EFiled: Dec 02 2013 10:10PM EST
Filing ID 54637884
Case Number 392,2013

IN THE SUPREME COURT OF THE STATE OF DELAWARE

NADIV SHAPIRA, M.D. and NADIV SHAPIRA, M.D., LLC, Defendants Below, Cross Appellants, v. CHRISTIANA CARE HEALTH SERVICES, INC., Defendant Below, Appellant / Cross Appellee, and JOHN HOUGHTON and EVELYN HOUGHTON, Plaintiffs Below, Appellees / Cross Appellees.	§	No. 392, 2013 On Appeal from the Superior Court of the State of Delaware, in and for New Castle County, C.A. No. N11C-06-092 MJB

APPELLEES/CROSS APPELLEES JOHN AND EVELYN HOUGHTON'S ANSWERING BRIEF

ASHBY & GEDDES
Randall E. Robbins (#2059)
Carolyn S. Hake (#3839)
500 Delaware Ave., 8th Floor
Wilmington, DE 19801
(302) 654-1888

Counsel for Appellees/Cross-Appellees, Plaintiffs Below John and Evelyn Houghton

Dated: December 2, 2013

TABLE OF CONTENTS

Page

TABLE OF CONTENTS (continued)

Page

TABLE OF CONTENTS (continued)

Page

TABLE OF CITATIONS

Case **Page(s)**

TABLE OF CITATIONS (continued)

Case **Page(s)**

TABLE OF CITATIONS (continued)

Case **Page(s)**

TABLE OF CITATIONS (continued)

Case **Page(s)**

Rules and Statutes

TABLE OF CITATIONS (continued)

Rules and Statutes (continued) **Page(s)**

Other Authority

NATURE AND STAGE OF PROCEEDINGS

This is a civil case against Defendant Christiana Care Health Services, Inc. ("CCHS") and Defendants Nadiv Shapira, M.D. and Nadiv Shapira, M.D., LLC ("Dr. Shapira"), involving alleged medical negligence and medical/administrative negligence arising out of Dr. Shapira's insertion of On-Q catheters manufactured by I-Flow Corp. ("I-Flow") into Plaintiff John Houghton ("Mr. Houghton") to purportedly treat his rib fracture pain in December 2009. Regarding Dr. Shapira, Plaintiffs presented evidence that: (a) Dr. Shapira breached the standard of care inserting the On-Q catheter; (b) Dr. Shapira was an employee, agent or apparent agent of CCHS; and (c) Dr. Shapira breached the standard of care in not disclosing to Mr. Houghton that: (1) he was conducting a study on the safety and efficacy of the On-Q to treat rib fracture pain; (2) the On-Q was experimental and not the standard of care to treat rib fracture pain; (3) he had a business relationship with I-Flow; (4) that he had an option of an epidural; and (5) the procedure had risks. Regarding CCHS, Plaintiffs presented evidence that CCHS was negligent in managing Dr. Shapira's rib fracture study and in approving his "expedited review" application to conduct the study.

On November 14, 2012, following an eight day jury trial, the jury returned its verdict finding that: (a) Dr. Shapira was negligent; (b) Dr. Shapira's negligence proximately caused injury and damages to Plaintiffs; (c) Dr. Shapira was an agent,

apparent agent or employee of CCHS; (d) CCHS was negligent; and (e) CCHS's negligence proximately caused injury and damages to Plaintiffs. The jury awarded $3.75 million in damages to Mr. Houghton and $650,000 for loss of consortium to Mrs. Houghton. The jury apportioned 65% of the liability to Dr. Shapira and 35% to CCHS. After the verdict, citing its position as an "excess insurer", CCHS requested a supplemental jury finding determining how much of the 35% liability assessed to CCHS should be apportioned to CCHS through the conduct of Dr. Castellano (its employee responsible for managing and approving Dr. Shapira's study) and how much should be apportioned to CCHS through its agency, apparent agency or employer relationship with Dr. Shapira. Of the 35%, the jury apportioned 25% to Dr. Castellano and 75% to Dr. Shapira.

On June 27, 2013, the Superior Court awarded Plaintiffs costs, pre-judgment and post-judgment interest, and denied CCHS' motion to substitute the jury's supplemental liability apportionment for their original liability apportionment.

In July 2013, CCHS appealed, and Dr. Shapira cross-appealed, against Plaintiffs, from multiple evidentiary and legal decisions of the Superior Court, claiming that those rulings constitute reversible error. Dr. Shapira also cross-appealed against CCHS from the Superior Court's decision granting CCHS's request for a supplemental jury fault allocation.

This is Plaintiffs' Answering Brief to Defendants' Opening Briefs.

SUMMARY OF ARGUMENT

Plaintiffs respond to CCHS's Summary of Argument as follows:

1. Denied. The informed consent statute was properly interpreted.

2. Denied. The Superior Court did not abuse its discretion.

3. Denied. CCHS waived its right to argue that the Superior Court erred in refusing to reform the verdict and should be estopped from making its argument.

4. Denied. The Superior Court properly awarded Plaintiffs pre-judgment interest, pursuant to 6 *Del. C.* § 2301(d).

5. Denied. The Superior Court's proximate cause instruction was legally accurate.

Plaintiffs respond to Dr. Shapira's Summary of Argument as follows:

1. Denied. *See* Response No. 1 to CCHS's Summary of Argument.

2. Denied. *See* Response No. 2 to CCHS's Summary of Argument.

3. This statement is directed toward CCHS. As such, Plaintiffs take no position on this argument. If Defendants should suggest the Supplemental Verdict Sheet somehow affects the validity of the verdict vis-à-vis Plaintiffs, Plaintiffs respectfully request the right to respond and take a position.

4. Denied. *See* Response No. 4 to CCHS's Summary of Argument.

5. Denied. *See* Response No. 5 to CCHS's Summary of Argument.

COUNTER-STATEMENT OF FACTS

On December 7, 2009, Mr. Houghton, a 72 year old retired pipefitter and plumber, was admitted to CCHS after falling off a ladder while doing plumbing and pipefitting work at one of his nine children's homes. (B455-457; B460-461). He fractured three ribs on the left, none displaced, and his pelvis. (AA478-479; B762-763). The parties agree he did not need surgery. (B452-453). The plan was to treat his pain and discharge him in a few days. (B324 at 35).

Although Plaintiffs' experts testified oral pain medication would have been sufficient to treat Mr. Houghton's rib fracture pain, (B324 at 33-35; B329 at 73-74), on his second day at CCHS, Dr. Shapira, a thoracic surgeon, treated Mr. Houghton's rib fracture pain with an On-Q catheter made by the I-Flow Corporation ("I-Flow"). (AA528-530). Each On-Q catheter has small holes like a garden hose and is surgically inserted over the ribs and is supposed to drain numbing medication over the injured ribs ("On-Q"). Dr. Shapira surgically inserted two On-Q catheters under Mr. Houghton's skin and over his ribs. The On-Q catheters came out one day later, and Dr. Shapira surgically reinserted them. (B452-454; B458-460; B469). This time, one catheter inserted by Dr. Shapira instead of going up and over Mr. Houghton's ribs went down and through his chest wall, diaphragm, into his abdomen, entering his colon at his splenic flexure and exiting at his transverse colon in breach of the standard of care. Dr. Shapira failed

to realize what he did. Two days later, Mr. Houghton underwent the first of several surgeries to save his life, and spent 49 nights recovering in a hospital and rehab facility, instead of a few days. (B764-766; B297 at 11; B298-299 at 13-19; B312 at 111; B834).

During this litigation, Plaintiffs learned that the On-Q was designed and FDA approved for use in surgical wounds to treat post-op pain, and was not the standard of care for rib fracture pain. The standard of care was pain medication and if necessary, an epidural. Plaintiffs also learned Dr. Shapira: (a) was under contract with and being paid by I-Flow to promote the On-Q for this "Off-Label" use by other physicians; (b) was writing articles on his on-going study which he submitted first to I-Flow and then to peer review journals; (c) was required to, but did not disclose to CCHS his business relationship with I-Flow; and (d) was the only physician in Delaware to ever use the On-Q for rib fracture pain.

During this litigation, Plaintiffs learned that CCHS: (a) had knowledge of Dr. Shapira's study; (b) was required to investigate Dr. Shapira's relationship with I-Flow (but did not); and (c) was required to instruct Dr. Shapira to inform patients that the On-Q was not the standard of care, that he was performing a study, and that he was being paid by the On-Q manufacturer.

Only Dr. Shapira Used the On-Q to Treat Rib Fracture Pain

The On-Q is manufactured by I-Flow. Although it is FDA-approved for

treatment of post-operative surgical pain ("On-Label Use"), it has not been approved by the FDA for non-surgical pain relief, such as treating rib fracture pain ("Off-Label Use"). (AA285). In the treatment of post-op surgical pain the surgeon places the On-Q in the open wound, but to treat rib fracture pain, Dr. Shapira inserts the On-Q under the skin and over the ribs using a semi-rigid metal tunneling device. (B473; B475-483). Dr. Shapira testified at his deposition that it was a "blind procedure" because he could not see where he was inserting it, but at trial changed his testimony and was impeached. (B385-386).

Dr. Shapira claimed he approached CCHS in 2004 or 2005 about using the On-Q to treat rib fracture pain, and CCHS trauma surgeons started referring him patients as an alternative to consulting with CCHS's anesthesia department. (B518-519; B534-535; B536; B431).

In large part by July 2009, all Dr. Shapira was doing at CCHS was the On-Q. (B394 at 21:5-10). It was obvious he was trying to start a new career in interventional pain management even though there are physicians who specialize and are board certified in this field, and he is not one. (B394-395 at 21:11-22:1).

It is undisputed that as of 2012, Dr. Shapira was the only physician at CCHS, and in Delaware, to ever use the On-Q for rib fracture pain, despite over 20 surgeons at CCHS who could do it. (B313-314; B331 at 111-112; B412; B413; B417; B438-439; B492, B502; B520-521; B522-524; B531-532, B537, B539-540).

The defendants relied on the CCHS trauma surgeons at trial, but they conceded they were not On-Q experts for rib fracture pain and did not know all its risks. (B311 at 97; B314 at 119; B417-419; B524).

It is an interesting fact that the Defendants claimed the On-Q was the standard of care, but when Dr. Shapira was unavailable patients were treated conventionally. (B520-521; B522-524; B526; B532; B313-314 at 115-116; B440; B413; B531-532; B491-493, B512; B441; B331 at 111-112).

Dr. Shapira's Relationship with I-Flow, the On-Q Manufacturer

In late 2007, Dr. Shapira entered into a contract with I-Flow to join its speaker's bureau, B289-290; B784-785, and paid Dr. Shapira to give presentations on using the On-Q, at CCHS and other hospitals, always with an I-Flow sales person. (B295; B494, B495-498). I-Flow also paid Dr. Shapira to prepare a pamphlet and create a video called "A New Solution for an Age Old Problem: Continuous Percutaneous Intercostal Nerve Block for Pain Relief after Acute Chest Trauma", showing him inserting the On-Q for rib fracture pain. (B774-B777; B290; B387; B414).

In 2009, Dr. Shapira billed I-Flow over $19,000, the majority of which was for "strategy" discussions between August 30 and October 2, 2009 with I-Flow's Marketing Director. (B391-392; B786-797). During these strategy discussions, Dr. Shapira renewed his contract with I-Flow. (B393).

Prior to entering into a contractual relationship with I-Flow, Dr. Shapira used the On-Q for rib fracture pain on a handful of patients in 2005 and 16 patients in 2006 and also in 2007. (B503; B603-760). In 2008, his first year of business with I-Flow, Dr. Shapira increased his usage of the On-Q by 400%, going from 16 times in 2007 to 64 times in 2008, and 58 in 2009. (B503; B603-760).

Dr. Shapira's Database

After executing the I-Flow contract in late 2007, Dr. Shapira created a CCHS database to collect data on how safe and effective the On-Q was for his patients. (B291; B603-760). Per the database, Mr. Houghton was Dr. Shapira's 156th patient. (B405-406; B603-617). In 2008, Dr. Shapira started writing manuscripts based on his growing database. (B503-504; B403).

Dr. Shapira's database and manuscripts were admittedly inaccurate. For example, he understated the number of complications and the number of infections by over 100%. (B404-408). He also misrepresented its effectiveness, for example, claiming it was very effective with Mr. Houghton who nearly died from it. (B406-408).

Dr. Shapira's Manuscripts

Shortly after Mr. Houghton's case in 2009, Dr. Shapira sent three manuscripts to an I-Flow salesperson, then to peer review journals. (B398-400). In one he wrote: "The procedure could be applied in all patients with blunt chest

trauma. None were excluded. *No complications*." (B400-402; B823) (emphasis added). In another, he admitted the gold standard for rib fracture pain is an epidural. (B411; B805). None were published, but Dr. Shapira advertised on his business website that they were. (*Id.*; B314 at 118; B836; B500-501, 51:8-52:19).

Interestingly, CCHS trauma surgeons Dr. Cipolle, Dr. Tinkoff and Dr. Fulda appear on the manuscripts, but they never used it for rib fracture pain. (B844).

CCHS's IRB

CCHS has an Institutional Review Board ("IRB") that must approve studies involving patients. (B366-367). One of the IRB's primary purposes is to protect the rights, safety and welfare of patients who are research subjects. (B347). Before conducting a study or chart review, physicians must seek IRB approval. (B366-367). "Prospective" and "retrospective" studies are treated differently. (B396 at 12; B101 at 49-52). A "prospective" study requires full IRB board approval, whereas a retrospective study may be approved in an "expedited review" by Dr. Castellano, the corporate director of CCHS's IRB. (*Id.*; B36).

Dr. Castellano testified CCHS' expedited review applications should have, but did not ask the physician to disclose any conflicts of interest. (B364-365).

Dr. Shapira's Many On-Q Study Interests After I-Flow Contract

Entering into the I-Flow contract also fueled Dr. Shapira to e-mail the head of CCHS's Department of Surgery in April 2008 that he prepared a randomized

protocol and manuscript comparing rib fracture patients treated with the On-Q to patients treated with pain medication. (B291-292; AA524). Dr. Shapira wanted an objective study, but he never got funding. (B291-292). Dr. Shapira also considered another randomized trial with Dr. Cipolle. (B316 at 127-28).

Dr. Shapira's efforts for I-Flow continued. On September 22, 2009, (2.5 months before Mr. Houghton) Dr. Shapira asked for IRB approval to study and publish on the efficacy of his On-Q use ("Rib Fracture Study"). (B504-507; B780-782). He requested expedited review from Dr. Castellano. (B780-782). Unlike a 2007 IRB application he made with Drs. Fulda and Tinkoff to "retrospectively" review patients he previously treated, Dr. Shapira's September 2009 application does not say "retrospective." (*Compare* B769-777 *with* B779-782).

Dr. Shapira's 2007 IRB application disclosed that he had already disseminated outside of CCHS the results of his on-going study, in violation of CCHS's IRB's policy, yet Dr. Castellano for the IRB inexplicably notified Dr. Shapira on October 6, 2009 that he was approved as principal investigator of his "research protocol" on the use of the On-Q for CCHS rib fracture patients, from September 28, 2009 through September 27, 2010. (B779; B363-364; B508). Dr. Castellano conceded the October 6, 2009 approval gave Dr. Shapira permission to review and analyze data collected on patients treated after the approval date, including Mr. Houghton. (B99 at 35-36).

Dr. Shapira was conducting a Prospective Study

Dr. Shapira incredulously claimed his ongoing data collection was done "retrospectively", but Dr. Giberson, one of CCHS's trauma surgeons, admitted it was a "prospective" study, and, even Dr. Castellano conceded it was a "concurrent" not "retrospective" study. (B528; B98 at 22; B368). Plaintiffs' experts also testified it was "prospective." (B327 at 49-50; B341 at 237-238; B185-186 at 5:7-9:21). Moreover, although Dr. Shapira claimed that he was not conducting research, he included the Rib Fracture Study in the "current research activities" on his CV. (B396-397; B844-845).

Dr. Shapira Seeks IRB Approval to Study the On-Q for Yet Another Use

On April 25, 2008, two days after submitting the Rib Fracture Study application, Dr. Shapira submitted a second application as Principal Investigator to study the On-Q in treating post-op cardiac surgery pain ("Cardiac Study"). B292 (AA480-517). The application stated narcotics was the standard of care and the study would compare patients treated with the On-Q to patients treated with the standard of care. (AA514). In the application, Dr. Shapira did not disclose his business relationship with I-Flow, answering "no" to the conflicts question. (AA516; B389). The IRB approved the study, but required Dr. Shapira, as Principal Investigator, to disclose in the patient consent forms that: (a) he was conducting a study; (b) it was an experiment funded by I-Flow; (c) the On-Q was

not the standard of care; and (d) they did not have to participate, and had the right to be treated with the standard of care. (AA480-488; B292-295).

CCHS had a Conflicts Policy that Dr. Shapira Violated

On October 1, 2009, CCHS revised its policy on conflicts of interest in research. (B579-589; B351). Physicians and investigators were required to disclose financial and professional relationships with product manufacturers to CCHS's Office of Sponsored Programs. (*Id.*). This policy was out of concern for risks to the "integrity of research," and for the "protection of human subjects who participate in research." (B579; B200-201 at 3-5; B348; B352; B354-355). Conflicts were managed: (a) by not allowing the research to go forward; (b) by having someone else obtain consent; or (c) by requiring full disclosure to the patient. (B349-351). Prior to the October 1, 2009 revision, CCHS's policy was substantially the same, except it required physicians to disclose their conflicts to the IRB instead of the Office of Sponsored Programs. (B354-355; B200-201 at 3-6; B202 at 9-11; B203 at 14; B173 at 34-35; B92-93 at 47-49; B113-114 at 32-35).

There is no dispute that Dr. Shapira should have but did not disclose his relationship with I-Flow in the cardiac and rib fracture studies to both CCHS's Office of Sponsored Programs and IRB for his conflict to be managed. (B200-201 at 3-6; B201-202 at 8-12; B203 at 14; B105 at 13-16; B354-356; B357-360; AA516; B352; B353; B474). Plaintiffs' expert Dr. Paynter testified that had

CCHS's IRB (and Dr. Castellano) complied with the standard of care, the IRB would have discovered Dr. Shapira's conflict, and required Dr. Shapira to disclose his relationship with I-Flow to Mr. Houghton. (B185 at 5:7-9:21). Dr. Castellano admitted Dr. Shapira should have been asked if he had a conflict for the Rib Fracture Study, and had he disclosed his conflict, his application would have gone to the full committee. (B364-365). Dr. Shapira admitted he would have informed patients of his conflict if required to do so. (B409).

Defendants Did Not Obtain Mr. Houghton's Informed Consent

On December 7, 2009, one day after Mr. Houghton was admitted, Dr. Bradley, from CCHS's trauma team, requested a consult with Dr. Shapira. B419-420. Mr. Houghton was given CCHS's generic consent forms for the On-Q procedure which did not disclose any risks specific to the procedure, and he testified that Dr. Shapira did not inform him of any or any alternatives. (B458-459; B470-471). Dr. Shapira admitted he did not tell him that he could have an epidural, (B410), and although Dr. Shapira claimed at trial that he did inform Mr. Houghton there was a risk of perforating an organ, (B386-387), that claim is contrary to his deposition testimony and his admission that he did not know it was a risk existed until *after* it happened to Mr. Houghton. (B510-511 at 80:17-81:1; B109-110 at 154-157). It was undisputed that Dr. Shapira did not tell Mr. Houghton of his relationship with I-Flow or that he was collecting data to study the

On-Q. (B458; B485-486; B487; B488).

Mr. Houghton testified that he would not have consented to the procedure had he known that: (a) Dr. Shapira had a business relationship with I-Flow; (b) Dr. Shapira was studying the On-Q's safety and effectiveness for treating rib fracture pain; (c) the On-Q was not the standard of care; (d) there were risks such as perforation; and (e) there were alternatives to the procedure. (B458-459; B468).

Plaintiffs' experts were not the only physicians to testify the standard of care required that Dr. Shapira disclose his business relationship with I-Flow to Mr. Houghton. (B327-328 at 51-53; B341-342; B185-186 at 5:7-9:21). One defense expert said it is "better practice" to disclose conflicts, (B375), but the standard of care only requires it when patients are part of a research study. (B177 at 95-96). Several CCHS physicians testified patients had a right to know of Dr. Shapira's relationship with I-Flow. (B315-316 at 124-126, B317 at 143; B435-437; B525).

Of significance is that Dr. Bradley, the CCHS trauma surgeon who ordered the consult with Dr. Shapira, testified that, had he known about Dr. Shapira's business relationship with I-Flow, he would *not* have either referred Mr. Houghton to Dr. Shapira or allowed him to insert the On-Q. (B421-422, B424-427). Dr. Bradley would have instead consulted his colleagues about contacting anesthesia. (B427). CCHS's trauma department head, Dr. Fulda, would have respected Dr. Bradley's decision. (B532-533).

Dr. Shapira's Numerous Breaches in the Standard of Care

Plaintiffs' experts testified that Dr. Shapira breached the standard of care when he pushed the On-Q catheter through Mr. Houghton's chest wall, diaphragm, splenic flexure, and mid-transverse colon, which Dr. Shapira admitted as well. (B326 at 42-43; B328 at 53; B340 at 233-234, B342 at 241-242; B389-390).

Plaintiffs' experts Dr. Gudin and Dr. Streisand also testified that: (a) Dr. Shapira's use of the On-Q to treat Mr. Houghton was experimental and not the standard of care; (b) the standard of care for treating rib fracture pain was an epidural; and (c) Dr. Shapira breached the standard of care by not informing Mr. Houghton of this and offering him an epidural. (B319-320 at 15-20; B322-323 at 27-28; B327-328 at 51-53; B340 at 234-236; B341-342 at 240-41). In testifying that it was experimental and not the standard of care, Plaintiffs' experts relied, *inter alia*, on the fact that: (a) there were only a handful of other physicians or hospitals *in the country* that used the On-Q to treat rib fracture pain, (B322-323 at 28-29; B325 at 39; B334-335 at 167-169; B343 at 263); (b) no one did it the same, (B325 at 37-39; B330 at 90-92; B333 at 161-163; B410-411; B371; B378-379; B446-448); (c) the procedure was still being studied at other hospitals and was referred to as "experimental," (B322 at 25-27; B142-145; B147-151); (d) a study being performed in April 2009 at Cooper Hospital clearly stated the standard of care was not the On-Q, (B147-151; B509); (e) there was no billing code because it

was so new, (B411-412; B376-377; B826-829); (f) the pamphlet Dr. Shapira gave Mr. Houghton was for post-op pain, not rib fractures, (B472; B590-602); and (g) there were no peer review articles about the On-Q being safe or effective for rib fracture pain. (B321 at 24).

Dr. Shapira's Video Contradicted His Defense

In 2012, three years after perforating Mr. Houghton's intestines, Dr. Shapira put on the internet a video showing him performing the On-Q insertion. (B386). In the video, Dr. Shapira states the procedure is "safe and simple" and mentions no risk of perforation. (B382-384; B386). Dr. Shapira admitted the video is misleading. (B388-389). CCHS required Dr. Shapira to take it off the internet upon learning of its existence during the litigation. (B389).

Since Dr. Shapira perforated Mr. Houghton's colon, Defendants were forced to claim perforation was a known risk and thus not a breach, as long as the patient was so informed. (B372; B336 at 185). This defense became somewhat contorted when Dr. Shapira testified he did not know perforation was a risk until he did it to Mr. Houghton. (B384). Dr. Shapira, himself, and defense expert Dr. Block admitted that if Dr. Shapira told Mr. Houghton what he put on the internet, then he breached the standard. (B383; B373-374).

ARGUMENT

I. THE TRIAL COURT PROPERLY FOUND THAT EVIDENCE OF DR. SHAPIRA'S BUSINESS RELATIONSHIP WITH I-FLOW WAS RELEVANT TO PLAINTIFFS' INFORMED CONSENT CLAIMS.

A. Question Presented

Whether it was proper for the jury to consider that Dr. Shapira failed to inform Plaintiffs that he had a financial and professional relationship with I-Flow, the company who markets the On-Q system, in determining whether Defendants breached their obligations to obtain Mr. Houghton's informed consent?

B. Standard and Scope of Review

This Court reviews statutory construction rulings *de novo*. *Leatherbury v. Greenspun*, 2007 WL 4216850 (Del.).

C. Merits of the Argument

Defendants incorrectly claim that the Trial Court found Dr. Shapira was *required* to disclose his financial relationship with I-Flow and that he was on its Speaker's Bureau to Mr. Houghton as part of the informed consent process. On the contrary, it is the Defendants who claim, as a matter of law, Dr. Shapira was *not* required to disclose this information to Mr. Houghton. The Trial Court simply held that the financial and professional relationship between Dr. Shapira and I-Flow, under this Court's decision in *Barriocanal v. Gibbs*, 697 A.2d 1169, 1172-73 (Del. 1997), *should be something that the jury, as the finder of fact, should be able*

to consider in deciding informed consent. (A376-A378). Thus, the jury was permitted to consider that: (a) Dr. Shapira was under contract with I-Flow to be on its Speaker's Bureau, and was paid over $19,000 in 2009 – the year of Mr. Houghton's procedure – to participate in strategy discussions with I-Flow's Marketing Director to promote this Off-Label use; (b) Dr. Shapira asked I-Flow to circulate a video he made, with I-Flow's money; (c) within months of entering into a contractual relationship with I-Flow, Dr. Shapira created a database on his On-Q patients to write research papers on product's purported safety and efficacy; (d) the number of rib fracture patients he treated with I-Flow's product immediately increased by 3.5 to 4 fold after he entered into the I-Flow contract; and (f) before submitting his research papers to peer review journals, he sent them to I-Flow for input. (A398-A399). The ruling was proper.

Defendants claim §§ 6801(6) and 6852 of Delaware's informed consent statutes specifically delineate the medical information that a physician is required to provide to a patient. According to Defendants, there is no mention that a physician must disclose financial conflicts of interest, and if the General Assembly wanted to include it, they would have. Defendants' reading of Delaware's statutes and this Court's decision in *Barriocanal* is too narrow and ignores their concession that disclosure is required if Dr. Shapira was performing a study.

Read together, Delaware's informed consent statutes require disclosure "of

the nature of the proposed procedure or treatment and of the risks and alternatives to treatment or diagnosis which a reasonable patient would consider material to the decision whether or not to undergo the treatment or diagnosis," as well as "information regarding [a nonemergency] . . . treatment, procedure or surgery to the extent customarily given to patients." 18 *Del. C.* §§ 6852; 6801(6). In *Barriocanal*, this Court interpreted these statutes broadly holding it was reversible error to exclude an expert's opinion that failure to disclose information specific to *the physician* performing the treatment, procedure or surgery fell below the standard of care required to obtain informed consent. 697 A.2d at 1172-73.

In *Barriocanal*, plaintiff's expert opined that the defendant surgeon was required to disclose "that he had not performed aneurysm surgery recently [including that he had no such operations in the prior year], that [CCHS] would be thinly staffed the day of surgery since it was Easter Sunday, and that there were other hospitals in nearby cities that specialized in this type of surgery" in order to obtain the patient's informed consent. *Id.* at 1170. The Superior Court excluded this evidence holding it did not comply with 18 *Del. C.* § 6852(a)(2). *Id.*

On appeal, this Court reversed and noted that "[i]n Delaware, informed consent in the context of medical malpractice is defined by statute":

> The patient must demonstrate that the health care provider failed to supply information "customarily given" by other "licensed health care providers with similar training and/or experience in the same or similar health care communities as that of the defendant at the time of

the treatment, procedure or surgery."

Id. at 1171-72 (quoting 18 *Del. C.* § 6852(a)(2)). The Supreme Court then looked to the definition of "informed consent" in 18 *Del. C.* § 6801(6):

> (6) "Informed consent" means the consent of a patient to the performance of health care services by a health care provider given after the health care provider has informed the patient, to an extent reasonably comprehensible to general lay understanding, of the nature of the proposal procedure or treatment and *of the risks and alternatives to treatment or diagnosis which a reasonable patient would consider material to the decision whether or not to undergo the treatment or diagnosis.*[1]

Id. at 1172 (emphasis in original). Looking at these statutory provisions together, this Court held "[t]he plain language of section 6852 requires a plaintiff to produce both evidence of the standard of care (i.e. 'information regarding [the relevant] treatment, procedure or surgery to the extent customarily given to patients, or other persons authorized to give consent for patients, by other licensed health care providers with similar training and/or experience in the same or similar health care communities as that of the defendant at the time of the treatment, procedure or surgery') and evidence of whether the health care provider met that standard (i.e., the information that the health care provider actually supplied at the time of the treatment, procedure or surgery)." *Id.*[2]

---

[1] The definition of "informed consent" in *Barriocanal* has not changed. 18 *Del. C.* § 6801(6).

[2] In conjunction with Delaware's change to a national standard in July 1998, the phrase in section 6852(a)(2) "by other licensed health care providers with similar training and/or experience in the same or similar health care communities as that of the defendant at the time of the treatment, procedure or surgery" was changed to "by other licensed health care providers in

This Court noted that plaintiffs' expert was prepared to testify that it was the "standard of care" for a surgeon to provide a patient these types of information (*i.e.*, the surgeon's experience with aneurysm surgery, the composition of the surgical team, and the availability of alternate treatment centers). Thus, plaintiffs' proffered testimony "tended to show that [the surgeon's] failure to inform his patient of his lack of recent aneurysm surgery, of the difference in hospital staffing on a holiday, and of the option of transfer to a teaching institution, fell below the applicable standard of care required to obtain informed consent." *Id.* This Court ruled this "qualification" information was relevant to the issue of informed consent and its exclusion was reversible error because it went to "the very heart" of plaintiffs' case and "might well have affected the outcome" of the trial. *Id.*

Barriocanal emphasized that its interpretation "comports with the capabilities of the jury system and of the adversary system generally." *Id.* at 1173. "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Id.*

Barriocanal held "qualification" evidence, including how many times a surgeon has performed a particular procedure, and how large a medical staff will

---

the same or similar field of medicine as the defendant." This Court's ruling in *Barriocanal* does not depend on whether a national or local standard of care is used.

be available on a holiday, was admissible, even though Delaware's informed consent statutes do not specifically delineate "qualification" or staffing evidence. Defendants weakly attempt to distinguish *Barriocanal* by claiming the qualification/staffing evidence in *Barriocanal* was "medical", but Dr. Shapira's conflicts of interest are not "medical" as a matter of law.

Indeed, the fact this information is "medical" is illustrated by Defendants' admission that Dr. Shapira's business relationship with I-Flow should have been fully disclosed to CCHS and the IRB in accordance with CCHS's conflicts policies because conflicts of interest situations introduce a "material risk" to the patient. *See, supra*, pp. 12-13. In addition, several CCHS physicians testified a patient has a right to know this information and Dr. Shapira admitted he would have disclosed the information to patients, if the IRB required it. *See, supra*, p. 14.

This case, like *Barriocanal*, involves: (1) a failure of the Defendants to disclose risks and alternatives to a treatment, procedure or surgery which a reasonable patient would consider material to the decision whether or not to undergo the treatment, procedure or surgery, *see* 18 *Del. C.* § 6801(6), and (2) the undisclosed "risk" information regarding such treatment, procedure or surgery is customarily given to patients. *See* 18 *Del. C.* § 6852(a)(2).

With regard to undisclosed "risks and alternatives," *Barriocanal* recognized *provider* specific information, like a physician's "qualifications" or experience, is

relevant because it may add to or influence the risks inherent in a procedure and may suggest to a patient that a viable and possibly preferable alternative is having it performed by another provider or declining to have it done. Like a surgeon who lacks experience or "qualifications" could add to or influence the risks a reasonable person would consider material, so too could a surgeon, like Dr. Shapira, who has a conflict of interest because of his financial relationship and desire to be published that may cause him to (a) increase the frequency that he uses the product on patients by 400% and (b) not disclose to patients its risks and alternatives.

There was also a sufficient factual basis for the jury to determine that a reasonable person in the Plaintiffs' position would find this information material to their decision to have the procedure performed by Dr. Shapira. In deciding what a "reasonable patient" would have done and whether the undisclosed information was "material", the jury heard Dr. Bradley, the referring physician, testify just how material this information was to him. Specifically, Dr. Bradley would not have ordered the consult with Dr. Shapira had he known about Dr. Shapira's business relationship with I-Flow. *See, supra*, p. 14. Dr. Bradley's reaction is conclusive evidence that he considered Dr. Shapira's relationship with I-Flow to be "medical" inasmuch as he would not have referred Mr. Houghton to Dr. Shapira, and thus Mr. Houghton would not have been treated with the On-Q since only Dr. Shapira used it. In addition, Plaintiffs' expert testified Mr. Houghton likely only needed oral

pain medication. (B324 at 33-35; B329 at 73-74).

In Delaware, the standard of care to which a health care provider is to be held is a question of fact for the jury to determine based on expert testimony. *DiFilippo v. Preston*, 173 A.2d 333, 336 (Del. 1961); *Barriocanal*, 697 A.2d at 1172-73. Here, as in *Barriocanal*, Plaintiffs offered expert testimony that the undisclosed information was information "customarily given to patients" by "other licensed health care providers in the same or similar field of medicine" as Defendants to obtain informed consent and that Defendants' failure to inform Plaintiffs of such information fell below the standard of care. Specifically, Plaintiffs' experts Dr. Gudin, Dr. Paynter and Dr. Streisand testified that, regardless of whether it was a "research study," under the standard of care, to obtain Mr. Houghton's informed consent for using I-Flow's On-Q catheter, Defendants were required to disclose Dr. Shapira's financial and professional relationship with I-Flow to promote the On-Q.

CCHS's *own* witnesses, admitted a patient has a right to know of their physician's potential or real conflicts of interest, regardless of whether they are part of a study. *See, supra*, p. 14.

CCHS's conflicts of interest policies also acknowledge that the *standard of care* requires the disclosure, evaluation and management of a physician's financial and professional relationship with a product's manufacturer. *See Suarez v. Wilm.*

Med. Ctr., Inc., 533 A.2d 1249, 1250-51 (Del. Super. Ct. 1987) (defense expert testified that the applicable standard of care is embodied in the medical center's policy manual and the defendant conformed with this standard of care); *Steiner v. Killeen*, 1999 WL 1223780, at *1 (Del. Super. Ct.) ("The jury found that Beebe was negligent; it breached its policy concerning the sponge count.").

It is also noteworthy that in order for the jury to find CCHS independently negligent, the jury had to first find that Dr. Shapira was conducting a "research study". CCHS's IRB is charged with managing conflicts in research studies, and Plaintiffs claimed that CCHS's independent negligence was its IRB Director Dr. Castellano's failure to require Dr. Shapira to disclose his conflict to Mr. Houghton. Defendants' expert Dr. Block testified it was the standard of care to tell patients in a research study that the physician had a business relationship with the product's manufacturer. (B177). And, CCHS's counsel conceded this point if Dr. Shapira was conducting a research study. (B275). Defendants' argument that Dr. Shapira did not have to disclose his conflict because he was not performing a research study ignores that the jury decided Dr. Shapira was performing a research study, thereby rendering Defendants' argument meaningless.

This case underscores why this type of information is medical under *Barriocanal* and Delaware's informed consent statutes. Once Dr. Shapira started a business relationship with I-Flow, suddenly 400% more patients were appropriate

candidates for the On-Q. Common sense and logic make it clear that after Dr. Shapira entered into the business relationship with I-Flow and expressed a desire to study their product and be published, he would have motivation to maximize the number of patients in his study so that he would have a statistically significant population base by not telling them of the risks and alternatives. It should come as no surprise that his database and manuscripts are inaccurate. This same person who did not accurately state the safety and efficacy of this product is also misrepresenting his credentials in his CV and website.[3] That is why the standard of care requires oversight of physicians such as Dr. Shapira and the information he was required to disclose was "medical" under *Barriocanal* and Delaware's informed consent statutes.

Various professional medical organizations, as well as federal government regulations pertaining to human subject research, also support Plaintiffs' informed consent claim. For example, the American Medical Association ("AMA"), of which Dr. Shapira is a member, (B840), requires disclosure of any significant

[3] Dr. Banbury, the head of CCHS's cardiac department called Dr. Shapira's CV "misleading" because Dr. Shapira claimed that he was an "attending surgeon" in CCHS's cardiac surgery department when he was actually hired by that department to serve in a public relations type position to help develop a heart rhythm center and was not seeing patients clinically. (B839; B338 at 214-216). Dr. Shapira also claimed on his website that he was instrumental in developing CCHS's arrhythmia center, despite the fact that he was terminated from his public relations position with the cardiac surgery department because it did not work out.[3] (B836; B499:14-19; B339 at 221-222). When confronted with this misrepresentation, Dr. Shapira explained that "it all depends on the [internet] reader" and then said it can be read "in a very sarcastic way." (B499 at 49:14-19).

financial interest. AMA Opinion 8.0315(6) – Managing Conflicts of Interest in the Conduct of Clinical Trials. The AMA also advocates patients are entitled "to be advised of potential conflicts of interest that their physicians might have." AMA Opinion 10.01(1) – Fundamental Elements of the Patient-Physician Relationship. Finally, the AMA requires that conflicts must be resolved to the patient's benefit. AMA Opinion 8.03 – Conflicts of Interest: Guidelines.

Similarly, federal regulations require clinical investigators conducting experimental treatment to disclose any *benefits* that might be gained *by someone other than the patient* as a result of the research in order to obtain the patient's informed consent. 45 C.F.R. § 46.116(a); 21 C.F.R. § 50.25(a). CCHS's IRB also may require additional information be given to research subjects to protect their rights or welfare, consistent with CCHS's policy requiring the management of conflicts. 45 C.F.R. § 46.109(b); 21 C.F.R. § 56.109(b). (B350-351).[4]

Although these guidelines and regulations are not controlling,[5] they do provide additional evidence on the standard of care when it comes to whether conflicts should be disclosed. *Duphily v. Del. Elec. Coop., Inc.*, 662 A.2d 821, 836 (Del. 1995) (federal safety regulations violation may be evidence of negligence); *Whitlock v. Duke Univ.*, 637 F. Supp. 1463, 1475 (M.D.N.C. 1986), *aff'd*, 829 F.2d

[4] CCHS concedes that the IRB abides by 45 C.F.R. §§ 46.109(b), 46.116(a) and 21 C.F.R. §§ 50.25(a), 56.109(b). (B123 at No.2).

1340 (4th Cir. 1987) (recognizing federal regulations as the standard of care).

Finally, the foreign cases Defendants rely upon are inapposite. *Brannon v. Northwest Permanente*, 2006 WL 2794881 (W.D. Wash. 2006), and *Beardon v. Hamby*, 608 N.E.2d 282 (Ill. App. Ct. 1992), did not involve informed consent, let alone a ruling that a physician's relationship with a manufacturer was irrelevant to informed consent. *Otis-Wisher v. Fletcher Allen Health Care, Inc.*, 2013 WL 3214714 (D. Vt.), and *Wright v. Jeckle*, 16 P.3d 1268, 1271 (Wash. Ct. App. 2001), are also not helpful because, unlike Vermont and Washington, Delaware recognized in *Barriocanal* that *provider* specific information, such as "qualifications" or experience, is relevant to informed consent because it may add to or influence the risks inherent in a particular procedure, surgery or treatment.[6] *Otis-Wisher* and *Wright* are also distinguishable on other grounds.

For example, in *Otis-Wisher*, although the court held that the financial and developmental relationship between plaintiff's physician and the medical device manufacturer was not relevant to plaintiff's lack of consent claim, the court held that that relationship may be relevant to plaintiff's lack of consent claim regarding her doctor's failure to inform her that the device was being used off-label. 2013

---

[5] The federal regulations explicitly state that the informed consent requirements in the regulations do not preempt any applicable state laws imposing additional informed consent requirements. 45 C.F.R. § 46.116(e); 21 C.F.R. § 50.25(d).

[6] Unlike Delaware, Washington courts have declined to interpret their state's informed consent statutes broadly as requiring disclosure of a physician's qualifications and experience. *See Whiteside v. Lukson*, 947 P.2d 1263 (Wash. Ct. App. 1997). Vermont has not ruled on the issue.

WL 3214714, at *8. Here, Defendants should have informed Mr. Houghton of the experimental nature (*i.e.*, the Off-Label use) of the On-Q to treat rib fracture pain.

Wright did not address whether a physician's business relationship with a drug manufacturer was relevant to informed consent. In *Wright*, patients brought a Consumer Protection Act ("CPA") class action against a physician advertising a weight loss program and drug that could be purchased only at the physician's office. The court found that plaintiffs had a valid CPA claim because the physician's business of selling diet drugs was not the practice of medicine (*i.e.*, health care) under Washington's informed consent statutes. 16 P.3d at 1271. Here, Dr. Shapira was practicing medicine, and no one claims otherwise.

Although, this Court need not look beyond *Barriocanal*, it is noteworthy that other jurisdictions recognize that a physician's failure to disclose his financial interest was a violation of informed consent because it might affect the physician's medical judgment. *Moore v. Regents of Univ. of Calif.*, 793 P.2d 479 (Cal. 1990); *Darke v. Isner*, 2004 WL 1325635 (Mass. Super.).

Defendants' remaining arguments are red herrings. First, they claim requiring a physician to disclose conflicts would lead to impractical results. At all times, CCHS had a policy defining what constitutes a conflict of interest between a physician and product manufacturer that has to be disclosed, evaluated and managed. (*See, e.g.*, B579-589). There is no dispute that Dr. Shapira met the

threshold and should have disclosed his conflict for the conflict to be managed.

The second red herring is raised by Dr. Shapira. Specifically, Dr. Shapira claims that the Trial Court's erroneous interpretation of Delaware's informed consent statutes had "a significant impact on what the jury heard." According to Dr. Shapira, "highly prejudicial" testimony about the fact that Dr. Shapira received compensation from I-Flow painted a picture that Dr. Shapira put money considerations before patient well being. This claim is without merit.

The alleged "damaging" testimony came from Dr. Shapira and Dr. Bradley and was not unduly prejudicial, and was not objected to. Dr. Shapira admitted that no one does for free what he did for I-Flow, and Dr. Bradley testified what Dr. Shapira did put money in his pocket and that is why it was a conflict. No witness testified as to Dr. Shapira's motivations. (B555). According to Dr. Shapira, the "most damaging" testimony was Dr. Bradley's, but Dr. Shapira chose not to object. It is not hard to figure out why he did not object, Dr. Bradley gave this "most damaging" testimony in response to CCHS's questions:

> CCHS's Counsel - Q: You were asked some questions [at your deposition] about . . . "Should Dr. Shapira have shared with you that he was receiving compensation from I-Flow, since you were asked to order consults with Dr. Shapira?" Your answer was, "Yes," correct?
>
> Dr. Bradley - A: As it states, yes. . . .
>
> CCHS's Counsel - Q: [A]nd when you were . . . asked that he was receiving compensation, what did you assume?

Dr. Bradley - A: *I assumed, as one might with compensation, that's money in your back pocket.* That is different from reimbursement.

(B423 at 73:18-23).

II. THE TRIAL COURT DID NOT ABUSE ITS DISCRETION IN RULING ON EVIDENTIARY ISSUES.

A. Question Presented

Whether the Trial Court properly ruled that: (a) Plaintiffs were permitted to present evidence that the use of the On-Q procedure for rib fracture patients was experimental, and Defendants were permitted to present evidence that it was not experimental; (b) CCHS trauma surgeons were permitted to testify that the On-Q procedure for rib fracture patients "was the standard course of treatment" at CCHS, but, since they were not expert witnesses, they were not permitted to give opinion testimony that it was the "standard of care" or that its use was not "experimental"; and (c) evidence regarding Dr. Shapira's data collection was admissible?

B. Standard and Scope of Review

This Court reviews evidentiary rulings for abuse of discretion. *Firestone Tire & Rubber Co. v. Adams*, 541 A.2d 567, 570 (Del. 1988). If the Court finds an abuse of discretion in admitting or excluding evidence, it then determines whether the error was so significantly prejudicial as to deny the appellant a fair trial. *Id.*

C. Merits of the Argument

1. The Trial Court did not abuse its discretion in ruling it was a jury question whether the procedure was experimental.

Defendants claim it was "critical" that Dr. Shapira present evidence the On-Q was *not* experimental. They ignore the Trial Court's ruling that it was a jury

question, and that *both* Plaintiffs *and Defendants* could present evidence on this issue. Specifically, the Trial Court ruled:

> I think it is a jury question. . . . I think opinions can be offered about that by experts based upon if they have proper foundation. You know, [Plaintiffs are] going to contend it is, and [Defendants are] going to contend it isn't. I mean, by saying it's the standard of care, [Defendants are] saying it's not experimental. The bottom line is that your argument, in my view, begs the question. I mean, I think that they have to be permitted to present that testimony, just as you want to present testimony that it was the standard of care.

(B266-267). The Trial Court's ruling was proper and not an abuse of discretion.

Defendants conceded that the question of whether the On-Q was experimental would normally be a "battle of the experts." (B83). However, they argue that since trauma surgeons at CCHS consulted Dr. Shapira, this meant it was not experimental at CCHS. Defendants ignore it was being studied at CCHS because Dr. Shapira was under contract with the manufacturer, it was being studied elsewhere, and the few places where it was used, every physician did it differently because it was so new and so experimental. There is something strange about the fact that 20 other physicians at CCHS could have used it, but chose not to, and when Dr. Shapira was unavailable patients did not get it.

Also, Defendants' suggestion that the On-Q for rib fracture pain is not experimental at CCHS because it is the only modality used is factually incorrect. Indeed, Defendants withdrew their motion *in limine* on this very issue because Dr. Shapira testified that epidurals are still used at CCHS to treat rib fracture pain.

(B271-274; B105 at 14; B109 at 152). Both the trauma surgeon at CCHS who ordered Mr. Houghton's consult with Dr. Shapira and the head of CCHS's trauma department also acknowledged that an epidural was still available at CCHS to treat Mr. Houghton. (B156-157 at 24-26; B158 at 43; B159-160 at 72-73; B91 at 20; B94 at 55; B340 at 236).

Plaintiffs also presented evidence that using the On-Q to treat rib fracture pain is not the care "ordinarily employed" outside of CCHS. Indeed, Defendants only identified a handful of physicians or hospitals *in the country* that use it.

Whether the procedure was experimental was a jury question. The standard of care is not based upon what *one* physician does. *See* 18 *Del. C.* § 6801(7) (standard of care requires use of "degree of skill and care *ordinarily* employed in the same or similar field of medicine as defendant."). (B322 at 28).

2. The Trial Court did not abuse its discretion in limiting the number of defense expert witnesses.

Plaintiffs identified three expert witnesses to testify that Dr. Shapira's use of the On-Q for rib fracture pain was experimental and not the standard of care. In comparison, Defendants identified nine so called "expert" witnesses to testify it was not experimental and was the standard of care. (B11; B50-B81).

Plaintiffs moved *in limine* under D.R.E. 403 to prohibit Defendants from calling all nine witnesses to offer cumulative, identical expert testimony and requested that Defendants be limited to four experts. The Trial Court noted that

certain of Defendants' purported "expert witnesses" were not, in fact, experts. Specifically, four of the nine "experts", Dr. Giberson, Dr. Fulda, Dr. Cipolle and Dr. Tinkoff, were CCHS trauma surgeons. Although identified as both fact and expert witnesses, Defendants admitted these four surgeons were not retained experts and that their thoughts and opinions as of 2009 are in the nature of fact and not "expert" testimony. (B63-71; B260-262; AA108; Dr. Shapira's O.B. pp. 19-20). Defendants admitted that "the only reason these CCHS trauma surgeons were identified as 'experts' was so Plaintiffs could not claim surprise." *Id.*

The Trial Court limited defendants to four experts under D.R.E. 403 because more would be cumulative and redundant, and also ruled the CCHS trauma surgeons could testify that the On-Q for rib fracture patients "was the standard course of treatment" at CCHS, but since they were not expert witnesses, they could not give expert opinion testimony that it was the "standard of care" or that it was not "experimental." (B262-265). Both rulings were not an abuse of discretion.

Defendants claim that the CCHS trauma surgeons were proffered as "actors/viewers", and as such, should have been treated "as an ordinary witness" per *Palmer v. Dolman*, 1986 WL 4877 (Del. Super. Ct.). *Palmer* does not support these claims. *Palmer* held that Rule 26(b)(4), governing discovery of facts known and opinions held by experts, does not apply to treating physicians' opinions that were not developed in anticipation of litigation because that rule only governs

where "the facts and opinions possessed by the expert were obtained for the specific purpose of preparing for the litigation in question." *Id.*, at *1-2. In holding that a treating physician is like an "ordinary witness", the court did not hold that the witness could express an opinion on something outside their expertise. *Id.* Here, the trauma surgeons did not perform the procedure, were not aware of all the risks, and did not consider themselves experts on the standard of care. *See, supra,* pp. 6-7.

In addition, there was no undue prejudice because the CCHS trauma surgeons were permitted to testify that the On-Q "was the standard course of treatment" at CCHS. Contrary to Defendants' claim, this was not an opinion, but factual in nature. Furthermore, Dr. Shapira as well as three defense experts, Drs. Gross, Block and Smith, all testified it was the standard of care. (B442; B443-444; B445; B369-370; B372; B332 at 150-152; B337 at 198-200).

3. The Trial Court did not abuse its discretion in permitting Plaintiffs' experts to refer to Dr. Shapira's data collection as evidence the procedure was experimental.

Starting in early 2008, after joining I-Flow's Speaker's Bureau, Dr. Shapira collected data on every rib fracture patient he treated with the On-Q, up to and including Mr. Houghton, and increased the frequency with which he treated rib fracture patients with the On-Q by 3.5 to 4 fold. Nonetheless, Defendants sought to preclude Plaintiffs' experts from testifying that this data, which Dr. Shapira was

collecting for his manuscripts and sharing with I-Flow, was evidence the On-Q was experimental. Defendants argued that "if something is experimental, it is undisputed that it has to be done under the auspices of the [IRB] at [CCHS]," and because the IRB head (Dr. Castellano) testified that Dr. Shapira's data collection was not evidence of an experimental use, no testimony to the contrary should be permitted. (B85-B86). The Trial Court ruled that experts testifying on whether the procedure was experimental were permitted to refer to Dr. Shapira's data collection as a basis for their opinion. (B267-270).

The court recognized that Defendants' argument is circular. Plaintiffs alleged that *both* Dr. Shapira and CCHS's IRB were negligent. In addition to claiming that Dr. Shapira failed to disclose his ties to I-Flow and the true nature of his experiment to CCHS's IRB and Mr. Houghton, Plaintiffs alleged that CCHS was negligent in approving Dr. Shapira's "expedited review" application and in not investigating his relationship with I-Flow.

Moreover, Defendants' argument is factually incorrect. Dr. Castellano testified that Dr. Shapira's project turned into a "research design protocol" and became a "research" study, which did require IRB approval. (B96 at 10-11; B361-364). According to Dr. Castellano, whether Dr. Shapira was conducting a retrospective "performance improvement data collection," which does not require IRB approval, or a prospective "research" study which does require IRB approval,

is determined by Dr. Shapira's *intent* in collecting data. (B102 at 58; B363).

Dr. Castellano conceded that "projects can turn into research projects when there is an intent to publish, an intent to disseminate generalizable information." (B100 at 47; B363-364). Dr. Castellano also conceded that he could not testify as to Dr. Shapira's intent, which was a question for the jury. (B102 at 60; B133 at 26:18; B134 at 33:11; B555).

Dr. Giberson, a CCHS trauma surgeon, admitted that Dr. Shapira was doing a "prospective" study, and Dr. Castellano, himself, conceded that Dr. Shapira was conducting a "concurrent" study. (B528; B98 at 22). Dr. Shapira started disseminating his data in 2008, which according to Dr. Castellano's testimony, changed his "performance improvement" to a "research study" requiring IRB approval. (B362-364; B100 at 47-48).

The Trial Court properly permitted Plaintiffs' experts to rely in part upon the fact that Dr. Shapira was collecting data on his rib fracture patients.

III. THE TRIAL COURT'S DECISION GRANTING PLAINTIFFS' PRE-JUDGMENT INTEREST WAS CORRECT.

A. Question Presented

Did the Trial Court err by awarding Plaintiffs' pre-judgment interest, pursuant to 6 *Del. C.* § 2301(d), where both Defendants chose not to accept identical, written settlement demands made by Plaintiffs in the amounts of $1.45 million, which were made more than 30 days prior to the date listed for "Trial" in the Scheduling Order, were valid for 30 days, and were less than the $4.4 million judgment entered against the Defendants jointly and severally?

B. Standard and Scope of Review

This Court reviews statutory construction rulings *de novo*. *State Farm Mut. Auto. Ins. Co. v. Enrique*, 16 A.2d 938, 2011 WL 1004604, at *2 (Del.).

C. Merits of the Argument

1. Plaintiffs' settlement demands satisfied 6 *Del. C.* § 2301(d).

Defendants do not dispute that: (1) this is a tort action; (2) prior to trial, Plaintiffs made identical settlement offers to Defendants; (3) the offers were valid for 30 days; (4) the offers were rejected; and (5) Plaintiffs' settlement offer to Dr. Shapira, and Plaintiffs' separate settlement offer to CCHS, were each for an amount less than the amount of the judgment entered against Dr. Shapira and CCHS jointly and severally. However, Defendants argue that Plaintiffs are not entitled to pre-judgment interest under section 2301(d) because they claim the

statute requires that Plaintiffs' offers had to be valid for a minimum of 30 days before "trial" and they claim "trial" in this case began on October 24th – the first day of "*jury selection*"– making Plaintiffs' September 26th offers two days too late. The Trial Court properly rejected Defendants' argument.

a. Plaintiffs' settlement demands were made "prior to trial" and were "valid for a minimum of 30 days".

Section 2301(d) requires: (1) a written demand made by a plaintiff to a defendant *prior to trial* to settle a tort action; (2) the demand, in fact, remains open for 30 days; and (3) the jury must award plaintiff more than the demand. The statute is clear, unambiguous and without qualification. As the Trial Court found, there is no requirement in the statute that the plaintiff *make* the demand more than 30 days prior to trial. Rather, the plain language of § 2301(d) only requires that a written demand be made "prior to trial" and be "valid for a minimum of 30 days."

Moreover, there is no support in the case law that section 2301(d) requires a demand be made more than 30 days prior to trial. Delaware cases have only noted that the statute requires the demand to remain open for at least 30 days, none have held *the demand be made* more than 30 days prior to trial.

b. Plaintiffs' settlement demands were made more than 30 days prior to when Judge Brady called the proceedings to order and commenced hearing the case.

Moreover, even if the statute required that a demand be made 30 days "prior to trial," Plaintiffs' demands were timely since they were made on September 26,

2012 – more than 30 days before trial began on October 31, 2012. Defendants' argument that "trial" begins at the *jury selection stage* as opposed to when the trial judge actually calls the proceedings to order and commences hearing the case (*i.e.*, opening statements and the presentation of evidence), belies a plain reading of the statute. Although the statute does not define when "trial" begins and there is no Delaware case law on this issue, the General Assembly used the term "trial" and not "jury selection." Had the General Assembly wanted a different result, it would have used different language. *See State v. Cooper*, 575 A.2d 1074, 1078 (Del. 1990) (noting that specific terms used by General Assembly indicate that it intended a specific meaning). Because section 2301(d) is clear and unambiguous, the language itself controls and is not subject to judicial interpretation. *Leatherbury*, 939 A.2d at 1288.

Moreover, Defendants' interpretation of the 2301(d) language "prior to trial" to mean prior any preliminary procedures, such as jury selection, would lead to unfair and illogical results. Often parties agree in the pre-trial stipulation or the court decides at the pre-trial conference to select a jury prior to the trial start date, which conference is usually within 30 days of the start of trial. If the section 2301(d) time limit begins when the jury is selected, a plaintiff's demand would be automatically rendered untimely if the jury is selected ahead of the trial date.

In addition, the Delaware cases Defendants cite to that a jury trial begins

when the jury is selected are inapposite. *State v. Cooke*, 2010 WL 3734113 (Del. Super. Ct.), and *Charbonneau v. State*, 904 A.2d 295 (Del. 2006), are criminal cases. The rule in criminal cases that jury selection marks the official beginning of a trial reflects the fact that a criminal defendant's right to be present during trial attaches at the point when the jury is being chosen and double jeopardy attaches with the impanelling of a second criminal jury. *Ison v. E.I. DuPont De Nemours & Co.,* 2004 WL 2827934 (Del. Super. Ct.), also did not hold that the impanelling of a jury inherently and necessarily marks the beginning of the trial. Rather, it merely appears that jury selection took place on the first day of trial.

Finally, contrary to Defendants' claim, it is not the general law outside of Delaware that a non-criminal trial necessarily "begins" with jury selection. Although jury selection has been interpreted as the formal beginning of trial for purposes of when a criminal trial begins, many courts have decided there is no compelling policy to mandate the choice of selecting the jury as the "beginning" of a trial in other contexts. Notably, none of the cases cited by Defendants involve calculating when a trial begins for purposes of determining the timeliness of a settlement offer. In fact, in examining when a trial begins for purposes of determining whether an offer of judgment was made "more than 10 days before the trial begins," courts have held that a trial begins when the trial judge calls the proceedings to order and actually commences hearing the case (*i.e.*, opening

statements and the presentation of evidence), not when preliminary procedures, such as jury selection, begin:

> [T]he policy behind Rule 68, [governing offers of judgment, which is encouraging settlement,] is best served by interpreting the phrase "before trial begins" to refer to the point in trial when *the actual presentation of evidence commences* [as opposed to when the jury is impanelled].

Schwartz v. Estate of Greenspun, 881 P.2d 638, 641-42 (Nev. 1994) (offer of judgment made less than 10 days before jury selection was timely because "trial begins" when evidence presented, not when jury selected); *Palace Station Hotel & Casino, Inc. v. Jones*, 978 P.2d 323 (Nev. 1999) (same); *Greenwood v. Stevenson*, 88 F.R.D. 225 (D.R.I. 1980) (same).[7]

Like offers of judgment, the policy behind section 2301(d) is to encourage settlement. This policy is best served by interpreting the phrase "prior to trial" to refer to the point when the trial judge actually calls the proceedings to order and actually commences to hear the case (*i.e.*, opening statements and the presentation of evidence). Parties have a better assessment of a case's realities just before trial and after discovery, and, thus it is logical to select opening statements as the last possible point in time for cutting off section 2301(d) offers.

---

[7] *See also Gilbert v. City of Caldwell*, 732 P.2d 355, 367 (Idaho App. 1987) (offer's timeliness determined by actual date of trial, not date trial originally scheduled); *Wilkins v. Gagliardi*, 556 N.W.2d 171 (Mich. App. 1996) (for purposes of offer, trial begins with openings and evidence).

c. The parties agreed that "Trial" would begin on October 29, 2012.

Finally, as the Trial Court noted, Defendants' claim that "trial" started on October 24, 2012 is at odds with the fact that the Scheduling Order and stipulated Amended Scheduling Order provided that "trial" would start on October 29, 2012:[8]

> 1. **Trial** – A jury trial in this matter is hereby scheduled to commence on **October 29, 2012**, beginning at 10:00 a.m. Jury Selection to be held **October 24, 2012**, beginning at 9:30 a.m. The Court has set aside **8** days to try this matter.

(AA71 (emphasis in original); *see also* B1-3).

In serving their § 2301(d) demands on September 26, Plaintiffs relied on the plain and unambiguous language in the *stipulated* Scheduling Order that "trial" was to begin on October 29th. Defendants should be estopped from now arguing they did not agree to the trial start date.

Indeed, the fact that "trial" was not starting until October 29th is reinforced by the fact that the October 24th and 25th jury selections were presided over by two different judges, and not by the trial judge, Judge Brady. Moreover, the Voir Dire, which was also agreed to by the parties in advance and which was read in open Court during jury selection on October 24th and 25th, emphasized that "[t]his trial will begin on Monday, October 29" and the two judges presiding over those jury selections also instructed the jury that "trial" would start on October 29th. (B277;

[8] Trial was delayed and did not actually begin until October 31, 2012 due to Hurricane Sandy.

B278; B279; B281; B282-283; B284-286). Finally, on October 31st, prior to opening statements, Judge Brady swore the jury, which had been selected over two days, since the jurors had never been sworn as a single unit. (B287; B288).

Defendants suggest that Plaintiffs' submission of written demands on September 26, 2012 amounts to a "failure to prosecute his claim" for which the Plaintiffs should not benefit. The suggestion plaintiffs' counsel failed to prosecute this claim is ridiculous. Although the discovery deadline was August 31, 2012, depositions were not completed until September 20th – 6 days before the demands were made – because Dr. Shapira identified nine physician witnesses in his *third* supplemental expert disclosure on June 28, 2012, and then had difficulty obtaining for Plaintiffs timely deposition dates for so many physicians. In accordance with Delaware practice and common sense, Plaintiffs waited to submit their demands until after discovery was completed and after they could consult their own experts on the nine witnesses' testimony. Section 2301(d) was enacted to promote settlement, which is exactly what Plaintiffs attempted to accomplish.

2. Section 2301(d) is not unconstitutional.

In a last ditch effort, Defendants contend the statute violates the Due Process and Equal Protection Clauses of the Delaware and United States Constitutions. Defendants fail to overcome the strong presumption that the statute is valid.

A statute is presumed to be constitutional and "will not be declared

unconstitutional unless it clearly and convincingly violates the Constitution." *Bullock v. State Farm*, 2012 WL 1980806, at *7 (Del. Super. Ct.). The party asserting the unconstitutionality of a statute bears the burden of overcoming the presumption of its validity. *Id.* The purpose of section 2301(d) has been well stated. Rather than impairing a defendant's right of access to the courts or raising an irrebuttable presumption that defendant is to blame for delays in settling cases, the statute was enacted with the legitimate goal of "promot[ing] earlier settlement of claims by encouraging parties to make fair offers sooner, with the effect of reducing court congestion." *Rapposelli v. State Farm Mut. Auto. Ins. Co.*, 988 A.2d 425, 427 (Del. 2010); Senate Bill 310 syn., 140th General Assembly (2000).

Since its enactment in 2000, this Court has interpreted section 2301(d) many times without raising any concerns about its constitutionality.[9] Moreover, the very arguments Defendants make were recently rejected by the Superior Court in *Bullock*. In addition, other jurisdictions have rejected similar constitutional challenges to statutory schemes that impose pre-judgment interest against defendants who elect to defend rather than settle.[10]

Finally, Defendants' reliance on *Maryland Cas. Co. v. Hanby*, 301 A.2d 286

---

[9] *See Enrique*, 2011 WL 1004604, at *1-3; *Rapposelli*, 988 A.2d at 427-29; *Christiana Care Health Servs., Inc. v. Crist*, 956 A.2d 622, 628-30 (Del. 2008).

[10] *See Galayda v. Lake Hosp. Sys.*, 644 N.E.2d 298, 302-03 (Ohio 1994) (holding that Ohio's pre-judgment interest statute did not unconstitutionally violate a defendant's right to a jury trial or impose a penalty upon a defendant for having exercised his right to a jury); *Lester v. Sayles*, 850 S.W.2d 858, 874 (Mo. 1993) (upholding Missouri's pre-judgment interest statute).

(Del. 1973), for the proposition that the time period in which Plaintiffs delayed in making a settlement demand could have and should have been excluded from an award of pre-judgment interest, is misplaced. Although this Court held that the trial court in *Hanby* had discretion in determining the date from which interest should be paid on an amount of judgment, *Hanby* did not involve an award of interest under section 2301(d). Notably, the statute has no exception for periods of delay or perceived delay during the litigation. It provides, without exception, that when the right to pre-judgment interest is established, interest "*shall* be added" to any final judgment "commencing *from the date of injury*." 6 *Del. C.* § 2301(d) (emphasis added). The statute is clear, unambiguous, and without qualification, and thus not subject to judicial interpretation. *Leatherbury*, 939 A.2d at 1288.

IV. CCHS HAS WAIVED ITS RIGHT TO ARGUE THE COURT ERRED WHEN IT FOUND THE VERDICT SHOULD NOT BE REFORMED.

A. Question Presented

Whether the Trial Court erred in finding the verdict should not be reformed?

B. Standard of Review

This Court reviews the Trial Court's denial of a motion to alter or amend a judgment for abuse of discretion. *Carriere v. Peninsula Ins. Co.*, 810 A.2d 349, 2002 WL 31649167, at *2 (Del.).

C. Merits of the Argument

Immediately after the verdict, counsel for CCHS asked the Trial Court at side bar for clarification of the jury's 35% finding of direct liability, claiming he thought there was "confusion" about whether the jury found CCHS independently liable as a result of Dr. Castellano's conduct or as a result of vicarious liability since jury interrogatories 4, 5 and 8 referred to CCHS instead of Dr. Castellano. (B557-561; A123-A125). To clear up any "confusion," CCHS requested a supplemental verdict sheet asking the jury to determine how much of the 35% liability assessed to CCHS should be apportioned to CCHS through its employee Dr. Castellano and how much should be apportioned to CCHS through its agency, apparent agency or employer relationship with Dr. Shapira. (B559-573). When asked by the court how this question would change things given that the jury found that CCHS was vicariously liable for Dr. Shapira's actions, CCHS's counsel stated:

> [CCHS] put [Dr. Shapira] on notice that we were in a position of an excess carrier, and they should settle the case. . . . That 35% becomes ours exclusively, and so if there's a lawsuit later on, we would need to know whether this was 35% independent or [attributable to CCHS's agency relationship with Dr. Shapira].

(B564-565). CCHS's counsel went on to say that the purpose of the supplemental question was to "save or clarify litigation later on." (B565-570).

Although the court noted that it did not believe that anyone on the jury was confused in any way throughout the trial, based on the representations of CCHS, the court reluctantly agreed to allow the supplemental question over Dr. Shapira's objection. The court remarked that it believed that it was best to err on the side of caution and allow the supplemental question, because it could be undone. (B570-574). The court also told the parties and made it "clear" to the jury that they would not disturb the 65/35 original apportionment and that they were only determining how much of the 35% liability assessed to CCHS should be apportioned to CCHS through the conduct of Dr. Castellano (CCHS's employee) and how much should be apportioned to CCHS through its agency, apparent agency or employer relationship with Dr. Shapira. (B574-575). Of the 35%, the jury apportioned 25% to Dr. Castellano and 75% to Dr. Shapira. (A126).

Despite the court's statements that the jury would not be disturbing the 65/35% original apportionment, CCHS moved to reform the Original Verdict Sheet. At the hearing, CCHS's counsel admitted that he did not actually ask for

the Supplemental Verdict Sheet because of CCHS's position as an excess insurance carrier, but instead his "purpose was to obtain the clarification from the jury because I still felt that . . . the interrogatories were inconsistent and that they could have been confused." (B577 at 30). The Trial Court discussed the impact that "CCHS's counsel's statement that CCHS was in the position of an excess insurance carrier had on the court's decision to allow the supplemental question", stating that she "decided to give the instruction because I thought it meant that it may change how the insurance money . . . [was] distributed." (B577 at 31). CCHS's counsel responded he "did not appreciate that at the time." (*Id.*).

The Trial Court stated it would not have given the supplemental instruction if CCHS had made its real purpose known:

> [I]f I had appreciated at the time that I gave the supplemental instruction that the purpose of that was to see if the jury really meant what the jury said, I would not have given it because I was satisfied that I had done what needed to be done to properly instruct the jury with the initial instructions and interrogatory sheet as to how to allocate responsibility and the bases upon which define liability. And had I realized at that point in time that the reason you wanted me to give the supplemental instruction was to make sure the jury really meant what they said in the initial verdict sheet, I would not have done it.

(B578 at 33; *see also* A359-A369). Finding that CCHS was trying to accomplish something that the Trial Court explicitly told them they were not permitted to do, the Trial Court denied CCHS' motion. (A359-A369). The court also found that CCHS's contentions were insufficient to rebut the presumption that a jury's verdict

is correct and just and that, contrary to its claim, CCHS was actually trying to substantively change the verdict sheet without any authority to do so. (*Id.*).

CCHS contends that the Trial Court erred when it denied its motion. Notably, CCHS does not claim its motion or the Supplemental Verdict Sheet affects the validity of the jury's verdict vis-à-vis Plaintiffs or that the jury's findings in the Supplemental Verdict or the Trial Court's denial of the motion entitles Defendants to a new trial. CCHS is not asking "to make any kind of substantive change to the findings made by the jury" only a "clerical reformation".

Plaintiffs took no position below on the Supplemental Verdict Sheet or CCHS' motion to reform the verdict based upon, *inter alia*, in reliance upon CCHS' representations and the fact that no one claimed either in any way affected the validity of the jury's verdict vis-à-vis Plaintiffs. (*See* B224-228). Now that the Trial Court found CCHS is attempting to accomplish something that the court explicitly told them they were not permitted to do (*i.e.*, to alter the 65%/35% apportionment of liability in the Original Verdict Sheet), and CCHS revealed that its true "purpose" for asking for the supplemental jury question, Plaintiffs believe that they are entitled to respond to CCHS's arguments on appeal. As discussed below, CCHS has waived any right to argue that the Trial Court erred.

First, CCHS should be estopped from arguing the Trial Court erred by denying its motion to reform the verdict because CCHS did not appeal this issue

against the party who opposed it below, Dr. Shapira.[11]

Second, CCHS waived any right to argue the Trial Court erred because it waived its objections at trial to the jury interrogatories, and thus, its "purpose" for requesting the Supplemental Verdict Sheet does not exist.

As discussed above, although CCHS originally requested the Supplemental Verdict Sheet because CCHS claimed it was an excess insurance carrier, at the hearing on CCHS's motion to reform the verdict, CCHS argued its true "purpose was to obtain the clarification from the jury because I still felt that . . . the interrogatories were inconsistent and that they could have been confused." (B577 at 30). CCHS claims the interrogatories were confusing because the Trial Court did not insert "Dr. Castellano's name in [jury interrogatory] questions 4, 5 and 8 [which] would have focused the jury on Dr. Castellano's negligence as the only way in which CCHS could be found independently negligent and would have avoided any confusion." Notably, however, *prior* to the jury instructions and jury interrogatories being given, CCHS *waived* any objection to those interrogatories.

Specifically, during the prayer conference, counsel for CCHS waived its objections to interrogatories 4, 5 and 8 not referring to Dr. Castellano, telling the

[11] Dr. Shapira opposed the giving of the Supplemental Verdict Sheet to the jury and CCHS's motion to reform the verdict, arguing that CCHS was actually requesting a substantive change to the original verdict and there was no legal basis to justify making that change. (B208-211). According to Dr. Shapira, once the jury returned the verdict assessing 35% of the liability to CCHS, "nothing further should have been done" because "[t]he original verdict was clear and consistent with the instructions given before deliberation." (B209).

court: "As long as you tell [the jury] the only claim is against Dr. Castellano, I'm happy." (B513-514). The court agreed to do so in the jury instructions and told CCHS: "[I]f there's anywhere or [way] you want to emphasize it, just let me know." (B514). Notably, prior to the jury instructions and jury interrogatories being given, CCHS failed to request anything further from the court, let alone for a jury interrogatory asking what percentage of the amount of negligence attributed to CCHS was related to the actions of CCHS's employee, Dr. Castellano, as opposed to the actions of CCHS's agent, apparent agent or employee, Dr. Shapira. Also, the Supplemental Verdict Sheet is not relevant as to whether jury interrogatories 4, 5 and 8 specifically refer to Dr. Castellano, as CCHS initially requested. Had those interrogatories referred to Dr. Castellano, the jury would still not have allocated what percentage of the jury's 35% verdict against CCHS was a result of vicarious liability and what percentage was due to CCHS's independent negligence.

Moreover, any suggestion by CCHS that the Supplemental Verdict itself creates some sort of an appealable issue should not be countenanced. For example, CCHS does not argue that it is entitled to a new trial because the jury's verdict was inconsistent. However, in arguing that the Trial Court erred in denying its motion to reform, CCHS contends that the Trial Court should have reconciled the "apparent inconsistencies" in the jury's verdict brought to light by the jury's clarification of its apportionment of CCHS's liability. Contrary to CCHS's claim,

the answers to the special interrogatories are not inconsistent.

Rather, the Supplemental Verdict Sheet confirms the original verdict's validity in favor of Plaintiffs since the jury found both times that CCHS was liable for damages as a result of the conduct of its employee Dr. Castellano and was also vicariously liable for the actions of Dr. Shapira. (A123-125; A126). Thus, the award of damages was properly assessed against CCHS as a consequence of wrongs perpetuated both by Dr. Castellano *and* by Dr. Shapira.

There is no basis for CCHS's suggestion that the jury was "confused" about the vicarious versus independent liability of CCHS. Indeed, when CCHS first argued "confusion" during the sidebar, Judge Brady responded that no one on the jury has been confused throughout the entire trial. (B570 at 20). During initial deliberations, the jury sent out two notes, neither of which dealt in any way with apportionment of liability. (AA 450-454; AA 456). The Supplemental Verdict Sheet was also returned without any notes from the jury.

Moreover, CCHS's suggestion that the jury should have been instructed the only way they could find CCHS liable was through the actions of Dr. Castellano lacks merit and any objection to the instructions has been waived. As the Trial Court found, the instructions on agency, acts of corporate defendants, apparent

agency and the imputation of an agent's negligence to the principal were proper.[12] Defendants did not object to any of these instructions. (AA434-435, AA446-449).

The parties' closing arguments were also clear that there were two different claims against CCHS, one for vicarious liability and one for independent negligence. With regard to any independent liability on the part of CCHS, both Plaintiffs and CCHS argued to the jury that Plaintiffs' independent claim against CCHS was based solely on the actions of Dr. Castellano as the corporate director of CCHS's IRB. (B548-549, B552, B553-554). Furthermore, to avoid "potential confusion," CCHS's counsel emphasized to the jury that interrogatories numbers 4 and 5 "only appl[y] to Dr. Castellano" and those questions should not be answered "yes" if the jury did not find that Dr. Castellano was negligent. (B553-554).

[12] The jury was instructed, *inter alia*, that Dr. Castellano was CCHS's employee and whatever the jury's finding was as to Dr. Castellano automatically pertained to CCHS and CCHS could be found liable for Dr. Shapira's actions if the jury found Dr. Shapira to be an employee, agent or apparent agent of CCHS. (A97-A99). The jury was also told that there were two defendants in this case Dr. Shapira and CCHS, and that they were to independently evaluate the claim against each one, and that if they find against one that does not mean that the other is also liable. (A96).

V. THE TRIAL COURT PROPERLY INSTRUCTED THE JURY WITH REGARD TO PROXIMATE CAUSE.

A. Question Presented

Whether the Trial Court properly instructed the jury on proximate cause?

B. Standard of Review

The Court reviews *de novo* a trial court's decision to issue a contested jury instruction. *Sammons v. Doctors for Emergency Services, P.A.*, 913 A.2d 519, 540 (Del. 2006). "In evaluating the propriety of a jury charge, the jury instructions must be viewed as a whole." *Ireland v. Gemcraft Homes, Inc.*, 29 A.3d 246, 2011 WL 4553166, at *3 (Del.) (citing *Culver v. Bennett*, 588 A.2d 1094, 1096 (Del. 1991)). A party is entitled to an instruction that is legally accurate, but is not entitled to have the jury instructed in a particular format. *Russell v. K-Mart Corp.*, 761 A.2d 1, 8 (Del. 2000) (citing *Culver*, 588 A.2d at 1096).

C. Merits of the Argument

Defendants challenge the Trial Court's instruction to the jury on proximate cause, claiming that the definitions of "remote cause" and "proximate cause" were inconsistent with this Court's holdings in *Spicer v. Osunkoya*, 32 A.3d 347 (Del. 2011), and therefore, not legally accurate. The claim has no merit.

First, there is no basis for Defendants' claim that the definition of "remote cause" was inconsistent with *Spicer*. CCHS requested that the Trial Court give an instruction on "remote cause" using the definition from *Spicer*, (A182-184), and

the court gave the requested instruction. (A105).

Second, contrary to Defendants' claim, the definition of "proximate cause" was accurate and properly stated Delaware's well established "but for" standard of causation. Defendants claim that it was not accurate to instruct the jury that: "Proximate cause is a cause that directly produces the harm, and but for which the harm would not have occurred. A proximate cause brings about, or helps to bring about, the plaintiff's injuries, and it must have been necessary to the result,"[13] (A105), purportedly because the phrase "or helps to bring about" is inconsistent with the "but for" proximate causation standard that the Delaware Courts have adopted.

The "proximate cause" definition is from Delaware's Pattern Jury Instructions. *See* Del. P.J.I. Civ. § 21.8 (2000). As Judge Brady held, the phrase "or helps to bring about" is accurate because Delaware has adopted the traditional "but-for" definition of proximate cause, and has long recognized that there may be more than one proximate cause, and therefore, there may be "help" from each. *Duphily*, 662 A.2d at 829; *Jones v. Crawford*, 1 A.3d 299, 302 (Del. 2010). The instruction also clearly stated that the conduct must have been necessary to the result. Since there were multiple defendants, and thus multiple allegations of

[13] Defendants wanted the Trial Court to instead instruct the jury that: "A proximate cause is one which in natural and continu[ous] sequence, unbroken by any efficient intervening cause, produces the injury and without which the result would not have occurred." (A182-A184).

proximate cause, it was appropriate to include such language.

This Court has found that similar instructions using the phrase "or helps to bring about" accurately state the law on Delaware's "but for" rule of proximate causation. In *Ireland*, a case decided by this Court only one month before *Spicer*, the trial court gave an almost identical definition of proximate cause to the jury as the one given by Judge Brady, including the phrase "or helps to bring about," and this Court held that the instruction accurately informed the jury of Delaware's but-for standard of causation. 2011 WL 4553166, at *3.[14]

In addition, the cases cited by Defendants are inapposite. Neither *Spicer* nor *Russell* changed Delaware's "but for" rule of proximate causation, as Defendants concede in their papers. *See* CCHS O.B., p. 33 ("In *Spicer*, this Court *reiterated* the legal standard for proximate cause.") (emphasis added). Also, contrary to Defendants' claim, the fact that the phrase "or helps to bring about" was not used in the instruction given in *Russell* does not mean that those words are not legally accurate. *Russell* merely stands for the proposition that a party is entitled to a legally accurate instruction, but to any particular format, even if the requested format is the Pattern Jury Instructions.

---

[14] *See also Pesta v. Warren*, 888 A.2d 232, 2005 WL 3453825, at *1-2 (Del.) (proximate cause definition using phrase "or helps to bring about" accurately stated Delaware's "but for" rule of proximate causation); *Baker v. East Coast Props., Inc.*, 2011 WL 5622443, at *3 (Del. Super. Ct.); *Hammond v. Colt Indus. Op. Corp.*, 565 A.2d 558 (Del. Super. Ct. 1989) (defining proximate cause as "that which brings about or produces, or helps to bring about or produce, the injury complained of, and 'but for' which the injury would not have occurred").

Furthermore, the definition of "proximate cause" was not inconsistent with the Court's holding in *Spicer*. In fact, Delaware courts have acknowledged that the opposite is the case. Specifically, the definition of "proximate cause" used by this Court in *Spicer* and *Russell* (which is the same language Defendants asked the Trial Court to use) has been described as "other words" for the definition of "proximate cause" given by the Trial Court here. *See Baker*, 2011 WL 5622443, at *3 ("Delaware applies the traditional 'but for' definition of proximate cause. Proximate cause is that which brings about or produces, or helps to bring about or produce the injury and damage and but for which the injury would not have occurred. *In other words, a proximate cause is one which in natural and continu[ous] sequence, unbroken by any efficient intervening cause, produces the injury and without which the result would not have occurred.*") (emphasis added).[15] The fact that Defendants wanted the Trial Court to use the "other words" is not grounds for a new trial. *Russell*, 761 A.2d at 4.

Finally, Defendants do not explain how their proximate cause argument applies to the facts of this case, and why it rises to the level of reversible error. If Defendants should later suggest that CCHS's independent alleged negligent acts were not properly considered by the jury because the proximate cause instruction

[15] *See also Hedrick v. Webb*, 2004 WL 2735517, at *4 (Del. Super. Ct.) (noting "proximate cause" has been described both ways).

included the words "brings about, or helps to bring about," such a claim would be a red herring. CCHS did not argue – in closings to the jury *or* to this Court – that CCHS's alleged violations of the standard of care were "broken by any efficient intervening cause" (*i.e.*, Dr. Shapira's alleged violations of the standard of care). They also chose not to request an intervening or superseding cause instruction or object to one not being given. Finally, any suggestion that the jury did not properly consider CCHS's independent alleged negligent acts is also without merit since the jury found CCHS liable for the acts of Dr. Shapira on the grounds that he was acting as an employee, agent or apparent agent of CCHS (which CCHS chose not to dispute). (A123).

CONCLUSION

For the foregoing reasons, the Trial Court's rulings should be affirmed.

ASHBY & GEDDES

/s/ Randall E. Robbins (#2059)
Randall E. Robbins (#2059)
Carolyn S. Hake (#3839)
500 Delaware Ave., 8th Floor
Wilmington, DE 19801
(302) 654-1888
Counsel for Appellees & Cross-Appellees, Plaintiffs Below

Dated: December 2, 2013