

No. \_\_\_\_\_

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In The  
**Supreme Court of the United States**

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**JUDITH FREI, *ET AL.*,**

*Petitioners,*

v.

**TARO PHARMACEUTICALS (USA) INC.,**

*Respondent.*

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On Petition for Writ of Certiorari to the  
United States Court of Appeals  
for the Second Circuit

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**PETITION FOR WRIT OF CERTIORARI**

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*Dated: October 29, 2021*

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### **QUESTION PRESENTED**

Whether, consistent with Due Process and Federal Rule of Civil Procedure 15, a court has discretion to dismiss a plaintiff's complaint under Federal Rule of Civil Procedure 8(a) without leave to replead when a plaintiff has not had an opportunity to replead to address the court's concerns, absent a finding that there is "good reason" for not allowing the plaintiff to replead?

## **PARTIES TO THE PROCEEDING**

Petitioners are plaintiffs in the district court and appellants in the Second Circuit:

Plaintiff/Appellant – Judith Frei  
Plaintiff/Appellant – Sandra Rhodes  
Plaintiff/Appellant – Charles Rhodes  
Plaintiff/Appellant – Shirley Hart  
Plaintiff/Appellant – Ray Hubler  
Plaintiff/Appellant – Marie Hubler  
Plaintiff/Appellant – William Murphy  
Plaintiff/Appellant – Bonnie Murphy  
Plaintiff/Appellant – James Walz  
Plaintiff/Appellant – Mary Beth Walz  
Plaintiff/Appellant – Trio Caldwell  
Plaintiff/Appellant – Beverly Caldwell  
Plaintiff/Appellant – Albert Delsantro  
Plaintiff/Appellant – Charlotte Delsantro  
Plaintiff/Appellant – Anna Thomas  
Plaintiff/Appellant – Charles David Smedley  
Plaintiff/Appellant – Edward Frisco  
Plaintiff/Appellant – Rebecca Frisco  
Plaintiff/Appellant – Larry E. Robinson  
Plaintiff/Appellant – Cecil Barkley  
Plaintiff/Appellant – Nancy Miller  
Plaintiff/Appellant – Larry Junkin  
Plaintiff/Appellant – Arthur L. Church  
Plaintiff/Appellant – Mable Church  
Plaintiff/Appellant – Jacqueline Boyd  
Plaintiff/Appellant – Cortis Boyd  
Plaintiff/Appellant – Brian Sukenik

Plaintiff/Appellant – Sandra White  
 Plaintiff/Appellant – Roger White  
 Plaintiff/Appellant – Mary Waters  
 Plaintiff/Appellant – Kevin Hilton  
 Plaintiff/Appellant – Clinton Humphrey  
 Plaintiff/Appellant – Tenna Humphrey  
 Plaintiff/Appellant – Bonnie Greene  
 Plaintiff/Appellant – Michael Hess  
 Plaintiff/Appellant – Sandra Bonekemper  
 Plaintiff/Appellant – Nancy Hagerman  
 Plaintiff/Appellant – Gary Melton  
 Plaintiff/Appellant – Dixie Melton  
 Plaintiff/Appellant – Christopher Freeman  
 Plaintiff/Appellant – Judith Freeman  
 Plaintiff/Appellant – Carolyn Sue Bean  
 Plaintiff/Appellant – Mark Thompson  
 Plaintiff/Appellant – Ada Duffy  
 Plaintiff/Appellant – Jefferie Harrison  
 Plaintiff/Appellant – Christen Harrison  
 Plaintiff/Appellant – Raniere Caserta  
 Plaintiff/Appellant – Couchita Caserta  
 Plaintiff/Appellant – Don Amburgey  
 Plaintiff/Appellant – Joyce Amburgey  
 Plaintiff/Appellant – Mona Simmons  
 Plaintiff/Appellant – Trina Owen  
 Plaintiff/Appellant – Rubie Hoda  
 Plaintiff/Appellant – Billy West  
 Plaintiff/Appellant – Mona Windham  
 Plaintiff/Appellant – Ronnie Windham  
 Plaintiff/Appellant – Jeanne Colborne  
 Plaintiff/Appellant – Tracie Shollenbarger

Plaintiff/Appellant – William Shelton  
Plaintiff/Appellant – Janice Shelton  
Plaintiff/Appellant – Pink Jones  
Plaintiff/Appellant – Annie Jones  
Plaintiff/Appellant – Cynthia Skiles  
Plaintiff/Appellant – Raymond Skiles  
Plaintiff/Appellant – Earl Hines  
Plaintiff/Appellant – Debra Hines  
Plaintiff/Appellant – James Skinner  
Plaintiff/Appellant – David Whitlock  
Plaintiff/Appellant – Jacqueline Whitlock  
Plaintiff/Appellant – Connie Luye  
Plaintiff/Appellant – Billy Karr  
Plaintiff/Appellant – Robyn Garcia  
Plaintiff/Appellant – Diane Mancinelli  
Plaintiff/Appellant – Charles Hershiser  
Plaintiff/Appellant – Mary Frances Hershiser  
Plaintiff/Appellant – Shelby Campbell  
Plaintiff/Appellant – Penny Watson  
Plaintiff/Appellant – Antonio Burdier  
Plaintiff/Appellant – Carmen Fernandez  
Plaintiff/Appellant – Benjamin Lucas  
Plaintiff/Appellant – Carla Ellis  
Plaintiff/Appellant – Kelly Roberts  
Plaintiff/Appellant – Rita Pennington  
Plaintiff/Appellant – Jane Starnes  
Plaintiff/Appellant – Linda Lanier  
Plaintiff/Appellant – Harsharan Sandhu  
Plaintiff/Appellant – James Thomas  
Plaintiff/Appellant – Barbara Walker  
Plaintiff/Appellant – David Sabo

Respondent Taro Pharmaceuticals (USA) Inc. was the defendant in the district court and the appellee in the Second Circuit.

### STATEMENT OF RELATED CASES

*Bennett, et al. v. Teva Pharmaceuticals, et al.*, No. 19-2126. U.S. District Court, District of Delaware. Dismissal entered March 2, 2021.

*Bennett, et al. v. Teva Pharmaceuticals, et al.*, No. 21-1642. U.S. Court of Appeals for the Third Circuit.

*Burns, et al. v. Mayne Pharma, et al.*, No. 20-248. U.S. District Court, District of Delaware. Dismissal entered March 18, 2021.

*Collette v. Wyeth Pharmaceuticals, et al.*, No. 16-1034, U.S. District Court, Northern District of California. Judgment entered June 22, 2020.

*Collette v. Wyeth Pharmaceuticals, et al.*, No. 20-16406, U.S. Court of Appeals for the Ninth Circuit. Mandate issued Aug. 16, 2021.

*Cook v. Par Pharmaceutical, et al.*, No. 15-529, U.S. District Court, Northern District of Alabama. Dismissal Order entered April 24, 2020.

*Cook v. Par Pharmaceutical, et al.*, No. 20-11926, U.S. Court of Appeals for the Eleventh Circuit. Mandate issued March 9, 2021.

*Garcia v. Zydus Pharmaceuticals, et al.*, No. 17-412, U.S. District Court, Southern District of Texas. Judgment entered May 25, 2017.

*In Re: Amiodarone Cases* – No. JCCP 04956. Superior Court of California, County of Alameda. Order entered Jan. 14, 2019.

*In Re: Amiodarone Cases* – No. A157035. California Court of Appeals, First Appellate District, Division Two. Remittitur issued Sept. 29, 2020.

*In Re: Amiodarone Cases* – No. JCCP 04956. Superior Court of California, County of Alameda. Order entered June 11, 2019.

*In Re: Amiodarone Cases* – No. A158160. California Court of Appeals, First Appellate District, Division Two. Remittitur issued Sept. 29, 2020.

*In Re: Amiodarone Cases* – No. JCCP 04956. Superior Court of California, County of Alameda. Order entered Dec. 2, 2019.

*In Re: Amiodarone Cases* – No. A159522. California Court of Appeals, First Appellate District, Division Two. Remittitur issued Sept. 29, 2020.

*In Re: Amiodarone Cases* – No. JCCP 04956. Superior Court of California, County of Alameda. Order entered Sept. 8, 2020.

*In Re: Amiodarone Cases* – No. A161023. California Court of Appeals, First Appellate District, Division Two.

*In Re: Amiodarone Cases* – No. JCCP 04956. Superior Court of California, County of Alameda. Order entered May 22, 2020.

*In Re: Amiodarone Cases* – No. A161762. California Court of Appeals, First Appellate District, Division Two.

*Jankowski, et al. v. Zydus Pharmaceuticals, et al.*, No. 20-2458. U.S. District Court, District of New Jersey.

*Jordan, et al. v. Teva Pharmaceuticals, et al.*, No. 20-1209. U.S. District Court, District of Delaware. Dismissal entered June 30, 2021.

*Jordan, et al. v. Teva Pharmaceuticals, et al.*, No. 21-2304. U.S. Court of Appeals for the Third Circuit.

*McDaniel v. Upsher-Smith Pharmaceuticals, et al.*, No. 16-2604, U.S. District Court, District of Tennessee. Dismissal Order entered May 25, 2017.

*McDaniel v. Upsher-Smith Pharmaceuticals, et al.*, No. 17-5741, U.S. Court of Appeals for the Sixth Circuit. Mandate issued Aug. 10, 2018.

*McDaniel v. Upsher-Smith Pharmaceuticals, et al.*, No. 19-1246, Supreme Court of the United States. Petition for Writ of Certiorari denied Oct. 6, 2020.

*Medford, et al. v. Eon Labs, et al.*, No. 20-412. U.S. District Court, District of New Jersey.

*Polt v. Sandoz, et al.*, No. 16-2362, U.S. District Court, Eastern District of Pennsylvania. Judgment entered May 26, 2020.

*Polt v. Sandoz, et al.*, No. 20-2125, U.S. Court of Appeals for the Third District. Dismissed March 10, 2021.

*Roncal, et al. v. Aurobindo Pharma USA, et al.*, No. 20-2643. U.S. District Court, District of New Jersey.

*Stelly v. Zydus Pharmaceuticals, et al.*, No. 20-570. U.S. District Court, Western District of Louisiana.



*Villarreal v. Taro Pharmaceuticals, et al.*, No. 17-35.  
U.S. District Court, Southern District of Texas.

*Vining, et al. v. Zydus Pharmaceuticals, et al.*, No. 20-13439. U.S. District Court, District of New Jersey.

*Walsh, et al. v. Upsher-Smith Laboratories, et al.*, No. 20-6531. District Court, State of Minnesota, County of Hennepin.

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## **PETITION FOR WRIT OF CERTIORARI**

Petitioners respectfully petition this Court for writ of certiorari to review the judgment of the United States Court of Appeals for the Second Circuit.

### **OPINIONS BELOW**

The opinion of the court of appeals (Pet.App.1a) is reported at 844 Fed. Appx. 444. The opinion of the district court dismissing Plaintiffs' claims based on preemption (Pet.App.10a) is reported at 443 F. Supp. 3d 456.

### **JURISDICTION**

The judgment of the court of appeals was entered on April 20, 2021. The court of appeals denied rehearing and rehearing *en banc* on June 21, 2021. (Pet.App.35a). This Court has jurisdiction under 28 U.S.C. § 1254(1).

### **RELEVANT CONSTITUTIONAL, REGULATORY, & STATUTORY PROVISIONS**

This case involves the Due Process Clause of the Fifth Amendment of the United States Constitution and Federal Rule of Civil Procedure 15. (Pet.App.37a-40a)

### **INTRODUCTION**

This Court should grant *certiorari* to address the important question of constitutional law presented here.

The Second Circuit dismissed Plaintiffs' claims as inadequately pleaded under Rule 8 of the Federal Rules of Civil Procedure on a basis Defendant had not

raised and the District Court had not addressed. The Second Circuit did not grant Plaintiffs an opportunity to replead, even though Plaintiffs were ready, willing, and able to do so to address any technical problems with their pleading. The Second Circuit also did not find that there was no “good reason” to allow repleading.

This Court has long recognized that a cause of action is a property right protected by constitutional Due Process. Refusing Plaintiffs an opportunity to replead without following Rule 15 of the Federal Rules of Civil Procedure violates Plaintiffs’ Due Process rights.

This Court should intervene to clarify that “[t]he provisions of [Rule 15] which are here involved must be read in light of the provisions of the Fifth Amendment that no person shall be deprived of property without due process of law.” *Societe Internationale Pour Participations v. Rogers*, 357 U.S. 197, 209 (1958).

## STATEMENT OF THE CASE

### A. Background facts

Plaintiffs’ doctors diagnosed them with non-life-threatening atrial fibrillation. (Pet.App.15a). Under Defendant’s influence, the doctors prescribed them amiodarone tablets to treat their atrial fibrillation. (*Id.*) They filled their prescriptions with Defendant’s amiodarone at various pharmacies. (*Id.*) Because they took amiodarone, they suffered severe and debilitating injuries. (*Id.*)

The FDA requires manufacturers to ensure consumers receive a warning called a “medication

guide.” But Plaintiffs did not receive medication guides when they filled their prescription, because Defendant did not provide sufficient medication guides (or the means of producing them) to the distributor or to the pharmacies where they filled their prescriptions. (Pet.App.22a-23a.) Had Plaintiffs received medication guides—which would have been adequate warnings under state law—they would not have taken amiodarone. (*Id.*) In failing to ensure Plaintiffs received medication guides, Defendant fell short of its duty to warn under state law. Although the learned intermediary doctrine can be a defense under some circumstances, several of Plaintiffs’ home states do not recognize the learned intermediary doctrine under these circumstances.

In their complaint, Petitioners alleged wrongful death based on Defendant’s failure to warn when it failed to ensure Plaintiffs received a medication guide and misled their doctors. (*Id.*)

**B. The district court holds that Plaintiffs’ failure-to-warn-via-Medication-Guide claims is preempted and does not permit leave to replead, because repleading would be futile.**

The district court had diversity jurisdiction under 28 U.S.C. § 1332. The district court held that Plaintiffs’ failure-to-warn claim—paralleling Defendant’s failure to provide a medication guide in accordance with FDA regulations—were preempted. It reasoned that the specific requirement to provide a medication guide is found in the FDCA. (Pet.App.23a). On the other hand, Plaintiffs had not cited a specific requirement to provide a medication guide under state law. (*Id.*) Instead, Plaintiffs relied on the state



tort principle of negligent failure to warn. “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.” (*Id.*) The court based this conclusion on the fact that plaintiffs referenced medication guides 400 times in their complaint. (Pet.App.24a) The court did not perform a choice-of-law analysis even though several of Plaintiffs’ states do not recognize the learned intermediary doctrine that undergirded the district court’s holding. (Pet.App.10a-31a)

**C. The Second Circuit affirms, holding that Plaintiffs’ failure-to-warn-via-Medication-Guide claim is preempted.**

The Second Circuit affirmed on different ground. It held that Plaintiffs had not adequately pleaded their failure-to-warn claims under Rule 8 of the Federal Rules of Civil Procedure. Specifically, it held that Plaintiffs failed to plead an adequate factual basis for their failure-to-warn claims, because the complaint “lacks any allegation that Taro violated the minimal requirements of § 208.24” or that “Taro violated [a] hypothetical enhanced duty” in state law. (Pet.App.7a) In particular, Plaintiffs did not plead that Taro failed to provide the “means to produce” Medication Guides. The court did not grant Plaintiffs an opportunity to replead and did not discuss Rule 15(c) of the Federal Rules of Civil Procedure.

**D. Proceedings after decision.**

Plaintiffs timely moved for rehearing *en banc*, arguing that they should have received an opportunity to replead. On June 21, 2021, the

Second Circuit rejected their motion for rehearing. (Pet.App.35a) On October 29, 2021, Plaintiffs timely filed this petition for certiorari. *See* USCS SUPREME CT R 13(1), (3) (petition for certiorari must be filed within 90 days of the denial of a petition for rehearing); *Order List: 594 United States*, 2021 U.S. LEXIS 3591, at \*1 (July 19, 2021) (extending time to file to 150 days for judgments or orders rendered before July 19, 2021).

## **REASONS FOR GRANTING THE WRIT**

### **I. The Second Circuit’s Decision Implicates Important Constitutional Issues That Have Not Been Settled by this Court.**

The Second Circuit’s summary order affirmed dismissal of Plaintiffs’ failure-to-warn claims under Rule 8, finding that Plaintiffs did not plausibly plead facts supporting their claims. It did not, however, find that repleading would be “futile” or find any “good reason” to deny repleading.

Thus, Plaintiffs request that this Court consider whether, consistent with Due Process and Federal Rule of Civil Procedure 15, a court can deny leave to replead when a plaintiff has not had an opportunity to replead to address the court’s concerns, absent a finding that there is “good reason” for not allowing the plaintiff to replead.

This Court has held that “a cause of action is a species of property protected by the Fourteenth Amendment’s” and the Fifth Amendment’s Due Process Clause. *Logan v. Zimmerman Brush Co.*, 455 U.S. 422, 428 (1982). “[F]or example—where a plaintiff’s claim had been dismissed for failure to

comply with a trial court's order—the Court read the ‘property’ component of the Fifth Amendment’s Due Process Clause to impose ‘constitutional limitations upon the power of courts, even in aid of their own valid processes, to dismiss an action without affording a party the opportunity for a hearing on the merits of his cause.’” *Id.* (quoting *Societe Internationale Pour Participations v. Rogers*, 357 U.S. 197, 209 (1958)).

Rule 15 of the Federal Rules of Civil Procedure provides that leave to amend a party’s pleading “shall be freely given when justice so requires.” FED. R. CIV. P. 15; *see also Foman v. Davis*, 371 U.S. 178, 182 (1962); *see also Day v. McDonough*, 547 U.S. 198, 209 (2006). “The Rule reflects ... the most important principles behind the Federal Rules,” including “that ‘mere technicalities’ should not prevent cases from being decided on the merits.” *Monahan v. N.Y.C. Dep’t of Corr.*, 214 F.3d 275, 283 (2d Cir. 2000) (quoting *Foman*, 371 U.S. at 182).

Accordingly, a court has discretion to deny leave to re-plead only “for good reason, including futility, bad faith, undue delay, or undue prejudice to the opposing party.” *McCarthy v. Dun & Bradstreet Corp.*, 482 F.3d 184, 200 (2d Cir. 2007); *Monahan*, 214 F.3d at 283.

Here, the district court dismissed Plaintiffs’ claims as preempted. It is, of course, futile to replead preempted claims. *See Spiegel v. Bekowies*, 669 F. App’x 38, 39 (2d Cir. 2016). At the district court, Plaintiffs fully addressed the only Rule 8 argument that Defendant made (which was different from the Second Circuit’s conclusion) and requested leave to re-plead in the event the district court dismissed under Rule 8. The Second Circuit, however, did not

address preemption or the learned intermediary doctrine in its summary order.

Instead, it held that Plaintiffs failed to plead an adequate factual basis for their failure-to-warn claims, because the complaint “lacks any allegation that Taro violated the minimal requirements of § 208.24” or that “Taro violated [a] hypothetical enhanced duty” in state law. (Pet.App. 7a).

The Second Circuit did not find that there was “evidence of undue delay, bad faith or dilatory motive on the part of the movant, undue prejudice to the opposing party, or futility” in the record. *Monahan*, 214 F.3d at 283.

In fact, Plaintiffs could easily remedy these defects in a new, good faith complaint. Therefore, repleading would not be futile. If they had been granted an opportunity to replead, Plaintiffs would have alleged that Defendant did not provide Medication Guides to pharmacies or distributors or the means to produce Medication Guides. Plaintiffs would also allege that Defendants’ distribution methods were inadequate under state law because they did not even attempt to distribute Medication Guides. As a district court recently held in an Amiodarone case applying Louisiana law, “The adequacy of [a generic drug manufacturer’s] distribution methods is a factual question which should be addressed after discovery.” *Stelly v. Zydus Pharm. United States*, No. 6:20-CV-00570, 2021 U.S. Dist. LEXIS 56380, at \*21-22 (W.D. La. 2021). Repleading would also not prejudice Defendant or cause undue delay, because this case remains at the motion-to-dismiss stage.

Furthermore, as Plaintiffs explained in their motion for reconsideration, Defendants did not raise the arguments accepted by the Second Circuit and the district court did not address them.

In short, Plaintiffs could easily address the garden-variety pleading defects raised by the panel in an amended complaint. By refusing to allow Plaintiffs an opportunity to amend, the Second Circuit violated Rule 15 of the Federal Rules of Civil Procedure and Plaintiffs' Due Process rights.

## **II. The Question Presented Is Important and Recurring.**

Until this Court clarifies the constitutional requirements of Due Process and Rule 15 of the Civil Rules of Procedure in dismissing a complaint for inadequate pleading, this problem is likely to reoccur continually.

To Plaintiffs' knowledge, this Court has never specifically addressed the constitutional limitations on dismissal under Rule 8 and the interplay between Due Process and Rule 15. In the Court's seminal decision on Rule 8, *Ashcroft v. Iqbal*, for instance, the Court remanded for the Court of Appeals to "decide in the first instance whether to remand to the District Court so that respondent can seek leave to amend his deficient complaint." 556 U.S. 662, 687 (2009).

Here, the Second Circuit dismissed Plaintiffs' claims for inadequate pleading without granting an opportunity to replead or even addressing Rule 15. It is not unusual for a first complaint to be deficient. If the Second Circuit's decision stands, it may create an

insurmountable procedural obstacle to Plaintiffs seeking to vindicate their rights in federal courts.

### **CONCLUSION**

The petition for a writ of certiorari should be granted.

Dated: October 29, 2021

Respectfully submitted,

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