App. 1

CASE NO. B269318

IN THE COURT OF APPEAL
SECOND APPELLATE DISTRICT

MARION LIU, Individually, as Successor-in-Interest to AUGUSTINE LIU, II, Deceased, and as Successor-in-Interest to AUGUSTINE LIU, SR., Deceased,

Plaintiff, Appellant and Cross-Respondent,

vs.

JANSSEN RESEARCH & DEVELOPMENT, LLC,

Defendant, Respondent and Cross-Appellant.

Los Angeles County Superior Court
Case No. BC 432264
The Hon. Richard L. Fruin, Judge Presiding

CROSS-APPELLANT'S OPENING BRIEF

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[10] **I.**
INTRODUCTION/SUMMARY OF ARGUMENT

This is a case of medical malpractice, but with a twist. Here the jury imposed liability on the remote *sponsor of a clinical study* for medical decisions made by the doctor conducting the study, who was also the decedent's treating physician.

Augustine Liu II (Liu) died while under the care of Madeleine Valencerina M.D. (Valencerina) from a latent, undiagnosed heart condition which developed over months or years and suddenly crashed soon after he entered a clinical research study sponsored by Janssen Research & Development LLC (JRD). His death resulted from Valencerina's failure to recognize the condition and refer or transfer him sooner for urgent or emergency care.

After settling with Valencerina, Liu's mother took the case to trial against JRD.

The ensuing judgment for Plaintiff depended on two unsound and unsupported premises: (1) JRD as sponsor had a *duty to intervene* in Valencerina's medical judgment and care for Liu and (2) a small test of dose risperidone, administered to Liu *during* his rapid deterioration, was a substantial factor in causing his death. Neither premise is supported, and the judgment must be reversed.

At minimum, a new trial is required, because a combination of evidentiary errors and rampant misconduct by counsel denied JRD a fair trial.

* * *

[60] • How IRBs in general, and by extension, Sterling may be corrupt. JRD's defense emphasized the regulatory process protections, which made clinical research safe, confirmed the safety and reasonableness of the study, the protocol, and the consent process, made it reasonable to rely on Valencerina and process safeguards to protect subjects, and supported FDA's allocation of responsibilities. The attack on the integrity of IRBs compromised all those positions and generally undermined the value of regulatory approvals and the overall reasonableness of accepting FDA's system for protecting subject safety.[39]

- How "Janssen" illegally withheld safety data from the FDA. JRD's attitude about safety was critical to the jury's impressions of its conduct and its drug. The damage to JRD's safety attitude was damaged further in closing when Plaintiff claimed—without *any evidentiary basis* whatsoever—that *JRD* knowingly hid Liu's EKG reports when he was transferred to Coast because they wanted to hide "another adverse event about this drug." Generally, JRD's overall stance before the jury was diminished, feeding into "heartless and corrupt" corporate stereotypes Plaintiff exploited throughout the trial.

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[39] The damage was heightened by the Court's instruction that FDA regulations were minimum standards and by Plaintiff's closing argument that compared FDA to the DMV and warned the jury to send a message to JRD, "Don't hide behind the regulations." 15 RT 3114, 3116-18, 3130, 3259-60.

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B269318/B270332

COURT OF APPEAL, STATE OF CALIFORNIA

SECOND APPELLATE DISTRICT, DIVISION 5

MARION LIU, INDIVIDUALLY AND AS THE SUCCESSOR IN INTEREST TO AUGUSTINE LIU, SR

Plaintiffs and Appellants,

vs.

JANSSEN RESEARCH & DEVELOPMENT, LLC,

Defendant and Respondent.

Appeal from Orders of the Superior Court of California, County of Los Angeles, Case No. BC432254 The Hon. Richard Fruin, Judge Presiding

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PETITION FOR REHEARNG

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[7] **INTRODUCTION**

There are numerous material facts that are not articulated or addressed in the Court's Opinion ("Opinion") in this case. Consideration of those facts is critical to a correct application of the relevant legal principles in assessing what duties defendant Janssen Research & Development, LLC ("Janssen") owed to Augustine Liu ("Leo") in the course of the clinical trial during which Leo died.

Because the Opinion misapplies the facts, its legal conclusions are unwarranted and its rationales are not supported by the applicable law. These issues should be reassessed by way of rehearing.

SUMMARY OF EVIDENCE

The Opinion does not include reference to all the material evidence *supporting* the legal conclusion that Janssen owed duties to Leo other than merely assuring that administration of the 1 mg. of risperidone did not contribute to his injury. Indeed, the evidence, including expert testimony based on industry standards and the actual language of Janssen's own drug study protocol, confirm that Janssen's duties were much broader. The

* * *

[43] respect to the conduct of the study.

B. The Opinion misapplies the law in its assessment of the duty issues.

The Opinion's general duty analysis turns on the issue of foreseeability and concludes that Leo's cardiomyopathy – and the malpractice of Janssen's clinical trial investigators in failing to discover and treat it – was not foreseeable to Janssen. (Opinion, pp. 16-20.)

The Opinion primarily (indeed, almost exclusively) relies on the decision in *Jackson v. AEG Live, LLC* (2015) 233 Cal.App.4th 1156 (*Jackson*) for its foreseeability analysis. That case, however, has no relevance whatsoever.

As the Opinion describes, in *Jackson*, "a concert tour promoter, at the request of the performer, agreed to pay for a physician to provide general medical services to the performer during the tour to ensure the performer's overall health." (Opinion, at p. 17.) The appellate court in *Jackson* found that it was not foreseeable to the tour promoter that the doctor's malpractice would result in the performer's death and, as such, the tour promoter had no duty to protect the performer from that malpractice. (*Jackson*, at 1174-1175.)

While giving lip service to the federal regulations, standards in the industry and Janssen's own clinical criteria [44] (Opinion, p. 17), the Opinion then goes on to analogize this case – and the relationships involved in it – with the situation in *Jackson*. But there is

simply nothing that can be extracted from the *Jackson* decision which bears on the issues here.

Janssen is not a concert tour promoter; it is a drug research company that routinely and, as part of its normal business practices, conducts human experimentation.

And the foreseeability that a clinical trial investigator may violate the protocol and/or may commit malpractice (even assuming there is a malpractice duty involved), is inherent in the existence and terms of the clinical trial protocol and the attendant clinical practice guidelines and the federal regulations imposing requirements for monitoring on the study sponsor.

And, as the Maryland Court of Appeals recognized, "special relationships are created between researchers and the human subjects used by the researchers" and also confirmed, "governmental regulations can create duties on the part of researchers towards human subjects out of which 'special relationships' can arise." (*Grimes v. Kennedy Kreiger Institute, Inc.* (Md. 2001) 782 A.2d 807.)

Although not cited in plaintiff's briefing on the appeal, *Grimes* is directly analogous to the situation in this case, while *Jackson* has no relevance at all. Indeed, plaintiff did argue that, consistent with *Grimes*, the government regulations, as well as [45] the clinical practice guidelines adopted by and referenced in Janssen's own protocol established its independent duty to protect Leo's health and safety at *every stage of the study*.

Furthermore, the Opinion's attempt to dismiss the Supreme Court's analysis in *Coffee v. McDonnell-Douglas Corp.* (1972) 8 Cal.3d 551 is fundamentally flawed. (Opinion, pp. 21-22.) The Opinion asserts that *Coffee* does not apply because the "principal distinguishing factor is that in *Coffee* the negligent actors were employees, i.e., agents, of the defendant, while that was not the case here." (Opinion, p. 22.) But that is an absolutely false distinction; indeed, in this case, as in *Coffee*, the negligence *was* on the part of Janssen's employees, i.e., *its medical monitoring staff*.

One critical part of the *Coffee* analysis as to the employer's duty was predicated on the employer's own undertaking to examine the plaintiff's fitness for employment. *Coffee* utilized its own employee doctors to make that determination – but the jury *exonerated the doctors*. Thus, the finding of duty in *Coffee* had nothing to do with whether the doctors committed malpractice, or whether it was foreseeable that the doctors would do so. Rather, in *Coffee*, the Supreme Court acknowledged that the employer had a duty *independent of the conduct of the physicians* to establish and enforce a procedure and protocol that would assure that any adverse results found in the pre-employment exam [46] would be transmitted to the proposed employee. (*Coffee*, *supra*, at 560-562.) Thus, the liability in *Coffee* arose *independent of* the malpractice liability (if any) of the employers' physicians. Rather the duty arose because of the relationship between the employer and the prospective employee and was breached when

employees *other than the physicians* failed to do what was necessary.

The same is true here: The duty in this case arose *independent of* the relationship between Janssen and its clinical trial investigators and *independent of* any malpractice of the clinical trial investigators. Rather, it was the negligence of Janssen's own employees, i.e., the medical monitoring staff, which is at issue. In other words, because Janssen had an independent duty to monitor the Leo's health and safety during the course of the study (including the result of any malpractice on the part of its clinical trial investigators), and its medical monitoring staff failed to do so, this situation is directly analogous to that in *Coffee*.

C. The Opinion also misapplies the law in its assessment of the experts' opinions on whether the administration of the 1 mg of risperidone was a substantial factor contributing to Leo's death.

Finally, the Opinion concludes that the causation opinions [47] of plaintiffs' experts that the administration of the 1 mg of risperidone to Leo was a substantial factor in contributing to Leo's death (though not his cardiomyopathy) were without foundation and thus should have been excluded. But the Opinion's analysis on this issue, like its analysis on the duty issue, does not correctly apply California law.

The Opinion repeatedly acknowledges that all that is required to show medical causation is a medical

expert's testimony to a reasonable degree of medical probability as to the cause of injury. (Opinion, pp. 27-28.) But the Opinion ignores the law providing that where expert opinions are derived from the application of accepted medical principles, they have foundation and it is for the jury to decide the issue. (*Roberti v. Andy's Termite & Pest Control, Inc.* (2003) 113 Cal.App.4th 893, 903-906.) Nothing posited by Janssen or articulated in the Opinion establishes that either Plunkett or Goodman failed to apply accepted medical principles.

Indeed, the very case cited in the Opinion as the basis for its conclusion, *Jennings v. Palomar Pomerado Health Systems, Inc.* (2003) 114 Cal.App.4th 1108, 1117 confirms that "an expert's opinion based on assumptions of fact without evidentiary support . . . or on speculative or conjectural factors . . . has no evidentiary value . . . and may be excluded from evidence." But there were no "assumptions of fact without evidentiary support" and there [48] were no "speculative or conjectural factors" underling the opinions of plaintiff's experts in this case. Rather, both Plunkett and Goodman confirmed that their opinions about the cause of Leo's death were based on a constellation of factors all established in the evidence, i.e., the risperidone, the Seroquel, the existing cardiomyopathy, the on-going liver failure, and the impending kidney failure, which pushed Leo over the edge to death. [9 RT 1874:7-1876:24.]

Accordingly, the conclusion that the expert opinions were without foundation and/or were speculative or conjectural is in direct conflict with the evidence and the applicable law.

CONCLUSION

Rehearing should be granted for the foregoing reasons and, upon rehearing the judgment should be affirmed.

Dated: January 18, 2018

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IN THE COURT OF APPEAL OF
THE STATE OF CALIFORNIA
SECOND APPELLATE DISTRICT

DIVISION 5

January 24, 2018

MARION LIU,
Individually and as Successor in Interest, etc.,
Plaintiff and Appellant,
v.
JANSSEN RESEARCH & DEVELOPMENT, LLC,
Defendant and Respondent.

B269318
Los Angeles County No. BC432264

THE COURT:

Petition for rehearing is denied.

S_____

SUPREME COURT OF CALIFORNIA

MARION LIU, INDIVIDUALLY AND AS THE SUCCESSOR IN INTEREST TO AUGUSTINE LIU, SR
Plaintiff, Cross-Respondent and Petitioner,

vs.

JANSSEN RESEARCH & DEVELOPMENT, LLC,
Defendant and Cross-Appellant.

JUDGMENT OF THE SECOND DISTRICT COURT OF APPEAL,
DIVISION 5
CASE NOS. B269318 / B270332
LOS ANGELES SUPERIOR COURT, CASE NO. BC432254

PETITION FOR REVIEW

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[6] **ISSUES**

ISSUE NO. 1: The Court of Appeal recognized in this case that "FDA regulations" impose a duty on a drug company testing its drugs on humans to "monitor the progress of [its] studies to ensure compliance with study protocols and the health and safety of participants." (Opinion, p.17.) Nevertheless, the Court of Appeal held that drug companies do not owe a duty to the participants of the drug studies they design, create safety protocals for, and staff, for the participants' medical monitoring during the study because, the appellate court concluded, it is *unforeseeable* that the physicians retained by the drug company to conduct the study would act negligently. As such, the Court of Appeal relieved defendant Janssen Research & Development, LLC ("Janssen") of all liability for the harm it caused despite the jury's finding it had been negligent. The issue for this Court is therefore: Does a drug company have a duty to medically monitor the participants of its drug study, and can it thus be liable for its failure to exercise its independent power to stop a clinical study and refer a participant to medical care when it is aware that the participant is suffering from a life-threatening medical condition making him unsuitable to participate in the study?

ISSUE NO. 2: Is it for the jury, as a matter of fact, or for a court, as a matter of law, to decide whether the opinion of a qualified medical expert that, to a reasonable medical probability, a drug was a substantial

factor in contributing to a plaintiff's injury or death is sufficient to establish causation?

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