No. 18-97

In The
Supreme Court of the United States

MARION LIU, Individually and as Successor
in Interest to Augustine Liu, Deceased,

Petitioner,

v.

JANSSEN RESEARCH & DEVELOPMENT, LLC,

Respondent.

**On Petition For A Writ Of Certiorari
To The California Court Of Appeal,
Second Appellate District, Division Five**

RESPONDENT JANSSEN RESEARCH & DEVELOPMENT, LLC'S BRIEF IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Whether, under California common law, a clinical trial sponsor has a tort duty to intervene in the medical judgments and medical care rendered by the principal investigator/study physician to a trial participant suffering from a pre-existing condition unrelated to the clinical trial.

The California Court of Appeal, Second Appellate District, Division Five (the "Court of Appeal"), in an unpublished non-precedential decision, held that there is no such duty under California law, resulting in a judgment in favor of Respondent Janssen Research & Development, LLC ("JRD").

2. Whether there is jurisdiction in this Court under 28 U.S.C. §1257(a), where the California Court of Appeal decided the case exclusively under state law, was not asked to resolve any question of federal law, and until Petitioner Marion Liu imaginatively reframed the issue in her petition as positing a *federal duty of care* governing clinical trials, she never presented any issue of federal law to the California trial and appellate courts, or to the California Supreme Court (which denied discretionary review).

3. Whether Petitioner's assertion of jurisdiction in this Court under 28 U.S.C. §1257(a) is frivolous, and whether damages or costs should be assessed against Petitioner's attorneys under Supreme Court Rule 42.2.

RULE 29.6 STATEMENT

JRD is a limited liability company, not publicly traded. The sole member of JRD is Centocor Research & Development, Inc., which is wholly owned by Janssen Biotech, Inc., which is in turn wholly owned by Johnson & Johnson, a publicly traded company. No publicly held corporation owns 10% or more of Johnson & Johnson's stock.

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JURISDICTION

As detailed below, there is no basis for jurisdiction under 28 U.S.C. §1257(a), because the state court judgment was based entirely on state law, and no federal claim was ever presented to the state courts.

STATEMENT OF THE CASE

A full statement of the factual and procedural history of the case is set forth in the decision of the Court of Appeal. Petitioner's Appendix ("Pet. App.") at 1a-14a.

Pursuant to its obligation under Supreme Court Rule 15.2 to address any misstatement of fact or law in the petition, JRD identifies the following misleading statements or omissions:

- Contrary to the statements at pages 6-7 and 8 of the petition, the trial court and Court of Appeal did not rule "that a clinical trial sponsor has no independent responsibility for intervening to protect the health and safety of a human clinical trial subject when its monitoring discloses that the clinical investigator has not followed the protocol with respect to which candidates should be enrolled." Neither the trial court nor the Court of Appeal made any finding that the investigator had violated the study protocol in admitting any subject, nor did the jury.

- On page 7, the petition is wrong to suggest that the jury was properly tasked with determining whether JRD had a duty to intervene. As the Court of Appeal held, the existence and scope of a legal duty is a question of law for the court. Pet. App. at 15a-16a. The court held there was no duty to intervene in a trial subject's medical care and medical decisions related to a preexisting condition, as a matter of law. *Ibid.*

- On page 8, the petition misstates the Court of Appeal's holding. The court never found that JRD's monitoring had "disclosed that the principal investigator was committing malpractice and thereby causing injury to the health and safety of that person." Petitioner's argument had gone further, asserting that JRD had an obligation to intervene affirmatively to *prevent* the investigator from committing malpractice and causing injury, even as to medical conditions having nothing to do with the study. The court rejected such a duty under California law.

- On page 11, the petition misstates the import of the various federal regulations and guidances. Of most relevance, Petitioner erroneously claims that federal guidelines require the sponsor of a clinical trial to take responsibility for the safety and well-being of human subjects in its studies. In fact, 21 C.F.R. §312.60 quite logically makes the investigator

who is conducting the study responsible for the safety and well-being of individual study subjects under the investigator's care, including rendering necessary medical care. The relevant guidances amplify and reinforce the investigator's responsibility for the safety, well-being, and medical care of the subjects.

- On page 12, the petition misstates the import of 21 C.F.R. §312.56. That regulation has nothing to do with the medical care of any individual trial subject.

- On page 19, the petition wrongly states that the jury "necessarily found" that JRD knew before decedent was admitted to the study "that he suffered from heart and liver conditions that made him unsuitable for the study." The jury made no such finding. Under the broad and undifferentiated negligence theories argued by Petitioner, such a finding was not required and cannot be imputed.

Most importantly for the jurisdiction and sanctions issues, Petitioner's Statement of the Case willfully violates Supreme Court Rule 14.1(g)(i). The Statement (petition at 2-8) failed to include a

> specification of the stage in the proceedings, both in the court of first instance and in the appellate courts, when the federal questions sought to be reviewed were raised; the method or manner of raising them and the way in which they were passed on by those courts; . . .

> specific reference to the places in the record where the matter appears . . . , so as to show that the federal question was timely and properly raised and that this Court has jurisdiction to review the judgment on a writ of certiorari.

Those required matters are not set forth in the petition's Statement because they do not exist, and there is no basis for this Court's jurisdiction.

There is no specification of when the purported "federal duty" question was presented for decision, because it was not.

There is no specification of how the federal question was presented and how it was resolved by the courts, because it was not.

There is no specific reference to the record to show the federal question was timely and properly raised below, because it was not.

REASONS TO DENY THE PETITION FOR WRIT OF CERTIORARI[1]

1. The judgment of the Court of Appeal was based entirely on California substantive law. Consequently, there is no basis for jurisdiction in this Court under 28 U.S.C. §1257(a).

The case was presented to the jury on a single theory of negligence under California common law. The jury was instructed solely under state law. The only instruction addressing federal law told the jury that compliance with federal clinical trial regulations was relevant but did not preclude a finding of negligence. In closing argument, Petitioner's counsel disparagingly compared the FDA to the Department of Motor Vehicles and urged the jury that JRD should not be allowed to "hide behind the regulations." Respondent's Appendix ("App.") at 7.

On appeal from the adverse jury verdict, JRD challenged the judgment for Petitioner solely on California state law grounds. App. at 3-5. In relevant part, JRD asked the court of appeal to reverse and render

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[1] JRD does not respond in this brief to Petitioner's arguments on the merits of the judgment below, for two reasons. First, there is no jurisdiction, and consequently, no basis for the Court to consider the certworthiness of the merits, or otherwise prolong this brief in opposition. Second, this Court does not sit to correct errors of law, especially errors of state law by state courts, even if the state court has, in the course of its decision, taken some measure of support or guidance from its interpretation of some aspect of federal law.

judgment in its favor. JRD argued that a clinical trial sponsor has no duty under California negligence law to intervene in the medical decisions made by the principal investigator/responsible physician to recruit, consent and admit a trial subject, or to intervene in the investigator's treatment of a pre-existing medical condition which happens to manifest during the course of the study. App. at 6.

Responding to Petitioner's contention that JRD was negligent to allow the decedent to receive the study drug, JRD also argued that the evidence was insufficient under California law to support a finding of causation. *Ibid.*[2]

In an unpublished opinion, the Court of Appeal agreed with JRD on both issues. Applying California law, it held that a clinical trial sponsor has no duty to intervene in medical decisions and care of trial subjects where the subject's medical condition was not caused by the study intervention. Pet. App. at 3a, 15a-16a, 17a, 20a-21a. It then concluded that there was no substantial evidence supporting a finding under California law that the decedent's condition had been caused or exacerbated by the study intervention. *Id.* at 3a, 16a, 24a, 25a, 30a, 32a. Accordingly, it reversed the

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[2] In the alternative, JRD sought a new trial on the grounds of evidentiary errors and attorney misconduct. *Ibid.* The Court of Appeal did not reach these issues, which were all based on California law. Pet. App. at 16a.

judgment for Petitioner with directions to enter judgment for JRD. *Id.* at 33a.

Petitioner sought rehearing in the Court of Appeal. No federal issue was raised. Rather, Petitioner argued that the court had gotten it wrong, because JRD *did* have a duty under California law, and there *was* substantial evidence supporting the conclusion that the study drug had contributed to decedent's death. App. at 10-18. Rehearing was denied without substantive comment. *Id.* at 19.

Petitioner sought discretionary Review in the California Supreme Court. No federal issue was raised. Rather, Petitioner argued that the Court of Appeal was wrong to hold that JRD had no duty to medically intervene under California law, and that there was no substantial evidence that the study drug had contributed to decedent's death. *Id.* at 22-25. Review was denied without substantive comment. Pet. App. at 59a.

Under Section 1257(a) and this Court's case law it is absolutely clear that there is no basis for this Court's jurisdiction unless the final judgment of the state court is based on a dispositive question of federal law. Certiorari jurisdiction is not available when the state court judgment was based entirely on state law. Indeed, there is no jurisdiction even where there has been a decision on the basis of both federal and state law, if the state law determination is an independent and adequate ground for the judgment. *See*, *e.g.*, *Fox Film*

Corp. v. Muller, 296 U.S. 207, 210 (1935); *Murdock v. City of Memphis*, 87 U.S. 590, 635-36 (1875).

There is no good faith argument that the judgment below was based on any question of federal law.[3]

Moreover, even if there were some federal issue lurking somewhere in the record, it could not conceivably have affected the judgment. As discussed above, the Court of Appeal squarely decided this case on the basis of California common law, the absence of a negligence duty to intervene, the absence of substantial evidence to support causation as to the study drug, and the lack of any basis under California agency law to hold JRD liable for the medical malpractice of the investigator. These would easily qualify as independent and adequate state grounds. Indeed, Petitioner argued, in seeking rehearing and Review, that those holdings were wrong, as a matter of California law, but never argued they were inadequate, if correct, to support the remedy of complete reversal.

The petition should be denied for want of jurisdiction.

2. Even if the petition were somehow interpreted to present a federal issue capable of supporting certiorari jurisdiction, the petition would need to be denied,

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[3] If Petitioner believes that the mere consideration of federal clinical trial regulations or guidelines by the Court of Appeal in the course of determining the scope of a state law duties can support jurisdiction, she is mistaken. *See Illinois v. Gates*, 462 U.S. 213, 218 n.1 (1983) (requiring a federal claim be "squarely considered and resolved").

because Petitioner never presented the "federal duty" issue to the state courts below. With few exceptions this Court will not consider questions raised for the first time in this Court. *Cardinale v. Louisiana*, 394 U.S. 437, 438 (1969). *See Webb v. Webb*, 451 U.S. 493, 501 (1981) (requiring that there be no doubt from the record that a claim under a federal statute or the federal constitution had been presented in state court).

Plaintiff presented no federal issue to the Court of Appeal, even in seeking rehearing, after the bases for the judgment had become clear. She presented no federal issue to the California Supreme Court in seeking discretionary review.[4]

The primary reasons for the presentation requirement are principles of federalism and comity – that in our dual system of government it is considered unwise and inappropriate to disturb the finality of state court judgments on the basis of a federal issue that the state court was not given a reasonable opportunity to consider. *Adams*, 520 U.S. at 90; *McGoldrick v. Compagnie Generale Transatlantique*, 309 U.S. 430, 434 (1940). It would be inappropriate under our federal system to revisit and potentially overturn the considered decision of the California courts on the basis of a federal issue they were never called upon to decide.

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[4] Even if Petitioner had raised a federal issue in her Petition for Review to the California Supreme Court, presenting the issue at that point would not have satisfied the presentation requirement. *See Adams v. Robertson*, 520 U.S. 83, 89 n.3 (1997) (per curiam); *Yee v. City of Escondido*, 503 U.S. 519, 533 (1992).

The Court has "almost unfailingly refused to consider any federal-law challenge to a state-court decision unless the federal claim 'was either addressed by or properly presented to the state court that rendered the decision.'" *Howell v. Mississippi*, 543 U.S. 440, 443 (2005) (per curiam) (quoting *Adams*, 520 U.S. at 86). For this additional, but unnecessary, reason, there is no basis for exercise of this Court's jurisdiction in this case. The writ should be denied.

3. Since at least 1803, the rules of this Court have recognized that frivolous efforts to invoke nonexistent jurisdiction in this Court may warrant sanctions. *See* Former Supreme Court Rule 17, 5 U.S. (1 Cranch) xviii (1803). That authority is currently located in Supreme Court Rule 42.2, authorizing the award of "just damages" and single or double costs for the filing of a frivolous petition.

As demonstrated above, and obvious, there is no good faith basis to invoke this Court's jurisdiction under 28 U.S.C. §1257(a), the independent and adequate state ground doctrine, and the presentation requirement. Despite the lack of any basis for jurisdiction, Petitioner filed the petition, which compelled reasonably cautious counsel for Respondent to oppose it. An opposition was important because Petitioner had willfully violated the requirements of Rule 14.1(g)(i), in order to mask the jurisdictional deficiency.

Given the crystal clarity of the state law bases for the Court of Appeal's judgment, the lack of any presentation of a federal claim to the state courts, the firmly

settled, indeed deeply-ingrained, nature of the law that bars jurisdiction under these circumstances, and Petitioner's violation of this Court's rule designed to illuminate the basis for the Court's jurisdiction, JRD respectfully requests that this Court award just damages or costs to JRD based on Petitioner's filing of a frivolous petition.[5]

CONCLUSION

For the foregoing reasons, the writ of certiorari should be denied, and the Court should enter an order allowing JRD to recover damages, or double costs under Rule 42.2.

August 22, 2018

Respectfully submitted,

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[5] JRD suggests that the award be imposed in equal shares against the four sets of counsel representing Petitioners, as all of them presumably ratified the decision to file the frivolous petition.