

WEDNESDAY, MAY 17, 2023

PERSPECTIVE

California appellate court decision reaffirms the vital gatekeeping responsibility of trial courts

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Last month, in *Onglyza Prod. Cases*, 307 Cal. Rptr. 3d 480, 2023 WL 3001055 (Ct. App. 2023), the California Court of Appeal issued a significant decision in a products liability Judicial Council Coordination Proceeding, when it affirmed a trial court's order excluding plaintiffs' general causation expert and entering summary judgment for defendants. The *Onglyza* case highlights the trial court's essential gatekeeping role and serves as a reminder that expert opinions must be based on reliable methodologies under California law. This article examines some of the methodological issues that were ultimately fatal to plaintiffs' case.

In *Onglyza*, plaintiffs sued pharmaceutical manufacturers of various diabetes medications, alleging that the main ingredient in the drugs, known as saxagliptin, caused heart failure and related cardiac conditions, including wrongful death. Before the manufacturers marketed the medications, as part of their original application for approval, the Food and Drug Administration required them to perform a study to evaluate saxagliptin treatment in certain patients who were at high risk for cardiovascular-related injuries. The study, known as the SAVOR study, concluded that saxagliptin did not increase or decrease the risk of any of the cardiac conditions that were studied as primary end points.

SAVOR did, however, report one statistically significant finding for one of the secondary end points studied—hospitalization for heart failure. The study noted that this finding was “unexpected and

should be considered within the context of multiple testing that may have resulted in a false positive result.” *Id.* at *1. The study cautioned that further investigation was needed and a “class effect should not be presumed.” *Id.*

After the SAVOR study, further study was done, including observational studies and a meta-analysis, none of which reported an association between saxagliptin and an increased risk of hospitalization for heart failure.

Relying on the single statistically significant finding from the SAVOR study, plaintiffs designated two experts to support their general causation theory: (1) a cardiologist who opined that saxagliptin was capable of causing heart failure; and (2) a biostatistician who concluded that study data showed a significant increase in the risk of hospitalization for heart failure for participants who took saxagliptin.

Defendants moved to exclude the cardiologist under *Sargon*—the seminal California Supreme Court case that clarifies the standard for admissibility of expert testimony and holds that trial courts

must act as gatekeepers to ensure that expert opinions are reliable and based on sound scientific methodologies. *Sargon Enterprises, Inc. v. Univ. of S. California*, 55 Cal. 4th 747 (2012).

and concluding that SAVOR alone supports causation was unreliable as he “failed to engage in a candid weighing of the evidence, choosing instead to avoid mentioning factors or entertaining conclusions

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After a *Sargon* hearing, the trial court granted defendants' motion, holding that:

(1) the cardiologist's opinions disregarding certain human data

that weighed against an ultimate conclusion of general causation;”

(2) the cardiologist's opinions regarding inferences that could be drawn from animal studies went

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beyond his expertise as he was unqualified to analyze animal data and those opinions “were not supported by a reliable methodology;” and

(3) the cardiologist’s application of nearly all of the Bradford Hill factors—a generally-accepted methodology used to assess causation—was unreliable as he failed to “employ[] the same level of intellectual rigor that characterize[d] the practice of an expert in the relevant field.” *Onglyza Prod. Cases*, No. 4909, 2021 WL 6015430, at *5-6, 12 (Cal. Super. Ct. Sep. 24, 2021).

Because plaintiffs were without any expert evidence of general causation, an essential element of their tort claims, the court granted summary judgment in favor of defendants.

Plaintiffs appealed, advancing various attacks on the trial court’s decision, and the Court of Appeals affirmed, rejecting each attack in turn.

Plaintiffs first argued that the

trial court exceeded its gatekeeping responsibility by excluding the cardiologist’s opinion, contending that the expert should have been permitted to place more weight on the SAVOR study and less weight on other evidence. But the Court held that the trial court appropriately found that the cardiologist’s opinion did “not contain a reliable methodology for weighing the evidence but a shifting results-based methodology that fail[ed] to logically and consistently weigh all relevant evidence.” *Onglyza Prod. Cases*, 2023 WL 3001055, at *5. Ultimately, the cardiologist’s reliance on only the SAVOR study to show a causal link was fatal. As the Court explained, “rarely, if ever, does a single study persuasively demonstrate a cause-effect relationship.” *Id* (citation omitted).

Plaintiffs next argued that the trial court improperly excluded the cardiologist’s opinion given

that he applied the Bradford Hill factors. The Court rejected this argument, finding that the trial court properly exercised its gatekeeping responsibility when it found that the cardiologist’s application of most of the Bradford Hill factors suffered from “serious flaws in [] methodology” and was not “founded on sound logic.” *Id* at *8 (citation omitted). For example, in analyzing the “consistency” factor (looking at whether similar findings are generated across multiple studies), the cardiologist disregarded inconsistent data from other human studies that weighed against his conclusion. In sum, the “shifting and unsound methodology [he] utilized in weighing the evidence” rendered his opinions unreliable. *Id*

Finally, plaintiffs argued that even without the cardiologist’s expert testimony, either (1) the unchallenged biostatistician’s expert

testimony or (2) other non-expert evidence was sufficient to raise a triable issue of fact as to general causation. The Court disagreed, observing that the “law is well settled that in a personal injury action causation must be proven ... based upon competent expert testimony.” *Id* at *9 (citation omitted). And the biostatistician had conceded that he was unqualified to provide a general causation opinion. Thus, there was no triable issue of fact as to general causation.

The *Onglyza* case reinforces the trial court’s substantial gatekeeping responsibility to exclude unreliable expert testimony. To survive a Sargon challenge, general causation experts’ opinions must be based on scientifically reliable methodologies. As was the case in *Onglyza*, expert opinions rife with methodological issues could result in a complete dismissal of the litigation.