., 384 F. Supp. 3d 425, 434 (S.D.N.Y. 2019). However, a defendant's mere violation of a statute "does not automatically constitute negligence per se. Only statutes designed

the protect a definite class of persons from a particular hazard, which persons within the class are incapable of avoiding, can give rise to a negligence per se for violation of the statute." Id.

Here, plaintiffs' negligence per se claim is premised on Taro's alleged "failure to ensure the Medication Guide was provided to Plaintiffs with prescriptions of Amiodarone, and to additionally provide adequate warnings regarding the unapproved 'off-label' use of Amiodarone for the treatment of A-fib." (Am. Compl. ¶ 188).

Aside from the federal medication guide regulation—which is not privately enforceable and, on its face, contains no duty on the part of manufactures to provide medication guides directly to patients—plaintiffs allege Taro violated N.Y. Education Law § 6811(9)–(11). The statute states it is a class A misdemeanor under state law to "manufacture, sell, deliver for sale, hold for sale or offer for sale of any drug, device, or cosmetic that is adulterated or misbranded"; "misbrand any drug, device, or cosmetic"; or "receive in commerce any drug, device or cosmetic that is adulterated or misbranded, and to deliver and proffer delivery thereof for pay or otherwise." N.Y. Educ. Law § 6811 (9)–(11).

Plaintiffs fail plausibly to plead that Taro has taken part in any of the above proscribed conduct. In one breath, plaintiffs argue "they did not plead that any of the FDA warning[s] were inadequate," (Pls. Mem. at 4), yet in a second argue Taro committed negligence per se by "misbranding" its product. Moreover, and again, the FDA approved the labeling

and warning information associated with Cardorone/amiodarone, and Taro, a generic pharmaceutical manufacturer, has on ongoing duty to provide the same warning labels and information distribution as those of the brand-name manufacturer. In other words, Taro's warning labels and disseminated information must remain identical to its branded equivalent. It is precluded under federal law from unilaterally altering such information. For these reasons, plaintiffs' negligence per se claim must be dismissed.

V. New York General Business Law Claims

Plaintiffs cannot state a plausible claim for deceptive trade practices under New York General Business Law Sections 349 of 350.

Section 349 of the New York General Business Law renders unlawful unfair or deceptive business practices. INV Accelerator, LLC v. MX Techs., Inc., 2020 WL 8822902, at *6 (S.D.N.Y. Feb. 24, 2020). "It is uncontroverted that Section 349 . . . prohibits deceptive practices that are directed at consumers." Amos v. Biogen Idec Inc., 28 F. Supp. 3d 164, 173 (W.D.N.Y. 2014); see also Oswego Laborers' Local 214 Pension Fund v. Marine Midland Bank, N.A., 85 N.Y.2d 20, 25 (1995). Indeed, [f]or purposes of [Section] 349, consumers are defined as those who purchase goods and services for personal, family or household use." INV Accelerator, LLC v. MX Techs., Inc., 2020 WL 8822902, at *6.

"[B]ecause a drug manufacturer's duty to warn of a drug's side effects runs to the doctor prescribing the drug, and not to the user of the drug, the issuance of [prescription] drug warnings, for purposes of

Section 349, is not an act directed at consumers, and therefore any alleged deceptive act related to the issuance of those warnings is not a 'consumer oriented' act actionable under Section 349." Amos v. Biogen Idec Inc., 28 F. Supp. 3d at 173.

As for Section 350, the statute states that "[f]alse advertising in the conduct of any business, trade or commerce or in the furnishing of any service in this state is hereby declared unlawful." To state a plausible Section 350 claim, a plaintiff must allege that the act, practice or advertisement was consumer-oriented and misleading in a material respect, and that plaintiff was injured as a result of such conduct. Medisim Ltd. v. BestMed LLC, 910 F. Supp. 2d 591, 607 (S.D.N.Y. 2012). "A plaintiff must also demonstrate reliance, which typically means he must point to a specific advertisement or public pronouncement upon which the consumer relied." Id.

Here, plaintiffs fail plausibly to plead the necessary elements of a Section 349 or 350 violation, let alone allege sufficient factual allegations which "raise a right of relief above the speculative level." Bell Atl. Corp. v. Twombly, 550 U.S. at 555. Indeed, plaintiffs merely allege Taro is liable for failing to counteract an allegedly pervasive and deceptive marketing campaign conducted decades ago by a brand-name manufacturer, and that Taro has failed to correct certain information on third-party applications and references for which Taro is not responsible. Simply, these allegations fail to state a plausible claim.

Accordingly, plaintiffs' claim for violations of New York General Business Law must be dismissed.

VI. Fraud

Finally, Taro contends plaintiffs fail to allege predicate acts of fraud with particularity, as required by Rule 9(b).

The Court agrees.

A claim for fraud under New York law requires a showing of "a misrepresentation or material omission of fact which was false and known to be false by defendant, made for the purpose of inducing the other party to rely upon it, justifiable reliance of the other party on the misrepresentation, and injury." Lama Holding Co. v. Smith Barney, Inc., 88 N.Y.2d 413, 421 (1996).

In addition, Federal Rule of Civil Procedure 9(b) requires that "[i]n alleging fraud or mistake, a party must state with particularity the circumstance constituting fraud or mistake." "[T]o comply with Rule 9(b), the complaint must: (1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." Lerner v. Fleet Bank, N.A., 459 F.3d 273, 290 (2d Cir. 2006). And "[t]o meet the requirement of Rule 9(b) a plaintiff must show the manner in which he was damaged by the implementation of a deceptive or manipulative practice or by a misrepresentation or omission." Moran v. Kidder Peabody & Co., 609 F. Supp. 661, 665 (S.D.N.Y. 1985).

Although plaintiffs' fraud claims related to the promotion and marketing of amiodarone appear to be based on a state law theory of recovery, and not

dependent critically on the FDCA—and thus, perhaps, not preempted—plaintiffs nevertheless fail to plead plausible fraud claims.

First, plaintiffs generally rely on In re Bayer Corp. Combination Aspirin Prods. Marketing & Sales Prac. Litig., 701 F. Supp. 2d 356, 372–73 (E.D.N.Y. 2010), to demonstrate their fraud claims must proceed. In that case, however, a brand-name manufacturer marketed, sold, and inappropriately labeled an over-the-counter product—that the FDA had not approved—to falsely imply that the drug was FDA-approved. Such is not the case here.

Second, although plaintiffs claim Taro failed to correct false and misleading information about amiodarone provided to physicians in third-party reference materials, plaintiffs do not connect these general allegations to their alleged personal injuries. For instance, plaintiffs do not allege plausibly what information, if any, was relied upon by their physicians in prescribing amiodarone for atrial fibrillation. Moreover, and fatal to their claims, plaintiffs' conclusory fraud allegations are not accompanied by specific or sufficient facts concerning Taro's marketing and promotional activities.

In short, plaintiffs have not sufficiently alleged plausible fraud claims, and they certainly have not done so with requisite particularity.

VII. Wrongful Death

Because plaintiffs fail plausibly to plead a wrongful act on the part of Taro, which caused the deaths of some of the plaintiff's related decedents, this derivative claim fails.

## CONCLUSION

The motion to dismiss is GRANTED.

The Clerk is instructed to terminate the motion (Doc. #27) and close this case.

Dated: March 9, 2020

White Plains, NY

SO ORDERED:

/s/
Vincent L. Briccetti
United States District Judge

**[ENTERED: March 11, 2020]**

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

----------X

JUDITH FREI; SANDRA RHODES; CHARLES RHODES; SHIRLEY HART; WILLIAM MURPHY; BONNIE MURPHY; JAMES WALZ; MARY BETH WALZ; TRIO CALDWELL; BEVERLY CALDWELL; ALBERT DELSANTRO; CHARLOTTE DELSANTRO; ANNA THOMAS; CHARLES DAVID SMEDLEY; EDWARD FRISCO; LARRY E. ROBINSON; CECIL BARKLEY; NANCY MILLER; LARRY JUNKIN; ARTHUR L. CHURCH; MABLE CHURCH; JACQUELINE BOYD; CORTIS BOYD; BRIAN SUKENIK; SANDRA WHITE; ROGER WHITE; MARY WATERS; KEVIN HILTON; CLINTON HUMPHREY; TENNA HUMPHREY; BONNIE GREEN; MICHAEL HESS; SANDRA BONEKEMPER; NANCY HAGERMAN; GARY MELTON; DIXIE MELTON; CHRISTOPHER FREEMAN; JUDITH FREEMAN; CAROLYN SUE BEAN; MARK THOMPSON; ADA DUFFY; JEFFERIE HARRISON; CHRISTEN HARRISON; RANIERE CASERTA; COUCHITA

19 **CIVIL** 2939 (VB)

**JUDGMENT**

CASERTA; DON AMBURGEY; JOYCE AMBURGEY; MONA SIMMONS; TRINA OWEN; RUBIE HODA; BILLY WEST; MONA WINDHAM; RONNIE WINDHAM; JEANNE COLBORNE; TRACIE SHOLLENBARGER; WILLIAM SHELTON; JANICE SHELTON; PINK JONES; ANNIE JONES; CYNTHIA SKILES; RAYMOND SKILES; JAMES SKINNER; DAVID WHITLOCK; JACQUELINE WHITLOCK; CONNIE LUTE; EARL HINES; and DIANA HINES,

Plaintiffs,

-against-

TARO PHARMACEUTICALS U.S.A., INC., and DOES 1-10, inclusive,

Defendants.

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It is hereby **ORDERED, ADJUDGED AND DECREED:** That for the reasons stated in the Court's Opinion and Order dated March 9, 2020, Taro's motion to dismiss is granted; accordingly, this case is closed.

**Dated:** New York, New York
March 11, 2020

**RUBY J. KRAJICK**

**Clerk of Court**

**BY:**

**/s/**

**Deputy Clerk**

**[ENTERED: June 21, 2021]**

**UNITED STATES COURT OF APPEALS**
**FOR THE**
**SECOND CIRCUIT**

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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 21st day of June, two thousand twenty-one.

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Judith Frei, Sandra Rhodes, et al.,

Plaintiffs - Appellants,

Ray Hubler, Marie Hubler,
Rebecca Frisco, Debra Hines,

Plaintiffs,

**ORDER**

v.

Docket No: 20-1208

Taro Pharmaceutical U.S.A., Inc.,

Defendant - Appellee,

ABC Corporations or Entities 1-50, et al.,

Defendants.

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Appellants filed a petition for panel rehearing, or, in the alternative, for rehearing *en banc*. The panel that determined the appeal has considered the request for panel rehearing, and the active members of the Court have considered the request for rehearing *en banc*.

IT IS HEREBY ORDERED that the petition is denied.

FOR THE COURT:

Catherine O'Hagan Wolfe

**U.S. CONST. amend. V**

No person shall be held to answer for a capital, or otherwise infamous crime, unless on a presentment or indictment of a Grand Jury, except in cases arising in the land or naval forces, or in the Militia, when in actual service in time of War or public danger; nor shall any person be subject for the same offence to be twice put in jeopardy of life or limb; nor shall be compelled in any criminal case to be a witness against himself, nor be deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use, without just compensation.

## FEDERAL RULE OF CIVIL PROCEDURE 15

### Rule 15. Amended and Supplemental Pleadings

(a) AMENDMENTS BEFORE TRIAL.

(1) *Amending as a Matter of Course.* A party may amend its pleading once as a matter of course within:

(A) 21 days after serving it, or

(B) if the pleading is one to which a responsive pleading is required, 21 days after service of a responsive pleading or 21 days after service of a motion under Rule 12(b), (e), or (f), whichever is earlier.

(2) *Other Amendments.* In all other cases, a party may amend its pleading only with the opposing party's written consent or the court's leave. The court should freely give leave when justice so requires.

(3) *Time to Respond.* Unless the court orders otherwise, any required response to an amended pleading must be made within the time remaining to respond to the original pleading or within 14 days after service of the amended pleading, whichever is later.

(b) AMENDMENTS DURING AND AFTER TRIAL.

(1) *Based on an Objection at Trial.* If, at trial, a party objects that evidence is not within the issues raised in the pleadings, the court may permit the pleadings to be amended. The court should freely permit an amendment when doing so will aid in

presenting the merits and the objecting party fails to satisfy the court that the evidence would prejudice that party's action or defense on the merits. The court may grant a continuance to enable the objecting party to meet the evidence.

(2) *For Issues Tried by Consent.* When an issue not raised by the pleadings is tried by the parties' express or implied consent, it must be treated in all respects as if raised in the pleadings. A party may move—at any time, even after judgment—to amend the pleadings to conform them to the evidence and to raise an unpleaded issue. But failure to amend does not affect the result of the trial of that issue.

(c) RELATION BACK OF AMENDMENTS.

(1) *When an Amendment Relates Back.* An amendment to a pleading relates back to the date of the original pleading when:

(A) the law that provides the applicable statute of limitations allows relation back;

(B) the amendment asserts a claim or defense that arose out of the conduct, transaction, or occurrence set out—or attempted to be set out—in the original pleading; or

(C) the amendment changes the party or the naming of the party against whom a claim is asserted, if Rule 15(c)(1)(B) is satisfied and if, within the period provided by Rule 4(m) for serving the summons and complaint, the party to be brought in by amendment:

(i) received such notice of the action that it will not be prejudiced in defending on the merits; and

(ii) knew or should have known that the action would have been brought against it, but for a mistake concerning the proper party's identity.

(2) *Notice to the United States.* When the United States or a United States officer or agency is added as a defendant by amendment, the notice requirements of Rule 15(c)(1)(C)(i) and (ii) are satisfied if, during the stated period, process was delivered or mailed to the United States attorney or the United States attorney's designee, to the Attorney General of the United States, or to the officer or agency.

(d) SUPPLEMENTAL PLEADINGS. On motion and reasonable notice, the court may, on just terms, permit a party to serve a supplemental pleading setting out any transaction, occurrence, or event that happened after the date of the pleading to be supplemented. The court may permit supplementation even though the original pleading is defective in stating a claim or defense. The court may order that the opposing party plead to the supplemental pleading within a specified time.

(As amended Jan. 21, 1963, eff. July 1, 1963; Feb. 28, 1966, eff. July 1, 1966; Mar. 2, 1987, eff. Aug. 1, 1987; Apr. 30, 1991, eff. Dec. 1, 1991; Pub. L. 102–198, § 11(a), Dec. 9, 1991, 105 Stat. 1626; Apr. 22, 1993, eff. Dec. 1, 1993; Apr. 30, 2007, eff. Dec. 1, 2007; Mar. 26, 2009, eff. Dec. 1, 2009.)