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Case Number 392,2013

IN THE SUPREME COURT OF THE STATE OF DELAWARE

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

MODIFIED REPLY BRIEF OF
CROSS APPELLANTS NADIV SHAPIRA, M.D. and NADIV SHAPIRA, M.D., LLC,
AS TO APPELLEES / CROSS APPELLEES JOHN AND EVELYN HOUGHTON

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Dated: December 26, 2013

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STATEMENT OF FACTS IN REPLY

Dr. Shapira adopts by reference the Statement of Facts from his Opening Brief. In addition, the Houghtons' Counter-Statement of Facts may contain inadvertent factual errors; those most relevant to Dr. Shapira's appeal are listed below:

The Houghtons' Brief at page 6, ¶2: Dr. Shapira "claimed" he approached CCHS in 2004 or 2005 and CCHS trauma surgeons began making referrals.

The citation accompanying this statement in the Houghtons' Brief is to testimony from CCHS trauma surgeon Fred Giberson that because the anesthesiologists at CCHS are so busy, pain management there "developed differently." Sometimes, there would be a significant delay or even "hesitation where anesthesia would not place the catheter [at all]," so the surgeons sought alternatives to epidural catheters. Thus, it was the trauma surgeons who began consulting Dr. Shapira in 2003-04 for On-Q catheter placements (not *vice versa*) as an "alternative method" to an epidural catheter for rib fracture pain relief.[1] Also, there is no evidence to support the Houghtons' assertion at page 6, ¶3 of their Brief, that "it was obvious Dr. Shapira was trying to start a new career in interventional pain management...."

[1] 11/9/12 (pm) Tr 10:10-11:11. (B518-519).

The Houghtons' Brief at page 9, ¶4: The I-Flow contract "fueled" Dr. Shapira to email the head of CCHS' Surgery Department about the possibility of conducting a randomized study on the On-Q.

No evidence was presented at trial to support this theory. Rather, Dr. Shapira testified that he wanted to do the study because "[p]eople need some proof. People need some comparison. And that was the idea behind this [study] protocol."[2]

[2] 10/31/12 Tr 110:10-12. (B292).

ARGUMENT IN REPLY

I. THIS COURT SHOULD REJECT THE HOUGHTONS' INFORMED CONSENT ARGUMENT WHICH WOULD IMPERMISSIBLY EXPAND THE 18 *DEL.C*. §6801(6) *PRESCRIPTION* OF INFORMED CONSENT AND THE §6852 *DESCRIPTION* OF HOW THAT PRESCRIBED INFORMATION SHOULD BE GIVEN.

Dr. Shapira's appeal of the trial court's handling of the informed consent issue is two-fold. First, it was error to extend *Barriocanal v. Gibbs*[3] to allow the Houghtons to argue that additional factors, such as a physician's motivation to perform the procedure, his financial relationships, his research activities, and the institutional research policies, should be part of the statutorily-defined standards of care: information "customarily given" to seek the patient's informed consent.[4] Second, and in tandem with its *Barriocanal* ruling, the trial court made a number of erroneous evidentiary rulings. The effect of these rulings was to enable the Houghtons to make a highly prejudicial and largely irrelevant depiction of the issue of informed consent, as set forth *seriatim* as bulleted points on pp. 11-13 and in footnote 54 on p.16 of Dr. Shapira's Opening Brief.

The Houghtons argue, at page 19 of their Brief, that this Court interpreted the informed consent statute "broadly" in *Barriocanal* and that defendants are now reading the statute and *Barriocanal* too narrowly. In actuality, this Court has always narrowly interpreted the Medical Negligence Statute, of which informed

[3] 697 A.2d 1169 (Del. 1997).
[4] *See* 18 *Del.C*. §6852.

consent is a part, in deference to the legislative intent of the Statute, as well as the fact that it was created in derogation of common law. [5]

Section 6801(6) of Title 18 *prescribes* what a physician must inform a patient to gain the patient's consent as (1) the nature of the proposed procedure and (2) the risks and alternatives to that proposed treatment. Section 6852 then explains what a plaintiff must prove to substantiate an informed consent claim as lack of the information "customarily given" to patients by a similarly-situated healthcare provider. However, the Houghtons were allowed to enlarge that particular phrase beyond the clear language of the Statute to include information which they apparently believe *should* be part of informed consent: Dr. Shapira's purported research activities and his relationship with the device manufacturer in derogation of Section 6801(6). Section 6852 merely explains, but does not expand upon, what Section 6801(6) *prescribes* the patient must be informed. In keeping with this Court's history of narrowly interpreting the Medical Negligence Statute, even when in so doing the result may be harsh,[6] there is nothing in the Statute indicating any legislative intent to *require* the disclosure of financial relationships or compliance with institutional research protocols. Thus, the Houghtons' argument at page 20 of their Brief, that the §6852 phrase regarding information "customarily

[5] *Dunn v. St. Francis Hosp., Inc*., 401 A.2d 77, 80 (Del. 1979), *Reyes v. Kent Gen. Hosp., Inc*., 487 A.2d 1142, 1146 (Del. 1984), *Ewing v. Beck*, 520 A.2d 653, 660 (Del. 1987), *Meekins v. Barnes*, 745 A.2d 893, 896 (Del. 2000), *Leatherbury v. Greenspun*, 939 A.2d 1284, 1289 (Del. 2007), *Dambro v. Meyer*, 974 A.2d 121, 130, 135 (Del. 2009).
[6] *Dambro*, 974 A.2d at 139-40.

given" should be grafted onto the §6801(6) definition of what information is to be given, is contrary to both the plain language, the intent of the statute, and long-standing interpretative law.

Barriocanal held that the "plain language" of §6852 requires a plaintiff to prove both the standard of care for giving information to obtain an informed consent, as well as its breach. In finding error for *exclusion* of plaintiff's expert (whereas here the issue is inclusion) for failing to "unequivocally" state the information customarily given to patients to gain their informed consent, the *Barriocanal* Court held that to require an expert to "articulate certain 'magic words' … would exact form over substance."[7] However, the *substance* of what the precluded expert in *Barriocanal* was prepared to testify to was "medical:" the ability (or lack thereof) of the surgeon to perform the procedure.[8] In other words, the expert testimony at issue in *Barriocanal* was "qualification" information, information that went to the ability of the surgeon to actually perform the surgery: his lack of relevant experience, a short-staffed operating room, and the possibility of transfer to a teaching facility.[9]

Although the Houghtons did attack Dr. Shapira's "qualifications" (his ability to perform the procedure), the key thrust of the Houghtons' informed consent

[7] *Barriocanal*, 697 A.2d at 1172.
[8] *Id*.
[9] *Id*.

argument (and thus their case) was not "medical." Their case was not about Dr. Shapira's ability to perform the procedure, his experience, or the propriety of the CCHS facilities. The Houghtons' case was about Dr. Shapira's relationship with I-Flow, his alleged motivation to perform the procedure, and allegedly putting his own interests above those of his patients, all of which were highly prejudicial and directly contrary to the truth.

The Houghtons note, at page 19 of their Brief, that the testimony excluded in *Barriocanal* addressed medical issues and medical qualifications, which is exactly the type of evidence that was excluded here: that Dr. Shapira was considered the On-Q "expert" at CCHS, that there was no other viable alternative at CCHS to the On-Q, that the On-Q is not experimental at CCHS, and that because the On-Q is the "standard treatment" at CCHS, it could rightly be considered the standard of care at that facility. Compare this to what was allowed, none of which was "medical" or even remotely related to the clinical considerations of the propriety of using an On-Q: extensive testimony about Dr. Shapira's relationship with I-Flow, his data collection (and whether this was or was not research), his attempts to be published on his experiences with the On-Q, and the minutiae of institutional research protocols at CCHS, all of which were described in greater detail in Dr. Shapira's Opening Brief at pages 11-13.

Further, it is significant that the Houghtons did not refute any of the specific points to prejudicial trial evidence contained in Dr. Shapira's Opening Brief. In sum, those specific points graphically illustrate the Houghtons' wrongful success in making their case all about Dr. Shapira's purported evil ways, not about medical negligence. Moreover, the counter-Statement of Facts, at pages 4 through 16 of the Houghtons' Answering Brief, simply bolsters this conclusion.

In support of the argument, at page 26 of their Brief, that *Barriocanal* requires disclosure of these factors as "medical," the Houghtons assert the relevance of federal regulations and American Medical Association Guidelines "pertaining to human subject research." The Houghtons acknowledge these are not controlling, as well they must, and the two cases they cite in support of this proposition are both irrelevant to the appeal at bar. At issue in *Duphily v. Del. Elec. Coop., Inc*.[10] were matters of "simple" negligence governed by the common law, not Statute. At issue in *Whitlock v. Duke Univ*.[11] was the informed consent "owed by a researcher to a subject in the *nontherapeutic* experimental context."

All of the above demonstrates why the appeal at bar is both legally and factually distinguishable from *Barriocanal.* The trial court's all-too-expansive interpretation of the informed consent Statute, in tandem with its erroneous evidentiary rulings, as argued in Dr. Shapira's Opening Brief and Argument II

[10] 662 A.2d 821 (Del. 1995).
[11] 637 F. Supp. 1463 (M.D.N.C. 1986) *Aff'd.* 829 F.2d 1340 (4th Cir. 1987).

herein, "went to 'the very heart' of [defendants'] case."[12] In *Barriocanal*, the Court noted it "might well have affected the outcome,"[13] whereas here it absolutely did affect the outcome. For these reasons, Dr. Shapira is entitled to a new trial.

[12] *Barriocanal*, 697 A.2d at 1173.
[13] *Id*.

II. THE HOUGHTONS' ANSWERING BRIEF UNDERSCORES THE SIGNIFICANCE OF THE IMMENSE PREJUDICE DR. SHAPIRA'S CASE SUFFERED DUE TO THE TRIAL COURT'S ERRONEOUS EVIDENTIARY RULINGS, BARRING THE CCHS TRAUMA SURGEONS FROM TESTIFYING THAT THE ON-Q WAS NOT EXPERIMENTAL AT CCHS AT THE TIME OF MR. HOUGHTON'S CCHS ADMISSION.

Lest there be any confusion or uncertainty about whether the "experimental" issue was a central part of this case, the Houghtons' Brief puts that question to rest when, in the first paragraph of the first page, they argue that Dr. Shapira breached the standard of care "in not disclosing to Mr. Houghton that: … (2) the On-Q was experimental and not the standard of care to treat rib fracture pain…."

The opinions of the out-of-state experts called by the Houghtons to address whether the On-Q for treatment of rib fracture pain was or was not experimental, which the jury heard, could not possibly have been as relevant or probative to the issue as the conclusions reached, as of December of 2009, by the CCHS trauma surgeons (who were in the best position to comment on the care rendered in their own facility). At the top of page seven of their Answering Brief, the Houghtons argue that "[d]efendants relied on the Christiana trauma surgeons at trial." This is correct as far as it goes; defendants did rely on those trauma surgeons but only to the extent permitted. What the Houghtons conveniently ignore is the fact that the most important part of the trauma surgeons' testimony, the conclusion that was

reached by them as of December 2009 that the On-Q was not experimental for rib fracture pain treatment, was barred by the trial court, and Dr. Shapira was unable to "rely" on that essential testimony.

Moreover, on page 30 of their Brief, the Houghtons argue that Dr. Shapira did not object to the testimony of Dr. Bradley. It is true that no objection was made at the time of his testimony. However, Dr. Bradley's testimony was permitted only because of the trial court's pre-trial interpretation of the informed consent Statute, and that position was preserved for appeal purposes when the trial court denied the defense application on how the statute should be interpreted in its October 23, 2012 bench ruling. Had the trial court upheld the defense position on the interpretation of the informed consent Statute, the cited testimony of Dr. Bradley would never have been permitted. Accordingly, the defense "objection" was preserved as of the trial court's opinion, which is challenged in this Appeal. Further, the trial court's ruling which prohibited the trauma surgeons from testifying as to the non-experimental nature of the On-Q, barred Dr. Shapira from cross-examining Dr. Bradley on that point. Dr. Bradley had a concern about the use of the On-Q to treat Mr. Houghton. The defense was unable to address that concern, via cross examination, which would have brought to his (and the jury's) attention that Dr. Bradley's senior colleagues, who were in charge of the trauma

department, and who had more experience with Dr. Shapira than Dr. Bradley, had concluded, as of December 2009, that this was *not* experimental treatment.

The result of all of this was a double fatal blow to Dr. Shapira's ability to defend the claims against him: (1) the trial court's improper interpretation of the informed consent Statute, coupled with (2) the trial court's improper refusal to let the CCHS trauma surgeons, the most knowledgeable at that institution of the effectiveness of the On-Q for rib fracture pain, testify as to its non-experimental nature. Either one of these rulings, viewed separately, forms the basis for a new trial but together these resulted in a fundamentally unfair and exceedingly prejudicial proceeding.

Additionally, on page 34 of their Brief, the Houghtons note "[w]hether the procedure was experimental was a jury question." This is true based on the trial court's ruling, a ruling which is challenged in Dr. Shapira's appeal at Argument II of his Opening Brief. However, if the experimental nature of the On-Q is a jury question, then fundamental fairness requires that the jurors be given all of the relevant evidence, which they were not, and which is why a complete new trial is now required.

Respectfully, what occurred at this trial begs the question of how Dr. Shapira could have participated in a fair trial after the trial court ruled that the experimental versus non-experimental issue was for the jury, then also ruled that

the trauma surgeons, in whose care Mr. Houghton was entrusted, were not allowed to testify on this critical issue. At page 33 of the Answering Brief, the Houghtons note:

> "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 is unavailable patients did not get it."

That testimony was permitted to be considered by the jury, yet Dr. Shapira was not able to rebut that testimony by having the jury consider the critical thoughts of the trauma surgeons. Dr. Shapira is not arguing that the trauma surgeons' testimony, that as of December 2009 the On-Q was not experimental, was legally binding or precluded the Houghtons from arguing the experimental nature of the On-Q. Rather, Dr. Shapira maintains that a new trial is required because the jurors were not given *all* the relevant information upon which to base their decision. Thus, the Houghtons' argument on page 36 of their Brief, that there was "no undue prejudice," is erroneous and clearly self-serving. Although Dr. Shapira was able to elicit testimony from the trauma surgeons that they routinely requested the On-Q when Dr. Shapira was available, this is not the same as saying it was not experimental. Routine use and experimental are not mutually exclusive.

The Houghtons' experts, Dr. Streisand[14] and Dr. Gudin,[15] opined that a procedure was experimental unless and until it had been accepted by a number of

[14] 11/2/12 Tr. 28:6-22. (B322).
[15] 11/2/12 Tr. 262:12-263:17. (B343).

institutions after peer review. Yet, defense expert Dr. Smith[16] testified that standard of care could be hospital-specific based on the resources available. For Dr. Shapira to properly defend the allegations against him, he needed to blend these two pieces of evidence together, and argue that while it may be that institutions which have not tried this procedure would consider it "experimental," at CCHS it was not "experimental" because of the experience and conclusions of the trauma surgeons. This argument was erroneously denied to Dr. Shapira, and that was a fatal and unwarranted blow to his entire defense.

The Houghtons, at page 35 of their Brief, also misstate the application of *Palmer v. Dolman*, [17] by maintaining that the trauma surgeons were not actors and viewers because they did not perform the procedure, were not aware of the risks and did not consider themselves experts on the standard of care. The Houghtons further assert that the *Palmer* Court did "not hold that a witness could express an opinion on something outside of their expertise." That, however, was not why Dr. Shapira wanted to offer the testimony of the trauma surgeons. The purpose of the trauma surgeons' barred testimony would have been to prove that, based upon their experience with having their patients treated with the On-Q for rib fracture pain and the results that they personally saw therefrom, they came to the conclusion that, at least as early as December 2009, the On-Q was not experimental. Thus,

[16] 11/2/12 Tr. 198:16-199:2. (B337).
[17] 1986 WL 4877 (Del. Super. Apr. 21, 1986).

Palmer is on point. The fact that the trauma surgeons did not perform the procedure (as they relied instead upon the expertise of Dr. Shapira to perform the procedure for them, upon their request), were not aware of its risks, and did not consider themselves experts on how the procedure should be performed, may all have been fertile ground for cross examination. Yet this was clearly not a proper basis to preclude this critical evidence from the jury's consideration. Equally important, and consistent with *Palmer*, is that the testimony of the trauma surgeons was not developed in anticipation of litigation. Their testimony was quite clear that these were thoughts held by them as of the time of Mr. Houghton's treatment, and, as such, *Palmer* is relevant, controlling and proves the trial court's error necessitating a new trial.

If the trial court's decision is upheld, a likely result will be that in future litigation in this State, the disclosure of treating physicians' conclusions and "opinions," held in their capacity as treating physicians not retained experts, would be chilled. This is not the way cases should be tried in Delaware. There should be full disclosure of everything, but the onus should not be placed on the party that proffered the testimony. Treating physicians must be permitted to testify that, at the time of the care rendered, they were of the opinion that the treatment utilized was standard, routine and considered non-experimental in their practice and/or at

their institution. To find otherwise would result in a dramatic and unwarranted departure from long-standing legal precedent in Delaware.

Finally, it is beyond dispute that the experimental issue was critical to the jury's decision. The jury found CCHS to be independently liable regardless of what apportionment number is used. The Houghtons' Brief, at page 25, acknowledges that for CCHS to be found independently liable, the jury had to first "find that Dr. Shapira was conducting a research study. Research studies are only conducted on experimental procedures. The finding of independent negligence on the part CCHS proves that the jury concluded that Mr. Houghton was part of an 'experiment.'" Had the jury found Dr. Shapira 100% and CCHS 0% liable, it could be argued that the jury based its verdict on a conclusion that Mr. Houghton's treatment should have been based solely on a regimen of medication (as the Houghtons' experts argued) and/or that Mr. Houghton's injury was 100% due to Dr. Shapira's improper technique (which was also argued). From the findings comprising the jury's verdict, it is apparent that the jury *had* to have found that Mr. Houghton was the subject of an experiment. However, the jury reached this conclusion due to (1) an improper interpretation of the informed consent Statute, as discussed above, and (2) an improper restriction on the relevant evidence, most especially the testimony of the CCHS trauma surgeons. For these reasons, Dr. Shapira is entitled to a new trial.

III. THIS COURT SHOULD REJECT THE HOUGHTONS' PRE-JUDGMENT INTEREST ARGUMENT WHICH IS CONTRARY TO THE LEGISLATIVE INTENT OF THE STATUTE.

The argument, at page 43 of Houghtons' Brief, that the parties have a "better assessment" of the case "just before trial," is contrary to the intent of the law and unavailing, given the detail of the Houghtons' Complaint, filed 15 months and 18 days prior to demand, as well as the breadth of discovery completed before the demand was made on September 26, 2012. On page 41 of their Brief, the Houghtons assert that the language of the Statute is "clear and unambiguous," and that "had the General Assembly wanted a different result, it would have used different language." Evident from the legislative history of this Statute is that the General Assembly *did* want a different result than what occurred here.

"The plain meaning of the statutory language" controls when statutes are unambiguous,[18] however by failing to define what is meant by "prior to trial," 6 *Del.C.* §2301(d) is ambiguous. Therefore, the Statute must be construed "in a way that will promote its apparent purpose and harmonize it with other statutes" within the statutory scheme.[19] When a statute is ambiguous, "[t]he goal of statutory construction is to determine and give effect to legislative intent."[20] The Synopsis of

[18] *Eliason v. Englehart,* 733 A.2d 944, 946 (Del.1999).
[19] *Id.*
[20] *Id.*

the original General Assembly bill[21] is both a "proper" and "instructive" source to establish that legislative intent.[22] That Synopsis states that the bill was introduced to provide a "financial incentive for insurance companies or wrongdoers [sic] to make prompt, good faith offers of settlement to plaintiffs." The bill was introduced to amend the law to promote *earlier* settlement with the effect of reducing court congestion.[23] Thus, it is neither logical nor consistent with legislative intent to select opening statements as the determinate "last possible point in time" for cutting off demands. The plain language of the Statute reads that such a demand must come 30 days prior to *trial*, not a specific point within a trial, such as opening statements.

This trial commenced when the trial court and the parties convened on Wednesday, October 24, 2012 to seat a jury. Jury selection is an integral part of a trial, not a "preliminary procedure," as the Houghtons contend at page 41 of their Brief. It is no less important than opening statements or witness testimony. Instantly, there was no procedural reason why jury selection took place on a day prior to opening statements and the opening of evidence. This was done simply for the convenience of the court and the parties and was no less a part of the trial (the

[21] S.B. 310, 140th General Assembly (Del. 2000). (AA582).
[22] *Carper v. New Castle County Bd. of Ed.,* 432 A.2d 1202, 1205 (Del.1981), *Leatherbury,* 939 A.2d at 1289.
[23] S.B. 310, 140th General Assembly (Del. 2000) Emphasis added. (AA582).

opening part), as the term "trial" is used in the Statute, simply because it took place on a different day.

The Houghtons' argument at page 44 of their Brief, regarding the stipulated Amended Scheduling Order, cuts both ways. The jury selection date is listed under the "Trial" heading on that Order. However, at the end of the day on October 24, 2012 (and October 25, 2012), the seated jurors were addressed in the same manner as they were after the evidence was opened and testimony began. This is clearly because the trial process had already begun. Despite the fact that these jury selection dates were well-known to both sides months in advance, the Houghtons now argue over *two days* – the difference between the jury selection on Wednesday, October 24, 2012 versus opening statements on October 31, 2012 (delayed from Monday, October 29, 2012 due to Hurricane Sandy). Notably, the Houghtons waited 15 months and 18 days into the pendency of this lawsuit before making a demand. In deciding whether they violated the terms of the Statute, it should be obvious that the Houghtons certainly violated its intent.

As for the Houghtons' argument at pages 41-42 of their Brief, regarding case law, the paucity of cases addressing this issue, and the absence of any cases on point, simply bolsters the importance of legislative intent argued above. For these reasons, the Houghtons' argument on pre-judgment interest should be rejected.

IV. DR. SHAPIRA ADOPTS ARGUMENT IV IN THE HOUGHTONS' ANSWERING BRIEF THAT CCHS WAIVED ITS RIGHT TO ARGUE THAT THE TRIAL COURT ERRED WHEN IT FOUND THAT THE VERDICT SHEET SHOULD NOT BE REFORMED.

V. DR. SHAPIRA ADOPTS THE REPLY ARGUMENT OF CCHS ON THE ISSUE OF THE JURY BEING IMPROPERLY INSTRUCTED ON PROXIMATE CAUSE.

CONCLUSION

For the foregoing reasons, as well as for the reasons set forth in Dr. Shapira's Opening Brief, a new trial is required.

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