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NOT TO BE PUBLISHED IN THE OFFICIAL REPORTS

IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA

SECOND APPELLATE DISTRICT

DIVISION FIVE

MARION LIU, as Successor in Interest to AUGUSTINE LIU, Deceased, Plaintiff and Appellant, v. JANSSEN RESEARCH & DEVELOPMENT, LLC, Defendant and Respondent.	B269318 (Los Angeles County Super. Ct. No. BC432264)
MARION LIU, Individually, Plaintiff and Respondent, v. JANSSEN RESEARCH & DEVELOPMENT, LLC, Defendant and Appellant.	B270332 (Los Angeles County Super. Ct. No. BC432264)

Consolidated appeals from judgments of the Superior Court of the County of Los Angeles, Richard Fruin, Judge. Judgment in case number B270332 reversed. Judgment in case number B269318 affirmed.

The Arkin Law Firm, Sharon Arkin, and Farrise Law Firm, Simona Farrise, for Plaintiff and Appellant.

Drinker Biddle & Reath, Alan J. Lazarus, John J. Powers, and William Hanssen, for Defendant and Appellant.

INTRODUCTION

Plaintiff Marion Liu (Liu) and her husband, Augustine Liu, sued defendant Janssen Research & Development, LLC (JRD, defendant) for the wrongful death of their son, Augustine Liu II (Augustine).[1] At the time of his death, Augustine was participating in a drug trial for a new medication, Risperidone, and had received a one-milligram test dose.

Liu's husband died before trial, but Liu was permitted to proceed on his behalf as his successor in interest. Before the matter was submitted to the jury, however, the trial court determined the claims by Liu's husband for noneconomic damages did not survive his passing and entered judgment in defendant's favor against Liu in her successor capacity. Liu timely appealed (B269318).

On Liu's individual wrongful death claim, a jury determined defendant was negligent and the negligence was a substantial factor in Augustine's death. Finding defendant 70 percent at fault, the net jury award to Liu for noneconomic

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[1] To avoid confusion and with respect, we will refer to plaintiff's son as Augustine.

damages was $5.6 million. Defendant timely appealed (B270332).

We consolidated the appeals from the two judgments. We conclude defendant did not owe Liu a duty of care to intervene in her son's medical care related to his preexisting heart disease. Defendant did owe a duty of care not to harm plaintiff's son insofar as administration of the drug itself, but the finding that the one-milligram test dose was a substantial factor in causing Augustine's death was not supported by sufficient evidence. Accordingly, we reverse the judgment on the jury verdict in Liu's favor against defendant.

It is unnecessary to discuss the merits of Liu's appeal from the adverse judgment in her successor capacity. Even if Liu's husband's wrongful death action for noneconomic damages survived his passing—and we agree with the trial court it did not—our duty and causation determinations foreclose any recovery by Liu in her successor capacity. We affirm the judgment in defendant's favor against Liu as her deceased husband's successor in interest.

FACTUAL BACKGROUND[2]

Augustine began treatment for mental illness in 2000, when he was 17 years old. He was diagnosed with schizophrenia in 2004 and was prescribed the antipsychotic drug, Seroquel. Dr. Madeleine Valencerina (Valencerina) became Augustine's treating psychiatrist in 2008, and she continued her patient on that medication.

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[2] We include an abbreviated fact discussion at this point for context. A detailed recitation of the trial evidence is not required for us to analyze the dispositive issues on defendant's appeal.

In late 2008, defendant obtained FDA approval for a proposed drug study to analyze the safety and efficacy of a long-acting injectable formulation of its antipsychotic drug, Risperidone (study drug). Defendant selected Valencerina as the study's principal physician/investigator for the trial. Valencerina conducted clinical trials through Clinical Pharmacological Studies, Inc. (CPS), an entity in which she held an ownership interest. The FDA and an institutional review board approved Valencerina as the principal physician/investigator and also approved defendant's proposed study protocol and plan for monitoring the progress of the study.

Valencerina invited Augustine to participate in defendant's drug study. Augustine completed the informed consent and related paperwork in Valencerina's office and enrolled in the study on February 19, 2009.

Augustine underwent a screening electrocardiogram (EKG)[3] and blood test that day. Valencerina reviewed the screening EKG on February 20, 2009 and blood test results on February 21, 2009. The EKG was "abnormal," with the report indicating "sinus tachycardia; old myocardial infarction" and "non-specific T wave abnormalities possibly secondary to heart disease." The blood test revealed slightly elevated liver enzymes. Valencerina concluded the results were not clinically significant and, based on Augustine's otherwise normal physical examination and denial of a family history of cardiac disease, admitted him to the study.

On February 22, 2009, Augustine entered College Hospital, a psychiatric facility, for the first phase of the study. A second

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[3] "EKG" reflects the German spelling, Elektrokardiogramm. The record includes references to ECG, the English equivalent.

blood test followed on February 23, 2009. One-half hour after that test, Augustine was injected with a non-therapeutic one-milligram dose of the study drug to test for adverse reactions to any of its ingredients.

Within two hours of receiving the test dose, Augustine underwent a second EKG. The EKG report issued the same evening, and it indicated Augustine's cardiac condition had worsened. Valencerina reviewed the February 23, 2009 blood test report on February 24, 2009. Augustine's liver enzyme levels were much higher than they had been on February 19, 2009. To rule out laboratory error, Valencerina ordered a retest on February 24, 2009.

On February 25, 2009, after the retest confirmed Augustine's liver enzymes had risen alarmingly, Valencerina transferred him from College Hospital to Coast Plaza Doctors Hospital, an acute-care facility. There, Augustine was diagnosed with cardiomyopathy, pneumonia, failing liver function, and altered mental state. Augustine died on the afternoon of February 26, 2009. The cause of death was dilated cardiomyopathy in conjunction with other factors, including multiple organ failures and pneumonia.[4]

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[4] Dilated cardiomyopathy is a progressive condition that can take years to develop. Persons with the condition may be asymptomatic until it reaches a critical point, at which time the heart rapidly decompensates, causing reduced blood flow to the organs which begin to fail as a result.

PROCEDURAL BACKGROUND

I. Summary Judgment for Defendant Partially Reversed

The fourth amended complaint (revised) alleged three causes of action against defendant (negligence, products liability, and negligent failure to warn). Also named with JRD in the negligence cause of action were Coast Plaza Hospital and the rest of the study defendants—Valencerina, Lau, CPS, College Hospital, and Collen. All study defendants except College Hospital and Collen successfully moved for summary judgment.[5]

In response, Liu petitioned for writ of mandate.[6] The majority of a different panel in this Division granted in part Liu's request for extraordinary relief, reviving the second cause of action for negligence as to JRD, Valencerina, Lau, and CPS. (*Liu v. Superior Court* (Apr. 19, 2013, B246461) [nonpub. opn.] (*Liu I*).)[7] In that opinion, the majority specifically did not reach issues of agency or vicarious liability vis-à-vis JRD. (*Liu I* at *8.)

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[5] The trial court denied the motion for summary judgment by study defendants College Hospital and Collen.

[6] She also appealed from the ensuing judgments in favor of these defendants, but voluntarily dismissed that appeal (B248529). Liu filed a second appeal in 2015 as successor in interest to her son's estate. This court dismissed that appeal on jurisdictional grounds in an unpublished opinion, *Liu v. Janssen Research & Development, LLC* (Mar. 23, 2017, B266368).

[7] The petition was not granted as to the cause of action against Valencerina for dependent adult abuse and the causes of action against defendant for strict products liability for failure to warn and negligent failure to warn. (*Liu I* at *27.)

Turning to the declarations of plaintiff's experts in opposition to the summary judgment motions, the majority in *Liu I* agreed "'[t]he rule that a trial court must liberally construe the evidence submitted in opposition to a summary judgment motion applies in ruling on both the admissibility of expert testimony and its sufficiency to create a triable issue of fact.'" (*Liu I* at *6.) The majority then determined the declarations by plaintiff's experts—a pharmacologist and a cardiologist—were sufficient to defeat summary judgment on the negligence theory: "Even if the evidence regarding [the one milligram test dose of] Risperidone should have been excluded as to causation, drawing the necessary inference in the light most favorable to the opposing party [citation] the improper care afforded [Augustine] was sufficient to support the causation conclusion, if such support is necessary. The expert's opinion on causation should not have been omitted or deemed insufficient at this stage." (*Liu I* at *8.) In the footnote appended to the last sentence of the foregoing excerpt, the majority also advised, "We render no opinion on the merits or on evidentiary issues that might arise at trial." (*Liu I* at *8, fn. 9.)

II. New Summary Adjudication Motion in the Trial Court

Plaintiff returned to the trial court and proceeded on a solitary cause of action for negligence. The negligence allegations referenced Valencerina, Lau, CPS, College Hospital, and Collen and described various acts of medical malpractice, at least some of which were alleged to have violated defendant's drug study protocols. There were no allegations, however, specifically

directed to any independent acts of misfeasance or nonfeasance by JRD.

Three study defendants—College Hospital and physicians Valencerina and Lau—filed a new motion for summary adjudication seeking a ruling that the second cause of action was for medical malpractice only and subject to the noneconomic damages limitation in Medical Injury Compensation Reform Act (MICRA). The trial court granted the motion, thereby imposing the MICRA cap on any recovery by plaintiff as to those defendants.[8]

The trial court denied defendant's request for joinder in the summary adjudication motion, finding defendant sought to raise issues beyond the scope of the original motion. In so doing, however, the trial court made the following observation: "As a general proposition, . . . the Court would note its agreement with [defendant's] argument to the effect that, under [*Lathrop v. Healthcare Partners Medical Group* (2004) 114 Cal.App.4th 1412], MICRA's limitations on liability apply where [a] plaintiff seeks to hold a principal vicariously liable for the acts of its employees/agents."

III. Trial Against Defendant

Eventually, only JRD remained a defendant under the negligence theory. Defendant filed a number of motions in limine, including two to exclude trial testimony by plaintiff's cardiologist and pharmacologist as to general and specific causation, i.e., the administration of the one-milligram test dose

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[8] Civil Code section 3333.2 limits noneconomic damages in medical malpractice actions to $250,000. Other than burial expenses, plaintiff sought only noneconomic damages.

contributed to decedent's demise. The trial court denied both motions, paving the way for cardiologist Jeffrey Goodman, M.D., and pharmacologist and toxicologist Laura Massey Plunkett, Ph.D., to testify.

The issues presented in defendant's appeal do not require us to summarize the 13 days of trial testimony. Suffice it to say, plaintiff presented evidence, including several expert opinions, to demonstrate Augustine was not competent to enroll himself in the drug study;[9] defendant, who also received Augustine's EKG and blood test results, did nothing to intervene in his care; defendant failed to intervene in the decision to administer the one-milligram test dose; and that dose was a substantial factor in Augustine's death.

Before the close of evidence, defendant moved to strike Goodman's testimony and moved for nonsuit on the causation issue. The trial court denied both motions.

At the close of evidence, defendant orally moved for a partial directed verdict, arguing Valencerina, as the study physician/investigator, was not defendant's agent for purposes of finding defendant vicariously liable for any medical negligence by Valencerina:

> [Defense counsel]: [W]e think . . . agency is simply not something that can be found [on] the facts and circumstances of this case given . . . that the focus here is on the medical care provided by Dr. Valencerina, [and] that Dr.

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[9] These allegations formed the basis for the first cause of action against Valencerina, not defendant. But the trial court eliminated the first cause of action in granting Valencerina's motion for summary judgment, and this court did not revive it.

> Valencerina had an obligation to exercise her independent medical judgment in making medical decisions on behalf of [decedent] in treating any conditions which arose during the course of the study. Dr. Valencerina had a fiduciary relationship with [decedent] which is inconsistent with the type of control that's needed for a finding of agency. The structure of clinical research studies themselves, including the way they're required to be structured under the federal regulations, makes it important and clear that there needs to be some independence between principal investigator and sponsor of the study, and also makes it clear that medical care to be given to individual subjects during the course of the study is the responsibility of the principal investigator and is not the responsibility of the study sponsor. . . .
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> And for those reasons and for the reasons we've stated earlier, we believe that [a verdict on] the issue of agency should be directed in favor of [defendant].

Plaintiff opposed the motion, arguing the trial court should submit the issue of agency to the jury. The trial judge disagreed with plaintiff and granted the motion in part[10]:

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[10] Plaintiff does not challenge any of the trial court's findings or conclusions in support of the order granting a partial directed verdict. She has consistently maintained the action against

The Court: . . . My view of the matter is that a physician/independent investigator is not an agent of the sponsor and there [are] a number of reasons for that.

To begin with, the FDA is trying to obtain unbiased information. I believe that's one of the reasons that it requires a protocol that has some independent oversight with respect to the way in which the study is conducted. I think that's one of the functions of the [institutional review board]. It's also one of the reasons that the protocol is approved by the FDA.

Secondly, I think that a physician in a clinical trial, at least as described in this case, is making judgments which are independent of the sponsor's interests and are intended to be in the interest of the patient or the subject for the purpose of protecting the subject from adverse consequences of the trial. I think that the physician in her or his unfettered discretion recommends inclusion of the subject in the trial and I think that the physician's responsibility during the trial to monitor the reaction of the subject to the environment and to the test drug is evidence that the physician is making decisions which are independent of the program or the structure imposed by the sponsor.

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defendant is based on its own negligence, not any vicarious liability stemming from Valencerina's medical malpractice.

> Consequently, . . . I am going to hold that the physician/independent investigator is not the agent of [defendant].

In granting a partial directed verdict at the close of evidence, the trial court identified two negligence theories that plaintiff could pursue against defendant: "I do think that a sponsor has independent responsibilities to the patient, and [defendant] in this particular structure has seen to it that it would obtain information about the reaction of the subject to the test drug and to the physical condition of the subject such that it had reasonably assumed responsibilities to make its own judgment separately from the physician as to whether or not this subject should stay in the program [or] should be - - if the circumstances warranted taken out of the program and provided medical care for the subject's benefit."

Rephrasing the trial judge's words, one issue was couched in terms of defendant's independent duty to intervene in Augustine's medical care, even if the medical issues preexisted, or were unrelated to, the study itself. Another was based on defendant's duty to monitor the administration of the study drug, including whether the one-milligram test dose was a substantial factor in causing Augustine's death. This ruling meant all the evidence concerning Augustine's competency to decide to participate in the study ultimately was not relevant to the issue of whether defendant owed a duty to decedent.[11] However, based

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[11] In *Liu I,* plaintiff "[did] not say the participation in the study per se caused or contributed to Liu's death; rather it was the decision to admit him to the study rather than to refer him immediately for a cardiac workup after the initial ECG and blood

on the trial court's decision, the jury was permitted to consider whether defendant had an independent duty to intervene and timely refer Augustine to a cardiologist or hepatologist or transfer him to an acute care facility for treatment of his preexisting heart disease.

The jury was presented with a special verdict form that asked whether defendant and Valencerina[12] were negligent and, if so, whether the negligence of either was "a substantial factor in causing the death of Augustine Liu II." The jury answered these four questions in the affirmative. The jury awarded Liu $3 million in general damages and $5 million in future damages. It assessed the percentages of fault at 70 percent for defendant and 30 percent for Valencerina. Based on the verdict, the trial court entered a judgment against defendant in the amount of $5.6 million.

DISCUSSION

I. Issues—Overview

Defendant raises a number of appellate issues. It first challenges the trial court's conclusion that it owed a duty to intervene in Augustine's medical treatment for his preexisting heart disease. Defendant next contends plaintiff's claims concerning Augustine's recruitment, consent, and enrollment in the study could not provide a basis for the jury's verdict.

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test results demonstrated the existence of serious cardiac problems and elevated liver enzymes; and why Liu's deteriorating condition was ignored." (*Liu I* at *4.)

[12] As noted above, the basis for Valencerina's liability was necessarily medical malpractice.

Defendant also challenges the sufficiency of the causation evidence, i.e., the one-milligram test dose was a substantial factor in Augustine's death. Finally, defendant contends misconduct by plaintiff's trial counsel and evidentiary errors compel reversal or, at a minimum, remand for a new trial.

The issue based on recruitment, consent, and enrollment is easily resolved. Several years before trial, any potential for Valencerina to be liable based on the circumstances of Augustine's enrollment in the study (first cause of action against her for dependent adult abuse) was eliminated when the trial court granted her motion for summary judgment. Although evidence on these questions was received during trial, the trial court granted defendant's motion for a partial directed verdict and determined Valencerina was responsible for the enrollment decision, but did not act as defendant's agent in doing so.[13]

We conclude as a matter of law that defendant undertook a general duty not to harm Augustine as part of the clinical study. That duty encompassed administration of the test dose. As a matter of law, we also conclude the scope of that duty did not

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[13] We repeat the relevant portion of the trial court's ruling: "[A] physician in a clinical trial, at least as described in this case, is making judgments which are independent of the sponsor's interests and are intended to be in the interest of the patient or the subject for the purpose of protecting the subject from adverse consequences of the trial. I think that the physician in her or his unfettered discretion recommends inclusion of the subject in the trial and I think that the physician's responsibility during the trial to monitor the reaction of the subject to the environment and to the test drug is evidence that the physician is making decisions which are independent of the program or the structure imposed by the sponsor."

extend to diagnosing or treating Augustine's preexisting heart disease or intervening in his medical care and the medical decisions related to that condition.

We also conclude the trial court should have stricken the one-milligram test dose/causation testimony by expert Goodman. That testimony was insufficient to support a finding the test dose was a substantial factor in Augustine's death. Although defendant did not make a similar motion to strike Plunkett's testimony, her opinion was nonetheless insufficient to establish causation.

These conclusions compel reversal and we do not address defendant's other appellate issues.

II. Duty

A. Existence and Scope of Duty: Questions of Law Subject to De Novo Review

"The existence and scope of duty are legal questions for the court." (*Merrill v. Navegar, Inc.* (2001) 26 Cal.4th 465, 477.) As explained below, "foreseeability is a crucial factor in determining the existence of duty [citation], and . . . '[f]oreseeability, when analyzed to determine the existence and scope of a duty, is a question of law to be decided by the court.'" (*Delgado v. Trax Bar & Grill* (2005) 36 Cal.4th 224, 237, quoting *Ann M. v. Pacific Plaza Shopping Center* (1993) 6 Cal.4th 666, 674.) We review the duty issue de novo. (*Coburn v. Sievert* (2005) 133 Cal.App.4th 1483, 1492.)

Preliminarily, we note that crafting a description of the duty issue in any negligence case is not a mere exercise in semantics. The description itself provides the framework for the appropriate duty analysis.

For example, plaintiff asserts defendant had "a general duty to assure that [Augustine's] health and safety were protected." She accordingly invokes Civil Code section 1714 and the duty analysis set forth in a long line of decisions spanning almost 50 years from *Rowland v. Christian* (1968) 69 Cal.2d 108 to *Cabral v. Ralphs Grocery Co.* (2011) 51 Cal.4th 764 (*Cabral*) and *Kesner v. Superior Court* (2016) 1 Cal.5th 1132 (*Kesner*). Under this analysis, the existence of a duty is the rule and courts will find an exception only "where 'clearly supported by public policy.'" (*Cabral, supra,* 51 Cal.4th at p. 771.)

We agree as a matter of law that defendant, as the drug manufacturer/sponsor of a clinical trial, undertook a general duty not to harm the study participants as part of the clinical trial protocols. Administration of the Risperidone test dose fell within the scope of this duty, and we will discuss the sufficiency of the evidence to support liability under this duty of care in part III, *infra.*

But the significant legal question that must be analyzed in this case is whether the general duty not to harm study participants encompassed a duty to diagnose or treat Augustine's preexisting, life-threatening heart disease and to intervene in the medical care and decisions precipitated by Augustine's abnormal test results. For the reasons that follow, we conclude it did not.

B. Analysis

Imposition of the more expansive duty advocated by plaintiff depends on whether it was foreseeable to defendant, as the study sponsor, that the study physicians would misdiagnose and fail to treat Augustine's life-threatening cardiac disease that also affected other organs.

Lack of foreseeability was pivotal in *Jackson v. AEG Live, LLC* (2015) 233 Cal.App.4th 1156 (*Jackson*). There, 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. The performer died from a fatal overdose of medication administered by the physician during preparations for the tour, and his heirs sought to hold the promoter liable on, inter alia, a common law negligence theory. (*Id.* at pp. 1165-1171, 1173.)

On appeal from an order summarily adjudicating the negligence claim in favor of the promoter, this court affirmed the trial court's determination the promoter did not have a duty to protect the performer from the medical malpractice or criminal negligence of the physician. The physician's negligent medical decision to administer a dangerous sedative without proper oversight was not a foreseeable consequence of the promoter's general instructions to the physician to maintain the performer's overall health. (*Jackson, supra*, 233 Cal.App.4th at pp. 1174-1175.)

In this case, although FDA regulations impose on study sponsors a general duty to monitor the progress of their studies to ensure compliance with study protocols and the health and safety of participants, that duty is intended to protect participants generally from foreseeable harm caused by the drug studies themselves, including participants' adverse reactions to study medications. That is the duty defendant undertook.

The jury found negligence by both Valencerina and defendant contributed to Augustine's death. Based on the trial court's rulings, Valencerina's negligence was necessarily medical malpractice, e.g., the study physicians' negligent medical

decisions in response to the abnormal medical tests, the first clinical signs of Augustine's preexisting, undiagnosed cardiac disease. As in *Jackson, supra*, 233 Cal.App.4th 1156, it is not foreseeable to a study sponsor that study physicians with the primary responsibility for participants' health and safety will fail to recognize, diagnose, and properly treat preexisting, life-threatening conditions that first manifest during drug studies, as Augustine's condition did here.[14]

Dekens v. Underwriters Laboratories Inc. (2003) 107 Cal.App.4th 1177 (*Dekens*) is also instructive. The plaintiffs' decedent in *Dekens* repaired small appliances. He died of mesothelioma, contracted as a result of exposure to asbestos, which was then a not-uncommon component in small electrical appliances. His heirs sued Underwriters Laboratories (U.L.) on a negligent undertaking theory, contending the defendant undertook a certification process to safeguard the health of consumers, including those individuals who repaired U.L.-certified appliances. (*Id.* at p. 1179.)

U.L. successfully moved for summary judgment, and the Court of Appeal affirmed. The appellate panel posed two threshold questions: "Did U.L. undertake to provide services [to the decedent] and, if so, what was the scope of that undertaking?"

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[14] Plaintiff contends there was no physician-patient relationship between the study physicians and Augustine. But the trial court ruled the negligence cause of action against the medical professionals was based on medical malpractice only because a physician-patient relationship existed during the study. In granting the directed verdict on the agency issue, the trial court found Valencerina, as the study physician/ investigator, had primary responsibility for Augustine's health and safety during the study.

(*Dekens, supra,* 107 Cal.App.4th at p. 1182.) The Court of Appeal agreed U.L. tested and certified appliances for safety based on electrical shock, heat, and fire, but found the undertaking did not include a "guarantee [of] safety from cancer-causing asbestos." (*Id.* at p. 1187.) The appellate panel explained, "U.L. met its burden on summary judgment by showing through admissible evidence that it never undertook to test small appliances for medical safety or to certify the appliances would not cause cancer. Plaintiffs failed to show a triable issue of material fact regarding the existence and scope of any such undertaking by U.L. The trial court properly granted summary judgment." (*Id.* at p. 1180.)

Here, defendant undertook the general duty to ensure study participants' health and safety during the study. That undertaking did not extend to protecting participants from unforeseeable medical malpractice by study physicians in response to undiagnosed, life-threatening conditions. Like the defendant's undertaking in *Dekens*, JRD's undertaking as the drug study sponsor cannot reasonably be construed to include a "guarantee of safety" from any and all acts of medical malpractice by physicians who bear the primary responsibility for safe-guarding the health of study participants.

The defendants in *Jackson* and *Dekens* prevailed in summary adjudication proceedings, while defendant here lost in a jury trial. Still, "[t]he existence of a duty of care is . . . decided on a case-by-case basis. [Citations.] '"While it is the province of the jury, as trier of fact, to determine whether an unreasonable risk of harm was foreseeable under the particular facts of a given case, the . . . court must still decide as a matter of law whether there was a duty in the first place, even if that determination

includes a consideration of foreseeability.'" (*M.W. v. Panama Buena Vista Union School District* (2003) 110 Cal.App.4th 508, 516 (*M.W.*).)

The verdict is a consideration in our analysis, however; and evidentiary conflicts concerning foreseeability would be resolved in plaintiff's favor. (*M.W., supra*, 110 Cal.App.4th at p. 516.) But the foreseeability evidence was not in conflict. Other than the abnormal EKG and elevated liver enzymes, Augustine did not present himself for participation in the study with any other symptoms. His advanced cardiomyopathy had not yet been diagnosed. The delay in diagnosing and treating Augustine's serious cardiac disease was not a foreseeable risk that would support an expanded scope of the general duty of care owed by defendant not to harm study participants.

In support of her duty analysis, plaintiff relies on *Kesner, supra,* 1 Cal.5th 1132 and *Coffee v. McDonnell-Douglas Corp*. (1972) 8 Cal.3d 551 (*Coffee*). However, neither decision provides authority for the broad scope of the duty plaintiff is advancing on appeal.

In *Kesner*, our Supreme Court determined employers and landowners owe a duty of care to prevent secondary exposure to asbestos that occurs when an individual carries the toxic fibers home on his or her person or clothing. (*Kesner, supra*, 1 Cal.5th at p. 1140.) The court in that case analyzed the duty issue under Civil Code section 1714 and the factors articulated in *Rowland, supra*, 69 Cal.2d 108. The foreseeability analysis was straightforward: An employer or landowner should reasonably foresee that individuals directly exposed to asbestos would, through their person, clothing, or other items, act as vectors and transfer asbestos to household members. (*Kesner, supra*, 1

Cal.5th at p. 1140.) The Supreme Court then determined no public policy considerations justified an exception to the general rule of duty in Civil Code section 1714. (*Id.* at p. 1156.)

The foreseeability factor in this case is significantly more tenuous: It is not reasonably foreseeable to a drug study sponsor that the response by study physicians—who, as the trial court found, are primarily responsible for the health and safety of participants while enrolled in drug studies—to a patient/participant's preexisting and undiagnosed disease, unrelated to the clinical trial, would fall below the standard of care for a medical practitioner.

In *Coffee, supra*, 8 Cal.3d 551, the defendant aircraft manufacturer required the plaintiff to undergo a pre-employment physical examination and blood test to determine his fitness to serve as a test pilot. (*Id.* at pp. 553-554.) The physicians who examined the plaintiff and cleared him for pilot duty were employees of the defendant. No medical practitioner reviewed the blood test results, however, because a secretary filed them away without first providing them to the physicians. (*Id.* at p. 555.) The blood test results indicated a likelihood the plaintiff was suffering from a disease serious enough that he would not have been hired. (*Id.* at pp. 555-556.)

Seven months later, the plaintiff was diagnosed with cancer. (*Coffee, supra*, 8 Cal.3d at p. 554.) He sued McDonnell-Douglas for failing to inform him of the results of his blood test and the three physician employees for failing to discover and disclose his preexisting disease. (*Id.* at pp. 554-555.) The jury returned a verdict in favor of the physicians, but against McDonnell-Douglas "on the negligence of other corporate

employees [the secretary]" and the defendant appealed. (*Id.* at p.p. 555-556.)

The Supreme Court rejected the defendant's argument that it owed no duty to the plaintiff, as a prospective employee, to ascertain whether he was physically fit to be hired. (*Coffee, supra,* 8 Cal.3d at p. 557-558.) The court concluded a prospective employer generally owes no duty to a prospective employee to ascertain whether the latter is fit for employment. But an employer who assumes such a duty may be liable if the task is performed negligently. (*Id.* at p. 557.)

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. Also, *Coffee* presented no issue concerning the scope of the employer's undertaking, as it was undisputed the employer voluntarily undertook to ascertain the plaintiff's fitness to perform his job duties. In this case, the study physicians, not defendant, voluntarily assumed the primary responsibility for Augustine's health and safety during the study, including the responsibility to competently diagnose and treat any preexisting, life-threatening diseases.

III. Sufficiency of the Evidence That the One-Milligram Test Dose Was a Substantial Factor in Augustine's Death

As detailed above, the trial court ruled defendant had an independent duty to monitor Augustine's reaction to the single test dose and remove him from the study if the results warranted that action. We agree. Defendant asserts the evidence was insufficient to establish the single test dose was a substantial factor in Augustine's death. According to defendant, the

testimony of plaintiff's causation experts that Risperidone can cause heart failure generally and that it did so specifically in this case, was speculative and otherwise unsupported by the necessary factual basis. Again, we agree.

A. Procedural Background—Causation

Defendant sought to exclude the causation testimony of plaintiff's experts Plunkett and Goodman, arguing their deposition testimony demonstrated they did not have a factual basis for their conclusion that the one-milligram dose of Risperidone contributed to Augustine's death.[15] The trial court denied the motions.[16] Both experts then testified the test dose was a substantial factor in Augustine's death.

Defendant moved to strike Goodman's causation testimony as it related to the test dose and also moved for a partial nonsuit on the causation issue on the basis the experts' test-dose causation opinions were conclusory and lacked factual support. The trial court denied both motions and sent the causation issue to the jury. The causation testimony of Plunkett and Goodman was conclusory and based on speculation rather than facts. It

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15 Plaintiff called eight medical experts to testify at trial.

16 "Trial judges have substantial gatekeeping responsibility when it comes to expert testimony. . . .' [¶] Based on the provisions of Evidence Code sections 801 and 802, [footnote omitted] 'the trial court act[s] as a gatekeeper to exclude expert opinion testimony that is (1) based in matter of a type on which an expert may not reasonably rely, (2) based on reasons unsupported by the material on which the expert relies, or (3) speculative." (*Sargon Enterprises, Inc. v. University of Southern California* (2013) 215 Cal.App.4th 1495, 1504.)

lacked the requisite probative value to meet plaintiff's evidentiary burden on the causation issue and was insufficient to support plaintiff's verdict.

1. Plunkett, Ph.D.

When asked if it was her "opinion . . . in this case that [Augustine's] death may have been contributed by the 1-milligram [dose] of [Risperidone]?", Plunkett responded, "Well, I'm not here to talk about his cause of death. I'm not the physician in the case. But I do believe the [Risperidone] posed a risk to his health, and what I saw was consistent with [Risperidone] being a contributing factor of his death, yes." Defense counsel did not object.

Plaintiff's counsel persisted: "Q. So to be very clear, in this case you are telling this jury that this 1-milligram injection of Risperidone given to [Augustine] on Monday morning could have had some contribution to his death on Thursday, the 26th, is that correct? [¶] A. Yes, based on the existence of another cardiotoxic drug [Seroquel] already in his system and the fact he had an abnormal EKG before he took the drug." [¶] "Q. And then [defendant] picks [Augustine] up for this clinical trial, knows he's got a bad heart from the EKG, knows he's on Seroquel, which is not good for the heart, injects him with a drug that's got known cardiac risk problems, and he's dead two days later? [¶] A. Yes. That's what happened. [¶] Q. Does that all make sense in the context of this is something that's consistent when you inject a cardiotoxic drug into a man that's got a bad heart, and he's already on a drug that's got cardiac risks; is that what you mean by that? [¶] A. Yeah. Yes, exactly." Defense counsel did not object.

Plunkett added that Risperidone could cause abnormal heart rhythms in the general population, including arrhythmias: "[Risperidone] was known to affect heart function; specifically it could affect blood pressure; and it could also affect the conduction system, the way that the heart controls its beat. So when I was talking about arrhythmias, it's that idea . . . ."

Plunkett further testified patients with heart problems like Augustine who are administered Risperidone can experience abnormal heart rhythms that can lead to sudden death and Augustine's death was consistent with the known toxicities of Risperidone: "Q. And we went through the data earlier that people with problematic hearts who get Risperidone, they can have problems? [¶] A. Yes, that's correct. [¶] Q. They can die? [¶] A. Yes. [¶] Q. They can have arrhythmias which lead to sudden death? [¶] A. Yes. [¶] Q. And based upon what . . . you saw in your review of these records as to how [Augustine] ultimately passed, was it consistent with everything that we've seen in all [the] scientific information? [¶] . . . [¶] Yes. What happened [to Augustine] would be consistent with the known toxicities of the particular drug."

2. Goodman, M.D.

Goodman also concluded the single test dose of Risperidone was a substantial factor in Augustine's death. "Q. Dr. Goodman, . . . do you have an expert opinion as to whether or not the 1 milligram injected short-acting, immediate-release dose that he received on the 23rd of February 2009 was a substantial factor that contributed to [Augustine suffering] . . . congestive heart failure? [¶] . . . [¶] Yes, I do. [¶] Q. . . . And can you tell the jury what that opinion is? [¶] A. Yes, I think that in this

gentleman with severe heart muscle dysfunction, liver failure, impending kidney failure, that the addition of a medication such as [Risperidone], which is metabolized by the liver and to some degree the kidney, I think that that medication actually pushed him over the edge and contributed - - was a substantial contributing factor to his ultimate demise." [¶] . . . "A. So in his specific case with heart muscle dysfunction, with severe liver failure, with kidney dysfunction, this 1-milligram dose did contribute to his death." [¶] . . . [¶] Q. "So the question you were looking at is not whether he had dilated cardiomyopathy and the 1 milligram. It's having dilated cardiomyopathy, did getting this injection, was it a substantial factor in putting him over the edge and causing his death? [¶] A. Correct. [¶]

On cross-examination, Goodman denied Augustine experienced an arrhythmia as a result of the test dose. "Q. Your claim is that [Augustine] sustained some type of an arrhythmia due to the single 1-milligram dose; correct? [¶] A. No. My testimony is that [Risperidone] was a substantial contributing factor in this specific case, in this 25-year-old with severe heart failure, kidney failure, and liver failure, that the addition of this 1-milligram dose of [Risperidone] contributed to his demise. [¶] . . . A. [T]he medication is known to be cardiotoxic. It's contraindicated in patients with this type of condition and . . . it did contribute to [Augustine's] demise. He probably died an arrhythmic death. It was a combination of pump, plus arrhythmia. So in a way he did die from an irregular heart rhythm, but we all die from an irregular heart rhythm. Eventually your heart stops . . . ."

Goodman, however, admitted on cross-examination that he could not identify how the single test dose caused an injury to

Augustine that contributed to his death. "Q. Are you able to identify for this jury the specific mechanism of injury that you claim the single 1-milligram dose caused in [Augustine]? [¶] A. No, I'm not, and neither is [defendant]. In your publications, it says the mechanism of cardiac issues is unknown.

B. Experts' Causation Opinions re: Test Dose Did Not Constitute Substantial Evidence

Jennings v. Palomar Pomerado Health Systems, Inc. (2003) 114 Cal.App.4th 1108 (*Jennings*) and the authorities it cites provide the blueprint for our analysis of the sufficiency of the evidence to support expert testimony as to causation. "'The law is well settled that . . . causation must be proven within a reasonable medical probability based [on] competent expert testimony. Mere possibility alone is insufficient to establish a prima facie case.'" (*Id.* at p. 1118.) "[T]he plaintiff must offer an expert opinion that contains a reasoned explanation illuminating why the facts have convinced the expert, and therefore should convince the jury, that it is *more probable than not* the negligent act was a cause-in-fact of the plaintiff's injury." (*Ibid.*)

It is equally well-established an expert's opinions based on assumptions without evidentiary support or on speculative or conjectural factors have no evidentiary value and may be excluded. (*Jennings, supra*, 114 Cal.App.4th at p. 1117.) Similarly, when an expert's opinion lacks a reasoned explanation that connects the factual predicates to the ultimate conclusion, the opinion has no evidentiary value. In short, an "'expert opinion is worth no more than the reasons upon which it rests.'" (*Ibid.*) Likewise, an expert's conclusory opinion, without an explanation of how the expert "employed his or her superior

knowledge and training to connect the facts with the ultimate conclusion, does not assist the jury." (*Ibid.*)

Based on our review of the causation testimony of Plunkett and Goodman, we conclude there was insufficient evidence that administration of the single, one-milligram dose of the study drug was a substantial factor in causing Augustine's death. As defendant points out, although Plunkett testified Risperidone could cause electrical or heart rhythm problems in the general population, such as arrhythmias, there was no evidence Augustine died from heart issues associated with arrhythmias or heart rhythm problems.

Instead, the evidence showed Augustine died from a mechanical or pump failure due to severe cardiomyopathy, i.e., his heart reached a crucial point where it could no longer pump a sufficient volume of blood to supply his vital organs. Plunkett concluded the test dose played a role in contributing to Augustine's demise, but she failed to provide a factual basis to support that belief and freely admitted she was not qualified to render such an opinion.[17] Her conclusion did not rise to the level of substantial evidence under *Jennings, supra*, 114 Cal.App.4th 1108. (See also *People v. Wright* (2016) 4 Cal.App.5th 537, 545 ["'when an expert bases his or her conclusion on factors that are "speculative, remote or conjectural," or on "assumptions . . . not supported by the record," the expert's opinion "cannot rise to the dignity of substantial evidence" and a judgment based solely on that opinion "must be reversed for lack of substantial evidence"'"].)

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[17] "I'm not here to talk about [Augustine's] cause of death. I'm not the physician in the case."

Goodman also concluded the test dose was a substantial factor in Augustine's death. Like Plunkett, he provided no factual basis for the opinion. (*Jennings, supra*, 114 Cal.App.4th at p. 1117.) Distilled to its essence, Goodman's opinion acknowledged Augustine was still on his daily 800-milligram dose of Seroquel, another cardiotoxic drug, and had a severely diseased heart that compromised his liver and kidneys. Nevertheless, Goodman unequivocally concluded the administration of *any amount* of the test drug—including the one-milligram dose Augustine actually received—was sufficient to push Augustine "over the edge." Goodman, however, did not provide a reasoned explanation that illuminated for the jury how or why such a low dose of Risperidone could have had such a substantial effect on Augustine's life-threatening disease. Instead, as Goodman admitted on cross-examination, he could not specifically identify how or why the test dose likely was a substantial factor in the death of an individual with such advanced cardiomyopathy. Assumptions and conclusions not based on facts or based merely on conjecture and speculation are not evidence of the ultimate fact they are intended to prove.

As the court in *Bockrath v. Aldrich Chemical Co., Inc.* (1999) 21 Cal.4th 71, 79, observed, "In cases like the one before us, presenting complicated and possibly esoteric medical causation issues, the standard of proof ordinarily required is '"a reasonable medical probability based upon competent expert testimony that the defendant's conduct contributed to [the] plaintiff's injury."' [Citations.] [¶] 'The substantial factor standard is a relatively broad one, requiring only that the contribution of the individual cause be more than negligible or theoretical.' [Citation.] Thus, 'a force which plays only an

"infinitesimal" or "theoretical" part in bringing about injury, damage, or loss is not a substantial factor' . . . ." Here, at best, plaintiff's causation experts opined as to a theory that might have contributed to Augustine's death, but did not provide the necessary factual basis to qualify that theory as substantial evidence.

IV. Appeal from Judgment Against Liu as Her Husband's Successor in Interest

The judgment against Liu in her capacity as her husband's successor in interest was based on the trial court's ruling that claims for noneconomic damages do not survive when the plaintiff in a wrongful death action dies before judgment. Our conclusions that defendant owed no duty of care to intervene in Augustine's medical care related to his preexisting heart disease and there was insufficient evidence of causation to support liability based the duty of care defendant did owe, insofar as administration of the Risperidone test dose was concerned, are dispositive of Liu's appeal.

We note only that the traditional pecuniary/nonpecuniary view of wrongful death damages for loss of a decedent's society and companionship (see, e.g., *Krouse v. Graham* (1977) 19 Cal.3d 59, 68) shifted; wrongful death damages for loss of a decedent's society and companionship are now characterized as noneconomic (*Boeken v. Philip Morris USA, Inc.* (2010) 48 Cal.4th 788, 795-796).[18] And "'noneconomic damages do not survive if the plaintiff

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[18] See also Civil Code section 1431.2, subdivision (b): "(1) For purposes of this section, the term 'economic damages' means objectively verifiable monetary losses including medical expenses, loss of earnings, burial costs, loss of use of property, costs of

dies before judgment.'" (*Sullivan v. Delta Air Lines, Inc.* (1997) 15 Cal.4th 288, 300.)

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repair or replacement, costs of obtaining substitute domestic services, loss of employment and loss of business or employment opportunities. [¶] (2) For the purposes of this section, the term '*non-economic damages' means* subjective, non-monetary losses including, but not limited to, pain, suffering, inconvenience, mental suffering, emotional distress, *loss of society and companionship, loss of consortium*, injury to reputation and humiliation." (Italics added.)

CACI No. 3921 defines the noneconomic damages a wrongful death plaintiff may recover to include the loss of the decedent's "love, companionship, comfort, care, assistance, protection, affection, society, [and] moral support . . . ."

DISPOSITION

The judgment in favor of plaintiff individually is reversed. The judgment against plaintiff as the successor in interest to her deceased husband is affirmed. Defendant is awarded costs on both appeals.

NOT TO BE PUBLISHED IN THE OFFICIAL REPORTS

DUNNING, J.*

We concur:

KRIEGLER, Acting P. J.

BAKER, J.

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* Judge of the Orange Superior Court, appointed by the Chief Justice pursuant to article VI, section 6, of the California Constitution.