IN THE DISTRICT COURT OF APPEAL OF THE STATE OF FLORIDA FIFTH DISTRICT

NOT FINAL UNTIL TIME EXPIRES TO FILE MOTION FOR REHEARING AND DISPOSITION THEREOF IF FILED

ROBERT DUMIGAN, INDIVIDUALLY AND AS THE EXECUTOR OF THE ESTATE OF EDITH DUMIGAN.

Appellant,

٧.

Case No. 5D21-1087 LT Case No. 05-2012-CA-038662-X

HOLMES REGIONAL MEDICAL CENTER, INC.,

Appellee.	

Opinion filed January 21, 2022

Appeal from the Circuit Court for Brevard County,
Michelle L. Naberhaus, Judge.

Stephen Joseph Biggie, of Arcadier, Biggie, and Wood, PLLC, W. Melbourne, for Appellant.

Andrew S. Bolin, of Bolin Law Group, Tampa, for Appellee.

COHEN, J.

Robert Dumigan ("Dumigan"), individually and as executor of the estate of Edith Dumigan, appeals the trial court's directed verdict entered in

favor of Holmes Regional Medical Center, Inc. ("Holmes Regional"). This case finds itself before this Court for the third time. Because the evidence presented did not warrant a directed verdict, we reverse.

In January 2008, Baxter Healthcare Corporation ("Baxter") informed Holmes Regional that certain vials of Baxter-manufactured heparin—a blood thinner—were contaminated, requiring recall. Baxter identified the contaminated vials by lot number. In response, Holmes Regional conducted three "sweeps" of multiple locations within the hospital to remove the drug from circulation: the first in January, the second in February, and the third on May 12.

On May 2, 2008, Dumigan, then 76 years old, was admitted to Holmes Regional for heart bypass surgery due to a blockage. At the beginning of the procedure, Dr. Fernando Abad, the anesthesiologist, administered heparin to Dumigan but did not record the lot numbers of the vials he used. Ten minutes after the heparin was administered, Dumigan developed significant hypotension—a drop in blood pressure. Over the next hour, Brooks Liles, the

¹ Holmes Reg'l Med. Ctr. v. Dumigan, 151 So. 3d 1282 (Fla. 5th DCA 2014) (denying Holmes Regional's petition for writ of certiorari); <u>Dumigan v. Holmes Reg'l Med. Ctr.</u>, 325 So. 3d 112 (Fla. 5th DCA 2020) (reversing summary judgment in favor of Holmes Regional). These cases will be referred to as Dumigan I and Dumigan II, respectively.

perfusionist, administered different vials of heparin to Dumigan through the cardiopulmonary bypass pump. Liles recorded the lot numbers of the vials he administered. The hypotension continued throughout the surgery.

Following the surgery, Dumigan was in a coma for 20 days, during which he developed heparin-induced thrombocytopenia ("HIT"), followed by heparin-induced thrombocytopenia with thrombosis ("HITT"). When he emerged from the coma, Dumigan experienced significant pain in his legs, which were black and blistered. He developed ischemia, a condition in which there is insufficient blood flow to an organ or body part; his legs were not functioning, and he developed gangrene. As a result, his left leg and right foot were amputated.

Four years later, Dumigan filed a complaint against Holmes Regional, alleging that as a result of inadequate pharmaceutical tracking and recall procedures, contaminated heparin remained at the hospital and was administered to him by Dr. Abad, who had not been informed of the contaminated heparin or its recall. Holmes Regional initially moved to dismiss Dumigan's suit, claiming that he had failed to comply with the presuit procedures required by Florida law in medical malpractice cases. After the trial court denied that motion, Holmes Regional petitioned this Court for a writ of certiorari. Dumigan I, 151 So. 3d at 1283. That petition was denied,

finding that the case sounded in negligence rather than medical malpractice.

Id. at 1288. After discovery, Holmes Regional successfully moved for summary judgment based primarily on impermissible inference stacking.²

That judgment was reversed on appeal. Dumigan II, 325 So. 3d at 113.

At trial, the evidence reflected that Jill Walling, the pharmacy buyer responsible for executing recalls, received the Baxter recall notice and supervised the three subsequent "sweeps" to retrieve the medication. She testified that, per hospital procedure, once heparin entered Holmes Regional's pharmacy, lot numbers were not tracked; and the vials were subsequently distributed to multiple locations throughout the hospital, including Pyxis machines,³ the satellite pharmacy, the operating room pharmacy, and heart boxes. Walling explained that, after a physician ordered heparin from the pharmacy for a surgery, it was delivered to the operating room and placed "somewhere in the [operating room] suite" but she was not "exactly sure where" within those suites.

In response to the January recall notice, Walling instructed technicians to visually inspect heparin vials located in Pyxis machines and "all other

² Specifically, the trial court concluded that the opinion of Dumigan's expert, Dr. Mark Levin, was based upon insufficient evidence and lacked a causal link, rendering a verdict for the plaintiff improper as a matter of law.

³ A Pyxis machine is an automated medication dispensing system.

areas" to remove contaminated heparin by lot number. Walling stated she did not know that contaminated heparin could have been stored in medication and anesthesia carts and did not instruct staff to search those locations specifically; she also was not aware of the "blue boxes" used by anesthesiologists for medication storage. Due to another recall notice received in February, Walling instructed staff to conduct a second search, this time pulling all Baxter heparin, regardless of lot number. She noted that no documentation was created or maintained for either sweep reflecting which areas were searched or which vials had been removed.

Walling testified that ten days after Dumigan's surgery, her supervisor ordered her to conduct a third sweep due to an urgent recall reminder from Baxter indicating reports of noncompliance at some hospitals. Specifically, the notice stated that some hospitals had failed to retrieve Baxter heparin from ancillary locations such as anesthesia carts. As a result, she was instructed to search those areas. When shown a pharmacy receipt documenting a hospital return of Baxter heparin in June, Walling stated that the receipt reflected a delayed credit for vials returned several months prior. Walling acknowledged that Holmes Regional's recall policy handbook required notification of a recall to all end users of the medicine.

Dr. Abad testified that he had not been notified about the recall of contaminated heparin. For Dumigan's surgery, he used heparin located in a blue box on his anesthesia cart, delivered by a pharmacy technician. Dr. Abad stated that he did not record in his anesthesiology report the lot numbers of the heparin he administered, as it was not standard practice to do so. He added that the drop in blood pressure ten minutes after he administered the heparin was the intended result of other medications he had administered for that purpose.

Liles testified that he also administered heparin to Dumigan later in the surgery, using different vials than Dr. Abad. Liles stated that he had been informed of the recall and was instructed to inspect and record the lot numbers of the heparin he used. He recorded those lot numbers in his perfusionist report.⁴

Dr. Levin, a hematologist and expert medical witness for Dumigan, presented a differential diagnosis opining that Dumigan's medical complications from the surgery were caused by heparin contaminated by oversulfated chondroitin sulfate. His diagnosis noted the dramatic drop in blood pressure to unsafe levels; swelling indicative of an anaphylactic

⁴ Liles was not responsible for recording the lot numbers of the vials used by Dr. Abad.

reaction; the emergence of the heparin antibody; and the rapid onset of significant, progressive thrombocytopenia. Dr. Levin also noted that Dumigan had not had an allergic reaction to heparin when he was treated with it during another procedure in 2010. As a result, Dr. Levin concluded that Dumigan would not have had an adverse reaction to heparin during the 2008 surgery had it not been contaminated. As to Dumigan's pre-existing conditions, Dr. Levin testified that it was unlikely that Dumigan's peripheral vascular disease would cause thrombosis in multiple locations when Dumigan had not experienced any symptoms of the disease previously.

On cross-examination, Dr. Levin agreed that HITT is a known risk and complication of heparin use, which is noted on the drug's package insert. He counsels his patients of the risks, including amputation, although he adds that it is a rare occurrence. While Dr. Levin agreed that lowered blood pressure is an intended and required state during cardiac bypass surgery, he opined that Dumigan's blood pressure dropped lower than expected and dropped further after Dumigan was removed from the bypass machine. As to the heparin antibody discovered in Dumigan's blood after surgery, Dr. Levin agreed that the timing was consistent with when the antibody would have developed from uncontaminated heparin in a patient having an atypical reaction to the drug. He acknowledged that thrombocytopenia is an expected

result of heparin but opined that the way it manifested in Dumigan was atypical and consistent with contaminated heparin use.

Timothy Hawkins, a hospital administration expert, described two mechanisms for properly conducting a recall: the first requires a hospital to record lot numbers upon receipt and track them throughout distribution—a procedure that is rarely practiced. The second option is to retrieve all the product, regardless of lot number. For either method, Hawkins testified that the national standard for medication recalls requires notifying all end users; he added that doing so is problematic without meeting with department managers to identify the end users and the locations where they store the recalled drug. Specifically, Hawkins explained that after a medication is delivered to a satellite pharmacy for use in the operating room, the drug is further distributed to multiple end users, including nurses, technicians, and anesthesiologists. Those end users store the medication in multiple locations, including in operating rooms, anesthesia machines and carts, and "even in lab coat pockets." According to Hawkins, the medication "wind[s] up everywhere," and without the necessary meetings "the product is still out there."

After reviewing Holmes Regional's records of the recall, Hawkins opined that the hospital had failed to document the implementation of the

recall from the time the notice was received to the alleged full removal.⁵ As a result, he saw no evidence that the secondary locations were searched and concluded that the hospital could not state with certainty that 100 percent of the product had been removed. Hawkins noted that Holmes Regional did not sign the standard certificate asserting that the hospital had removed all the recalled product.

On cross-examination, Hawkins acknowledged he was unaware that Holmes Regional had conducted a "full sweep" in February to remove all heparin, regardless of lot number, and noted that such a procedure would fall within the appropriate standard of care. Nonetheless, he maintained that the lack of notice to end users and the lack of required recall documentation did not fall within the standard of care.

At the close of Dumigan's case-in-chief, Holmes Regional moved for a directed verdict, arguing that a jury could only find for Dumigan through impermissible stacking of inferences.⁶ Holmes Regional alleged that there

⁵ Hawkins testified that this documentation is required by the U.S. Food and Drug Administration.

⁶ Generally, the improper stacking of inferences doctrine states that "stacking the inference of the existence of an essential fact to be drawn from circumstantial evidence cannot be made the basis of a further inference of an essential fact, unless it can be said that the initial inference was established to the exclusion of any other reasonable inference." <u>LaBarbera v. Millan Builders, Inc.</u>, 191 So. 2d 619, 621 (Fla. 1st DCA 1966).

was a complete lack of direct evidence and, as a result, Dr. Levin's opinion was dependent upon inferences drawn purely from circumstantial evidence, just as a jury verdict in favor of Dumigan would be. In granting a directed verdict, the trial court agreed, reasoning as follows:

So the Jury could infer that as a result of Holmes Regional's failure to do the things that they spoke of, obtain a certificate, advising end users of the recall, that contaminated Heparin may have remained somewhere in the Hospital, that would be a permissible inference under the law. But to find that the contaminated Heparin ended up in the possession of Dr. Abad and in the operating room on the day of the Plaintiff's surgery would require another inference to be drawn from an inference already made that contaminated Heparin remained on the property.

So, this is where we get into the issue of stacking inferences. So even stopping there, you can't get to issues of causation without having gone through the stacking of inferences.

This appeal followed.

The standard of review for a trial court's ruling on a motion for directed verdict is de novo, and the court must look at all evidence in the light most favorable to the nonmoving party. Publix Super Mkts. Inc. v. Bellaiche, 245 So. 3d 873, 875 (Fla. 3d DCA 2018) (citation omitted). "It is well established that directed verdicts in negligence actions should rarely be granted."

Martinez v. Lobster Haven, LLC, 320 So. 3d 873, 881 (Fla. 2d DCA 2021) (citation omitted). If there is any evidence to support a verdict for the nonmoving party, it is improper to enter a directed verdict. Liggett Grp., Inc. v. Davis, 973 So. 2d 467, 475 (Fla. 4th DCA 2007).

Both parties cite to the First District's decision in LaBarbera in support of their respective positions on inference stacking, just as they did in Dumigan II. In LaBarbera, homeowners sued their homebuilder, alleging that negligent construction led to the malfunction of their central heating unit and subsequent fire damage. 191 So. 2d at 620. Specifically, the homeowners contended that the builder had negligently placed insulation over the louver opening located in the ceiling of the furnace room; the resulting air blockage led to a flame surge out of the combustion unit, igniting flammable materials in the room and causing significant damage. Id. Following a jury verdict in favor of the homeowners, the defendant builder successfully moved for judgment notwithstanding the verdict. Id. at 620–21. The trial court found that the homeowners' right to recovery "depended upon the construction of one inference onto another in order to establish the ultimate facts necessary to support the issue of liability." Id. at 621.

On appeal, the First District agreed that the initial inference—that the louver was obstructed by negligently placed insulation materials before the

fire occurred—was drawn purely from circumstantial evidence and there was substantial evidence to the contrary. <u>Id.</u> at 622. Because of the possibility of reasonable contrary inferences, the initial inference "cannot be said to have so risen to the status of an established fact as to support a second inference leading to the conclusion that defendant's negligence was the proximate cause of the fire." <u>Id.</u> However, the appellate court found that the expert's testimony was based on direct evidence in addition to the initial inference. <u>Id.</u>

The expert opinion of this witness was based upon physical facts found to exist at the time of his inspection of the premises and examination of the heating unit on the day following the fire, which included the clogged condition of the ceiling louver. It is true that one of the facts assumed by this witness in reaching his conclusion was that the ceiling louver was clogged and obstructed before the fire occurred, which fact appeared only as an inference from other facts in evidence. The utilization of this inferred fact in reaching his unequivocal conclusion with regard to the origin and nature of the fire does not reduce the testimony of the witness to that of an inference drawn from circumstantial evidence.

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The <u>LaBarbera</u> court's analysis questioned the application of the rule against stacking of inferences to expert testimony, finding it problematic due to the different nature and function of the inference. The court stated:

Although a conclusion expressed by an expert witness in response to a hypothetical question may, in one sense, be characterized as an inference, we do not believe it to be the character of inference which falls within the prohibition against constructing an inference upon an inference to arrive at an ultimate conclusion. To hold otherwise would render incompetent every opinion of an expert witness given in response to a hypothetical question if it were found that one of the several facts forming the basis of the question consisted of an inference drawn from circumstantial evidence. Such a result would not comport with logic, reason, or the practicalities of the judicial process.

<u>Id.</u> As a result, although the court acknowledged the substantial evidence suggesting that the louver was not clogged before the fire, the court reversed the order of dismissal and remanded for a new trial. <u>Id.</u>

Applying the rationale of <u>LaBarbera</u> to the instant case, Holmes Regional focuses on the court's assertion that an initial inference does not rise to the level of an established fact when circumstantial evidence allows for reasonable contrary inferences. Holmes Regional argues that, from the evidence, a jury could logically infer that contaminated heparin did not remain at the hospital, vitiating any subsequent inferences. Pointing to Dr. Levin's testimony, Holmes Regional notes medical evidence that there were multiple alternative explanations for Dumigan's complications, such as: (1) Dumigan's pre-existing conditions; (2) HITT is a known risk of uncontaminated heparin; (3) lower blood pressure is an intended condition

during cardiac bypass surgery; and (4) the expected presence of the heparin antibody in Dumigan's blood prevented the allergic reaction to it in 2010.

While Holmes Regional articulates the rule correctly, it overlooks the distinction made by the <u>LaBarbera</u> court when the rule is applied to expert testimony: even if an expert relies, in part, on an inference in order to render an opinion on causation, that opinion does not constitute impermissible stacking when it is also drawn from direct evidence. <u>See id.</u> Significantly, <u>LaBarbera</u> articulated the fundamental Catch-22 created in this context: to generate an opinion, the expert must rely to some degree on the assumption underlying the hypothetical question. As a result, unless an expert opinion is based purely on speculation, impermissible stacking will not be found in this context. Id.

The Florida Supreme Court reinforced this proposition, particularly in the context of medical experts providing a differential diagnosis, in <u>Castillo v.</u>

<u>E.I. Du Pont De Nemours & Co., Inc., 854 So. 2d 1264 (Fla. 2003).</u>

"Differential diagnosis is a term used to describe a process whereby medical doctors experienced in diagnostic techniques provide testimony countering

⁷ Holmes Regional's reliance on <u>Voelker v. Combined Insurance Co.</u> of America, 73 So. 2d 403 (Fla. 1954), as an example of impermissible stacking is unpersuasive, as that case dealt with myriad causation theories drawn purely from circumstantial evidence and contained no medical expert testimony.

other possible causes . . . of the injuries at issue." <u>Castillo</u>, 854 So. 2d at 1270–71 (citations and internal quotations omitted). It is well-settled that this mechanism is an accepted form of proof of medical causation—even though it relies, in part, upon an inference. Id. at 1271.

In that case, Donna Castillo, a woman who gave birth to a child with birth defects, alleged that those defects were caused by a Du Pont fungicide, Benlate, sprayed on her as she walked by a farm. Id. at 1266. It was undisputed that the farm used Benlate at one time, but uncertain whether it was used during the period at issue. Id. at 1267. At trial, Castillo presented an expert medical witness who provided a differential diagnosis to support causation. Id. However, Du Pont maintained that there was insufficient evidence of causation, and inference stacking was required in order to find that the substance sprayed on Castillo was Benlate. Id. at 1279. The Court disagreed and concluded that there were enough independent facts pointing to that conclusion, including (1) the expert's testimony that, based on multiple test results, only a finger-nail-sized amount of Benlate was enough to cause the birth defect; and (2) Castillo's testimony that she was "wet all over" after being sprayed. Id. The Court held that these facts were independent—or parallel—of each other, rather than stacked. Id.

Here, Dr. Levin's differential diagnosis was similarly based on multiple independent medical facts: (1) the substantial drop in blood pressure after heparin was administered; (2) the prolonged period of time that the pronounced hypotension continued; (3) subsequent swelling; (4) the positive test for the heparin antibody; (5) the speed with which thrombocytopenia appeared and progressed; and (6) Dumigan's exposure to uncontaminated heparin two years later without an allergic reaction. Further, there were additional, independent non-medical facts to support the conclusion that Dumigan received contaminated heparin, including: (1) the heparin return receipt dated one month after the surgery, despite Holmes Regional's contention that a full recall was completed in February; (2) Holmes Regional's stipulation that the lot numbers of the vials were not recorded upon receipt, distribution, or retrieval and the locations searched were not documented; (3) Liles' testimony that he was still inspecting vials for contamination on the day of the surgery; (4) Dr. Abad's testimony that he was not aware of the recall and did not inspect his cart or the administered vials to determine whether they were listed in the recall notice; (5) Walling's testimony that she did not know heparin was stored in anesthesia or medicine carts; and (6) her testimony that she could not be sure if all the contaminated heparin was removed.

Ultimately, when viewed in the light most favorable to Dumigan, doubt exists as to whether contaminated heparin was still circulating and whether it was administered to Dumigan; Holmes Regional cannot conclusively state that it removed all contaminated heparin prior to his surgery when it failed to track lot numbers or obtain a certificate of compliance with the recall. As such, the evidence in this case, while conflicting and susceptible to different reasonable inferences, should have been submitted as a question of fact to be determined by the jury. See Cox v. St. Joseph's Hosp., 71 So. 3d 795, 801 (Fla. 2011) ("[W]hile a directed verdict is appropriate in cases where the plaintiff has failed to provide evidence that the negligent act more likely than not caused the injury, it is not appropriate in cases where there is conflicting evidence as to the causation or the likelihood of causation."). The trial court erred in making a credibility determination and weight evaluation when granting a directed verdict. See Liggett, 973 So. 2d at 475 ("If there is any evidence to support a verdict for the nonmoving party, a directed verdict is improper." (citation omitted)); see also White v. City of Waldo, 659 So. 2d 707, 708 (Fla. 1st DCA 1995) ("[A] party who moves for a directed verdict admits for the purpose of testing the motion the facts in evidence and in addition admits every reasonable and proper conclusion based thereon which is favorable to the adverse party." (citation omitted)).

Additionally, we note that these very issues were raised and decided in <u>Dumigan II</u>. See <u>Dumigan II</u>, 325 So. 3d at 113. In <u>Dumigan II</u>, this Court stated that "[t]he issue at summary judgment turned on Mr. Dumigan's ability to prove that [Holmes Regional] administered contaminated heparin to Mr. Dumigan when [it] did not record the lot numbers of the product that it gave to Mr. Dumigan." <u>Id</u>. The issue of whether Dumigan was given contaminated heparin has not changed; furthermore, the alleged impermissible stacking within Dr. Levin's opinion was already raised and addressed in <u>Dumigan II</u>.8 The trial court believed that the analysis was different here because <u>Dumigan II</u> involved summary judgment rather than directed verdict.

The factual inquiry in both types of motions is essentially the same, as the Florida Supreme Court explained when it adopted the new summary judgment standard. See In re Amends. to Fla. R. Civ. P. 1.510, 317 So. 3d 72, 75 (Fla. 2021) ("First, those applying new rule 1.510 must recognize the fundamental similarity between the summary judgment standard and the

⁸ Although the <u>Dumigan II</u> opinion did not directly address the stacking of inferences, that was the primary issue in that appeal, fully briefed and presented at oral argument because the trial court had found that Dr. Levin's testimony lacked a sufficient factual basis. <u>Dumigan II</u> was decided adversely to Holmes Regional. <u>Dumigan II</u>, 325 So. 3d at 112. Had Holmes Regional's stacking of inferences argument prevailed in the prior appeal, the granting of summary judgment in its favor would have been affirmed.

directed verdict standard." (citing <u>Anderson v. Liberty Lobby, Inc.</u>, 477 U.S. 242, 251–52 (1986) ("[T]he inquiry under each is the same: whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law."))). Accordingly, the fact that this Court decided the same issue following the grant of summary judgment does not meaningfully distinguish <u>Dumigan II</u> from the present appeal. ¹⁰

Dumigan next argues that the trial court erred by excluding as irrelevant the testimony of Dr. John McKinney, a cardiac surgeon who worked at Holmes Regional in 2008. However, after reviewing the proffered testimony, we find no abuse of discretion in the trial court's ruling. See Ramirez v. State, 810 So. 2d 836, 853 n.51 (Fla. 2001) ("Rulings on evidentiary matters generally are within the sound discretion of the trial court. Discretion is abused only where no reasonable person would view the matter as the trial court did." (citations omitted)).

⁹ While we recognize that the old Florida summary judgment standard was applied in <u>Dumigan II</u>, under that stringent standard a reversal was even more warranted. Regardless, under either standard the threshold for ending the case was not met.

¹⁰ This is not a circumstance where the evidence presented at trial differs from the facts relied upon at the summary judgment stage.

While Dumigan has also raised the specter of spoliation in the context of an adverse inference jury instruction, see Pub. Health Tr. of Dade Cnty. v. Valcin, 507 So. 2d 596 (Fla. 1987), that issue is moot given our reversal for a new trial. See Kloster Cruise Ltd. v. Segui, 679 So. 2d 10, 12 n.2 (Fla. 3d DCA 1996) (noting that jury instruction argument was moot in light of court's reversal for new trial).

In sum, we reverse the trial court's grant of a directed verdict in favor of Holmes Regional and remand for a new trial. We affirm the trial court's evidentiary ruling regarding Dr. McKinney's testimony, and we decline to address the <u>Valcin</u> jury instruction.

AFFIRMED IN PART, REVERSED IN PART AND REMANDED FOR A NEW TRIAL.

HARRIS and WOZNIAK, JJ., concur.